

# Preliminary Evaluation of Quantitative Medical Laboratory Measurement Procedures Implementation Guide

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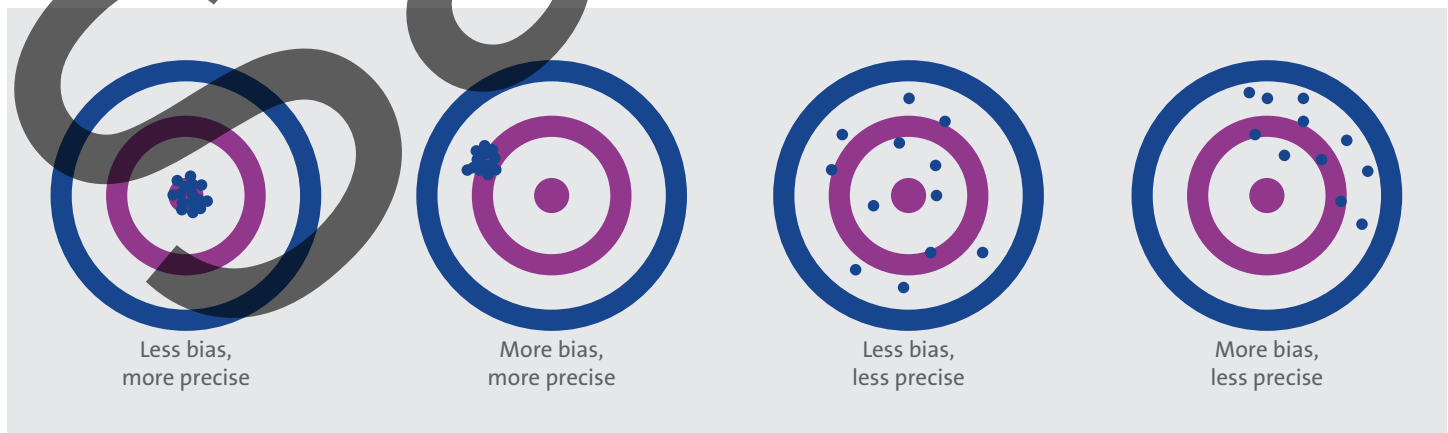
## Introduction

This implementation guide describes the minimum procedures necessary for a medical laboratory to make a preliminary decision about a new measurement procedure's acceptability before using the procedure for laboratory testing. This preliminary testing evaluation is conducted before verification testing **and does not replace verification testing** for the measurement procedure. The laboratory can also conduct this preliminary evaluation to help detect problems that may warrant immediate correction, referral to the developer, or expanded investigation before a new device is placed into service. This implementation guide describes procedures for the preliminary evaluation of linearity, proportional and constant bias, linear drift, sample carryover, and precision of a medical laboratory measurement procedure. For additional information, see CLSI EP10.<sup>1</sup>

**IMPORTANT NOTE:** The study described in CLSI EP10<sup>1</sup> is not intended for use by a developer to establish performance for a new commercial test or laboratory-developed test. Instead, developers should see CLSI EP19<sup>2</sup> for more information on CLSI documents related to establishing measurement procedure performance. In this implementation guide, "developers" includes both commercial manufacturers and laboratories that create new measurement procedures or modify regulatory-cleared and -approved commercially available measurement procedures in a way that could modify performance characteristics and/or change the intended use.

## Accuracy: A Combination of Precision and Bias

Measurement procedures must be precise and have low bias to provide accurate results. The figure below uses four targets to show different degrees of precision and bias, with the left-most target showing more precision and less bias than the other three targets.



High precision (low coefficient of variation expressed as a percentage [% CV] or low standard deviation) means that when a sample is run repeatedly, the results are very close to each other. Precision can be broken into various components. Measurement of a single run is called “within-run precision.” “Repeatability” is measured when all components are held essentially the same (eg, single run, operator, lot calibration). “Reproducibility” is measured among different test sites when components (eg, runs, days, operators, lots, instruments) are varied across multiple runs, although not every component needs to differ for each run. For example, the same lot of reagent can be used across multiple runs, as long as different lots of reagent are used within the series of runs.

The figure below depicts an example of the difference between constant and proportional bias. Constant bias is sometimes referred to as a “shift” in the results up or down (in the figure, a shift up), whereas with proportional bias, the absolute difference becomes larger or smaller (in the figure, becomes larger) as the values get higher.

