

Verification of Comparability of Patient Results Within One Health Care System Implementation Guide



EP31-Ed1-IG

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.

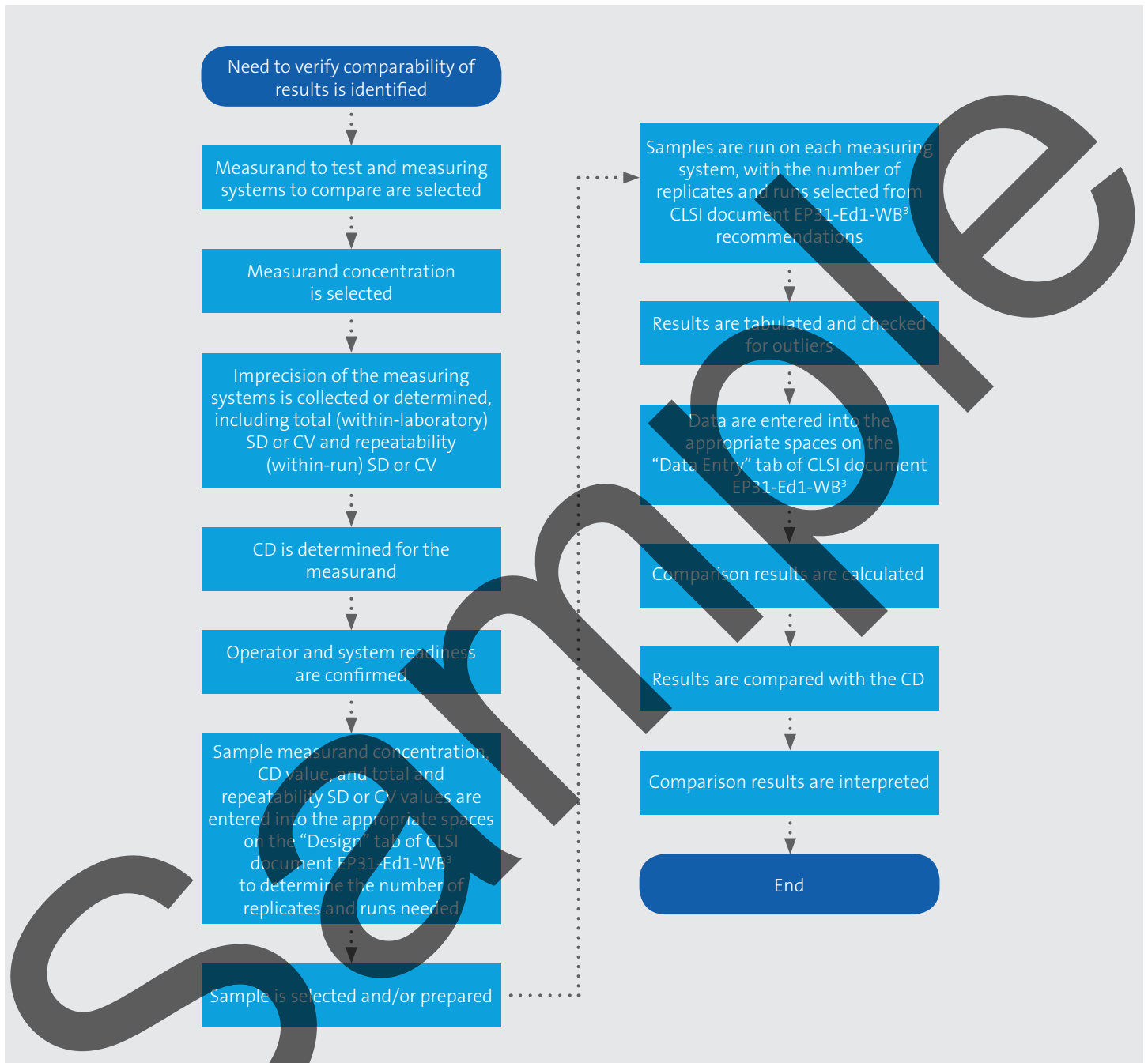
IMPORTANT NOTE: The study outlined in this implementation guide and described in CLSI document EP31¹ is not intended for use by a test developer to establish or validate comparability of results for the purpose of comparing different tests. Instead, test developers should consult CLSI document EP09² 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.



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