

Preliminary Evaluation of Quantitative Medical Laboratory Measurement Procedures Implementation Guide

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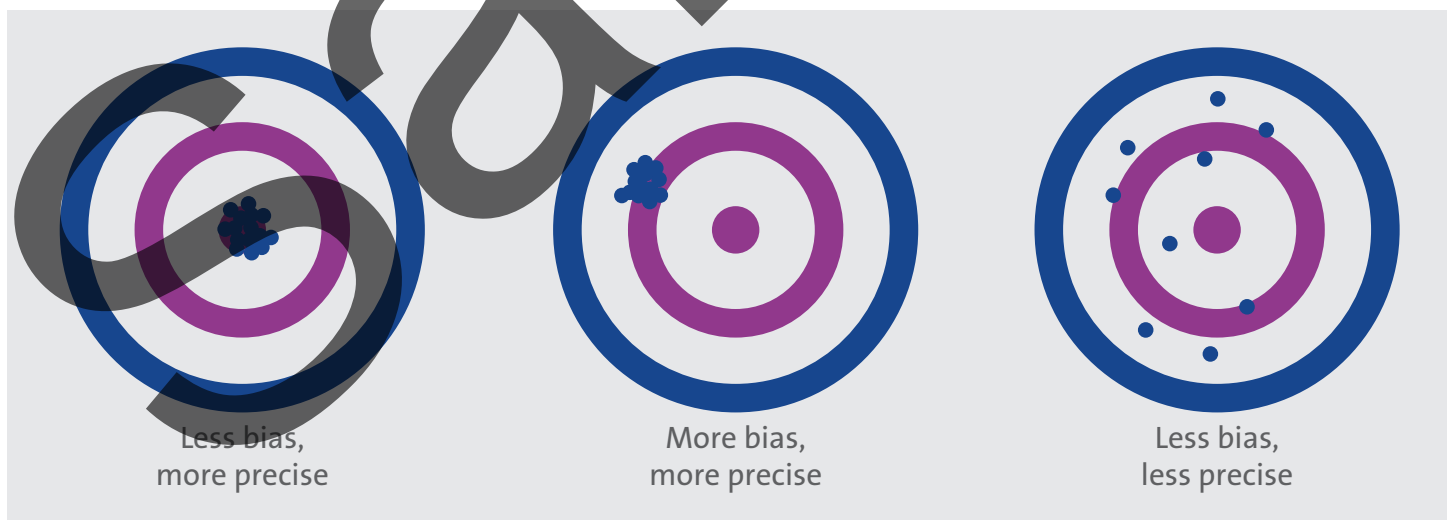
Introduction

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. This implementation guide describes procedures for the preliminary evaluation of linearity, proportional and constant bias, linear drift, sample carryover, and precision for quantitative measurement procedures. For additional information, see CLSI document EP10.¹

IMPORTANT NOTE: The study described in CLSI document EP10¹ is not intended for use by a test developer to establish performance for a new commercial test or laboratory-developed test. Instead, test developers should see CLSI document EP19² for more information on CLSI documents related to establishing measurement procedure performance. Laboratories and commercial manufacturers are collectively referred to as "developers" in this implementation guide.

Accuracy: A Combination of Precision and Bias

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



High precision (low coefficient of variation expressed as a percentage [% CV]) 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 when all components (eg, runs, days, operators, lots) 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 the difference between constant and proportional bias. Constant bias is sometimes referred to as a “shift” in the results, whereas with proportional bias, the absolute difference becomes greater as the values get higher.

