Introduction

This implementation guide describes the minimum procedures necessary for a medical laboratory to verify the comparability of patient results across a health care system. For additional information on verifying comparability of results, see CLSI document EP31.¹

NOTE: This verification process can be used only when the measurement procedure produces quantitative numerical results.

IMPORTANT NOTE: The study outlined in this implementation guide and described in CLSI document EP31¹ is not intended for use by a test developer to establish or validate comparability of results for the purpose of comparing different tests. Instead, test developers should consult CLSI document EP09² for guidance on establishing and validating measurement procedure comparisons. Laboratories and commercial manufacturers are collectively referred to as “developers” in this implementation guide.

Why Is it Important to Verify Comparability of Results?

Individual patients often have medical care appointments at multiple facilities within a health care system. For example, a patient scheduled for surgery might visit a primary care physician’s office, a hospital, and a central laboratory. Testing can be done at any of these locations, and the results may be available to multiple providers in the health care system. The laboratory needs to ensure that providers are reviewing comparable results, regardless of where the testing was performed.
Verification of the Comparability of Results

The comparability of results verification process is outlined in the figure below.

Need to verify comparability of results is identified

Measurand to test and measuring systems to compare are selected

Measurand concentration is selected

Imprecision of the measuring systems is collected or determined, including total (within-laboratory) SD or CV and repeatability (within-run) SD or CV

CD is determined for the measurand

Operator and system readiness are confirmed

Sample is selected and/or prepared

Samples are run on each measuring system, with the number of replicates and runs selected from CLSI document EP31-Ed1-WB1 recommendations

Results are tabulated and checked for outliers

Data are entered into the appropriate spaces on the “Data Entry” tab of CLSI document EP31-Ed1-WB1

Comparison results are calculated

Results are compared with the CD

Comparison results are interpreted

End

Abbreviations: CD, critical difference; CV, coefficient of variation; SD, standard deviation.