User Verification of Bias (Trueness) Implementation Guide

Implementation Guide
EP15-Ed3-IG2

Introduction

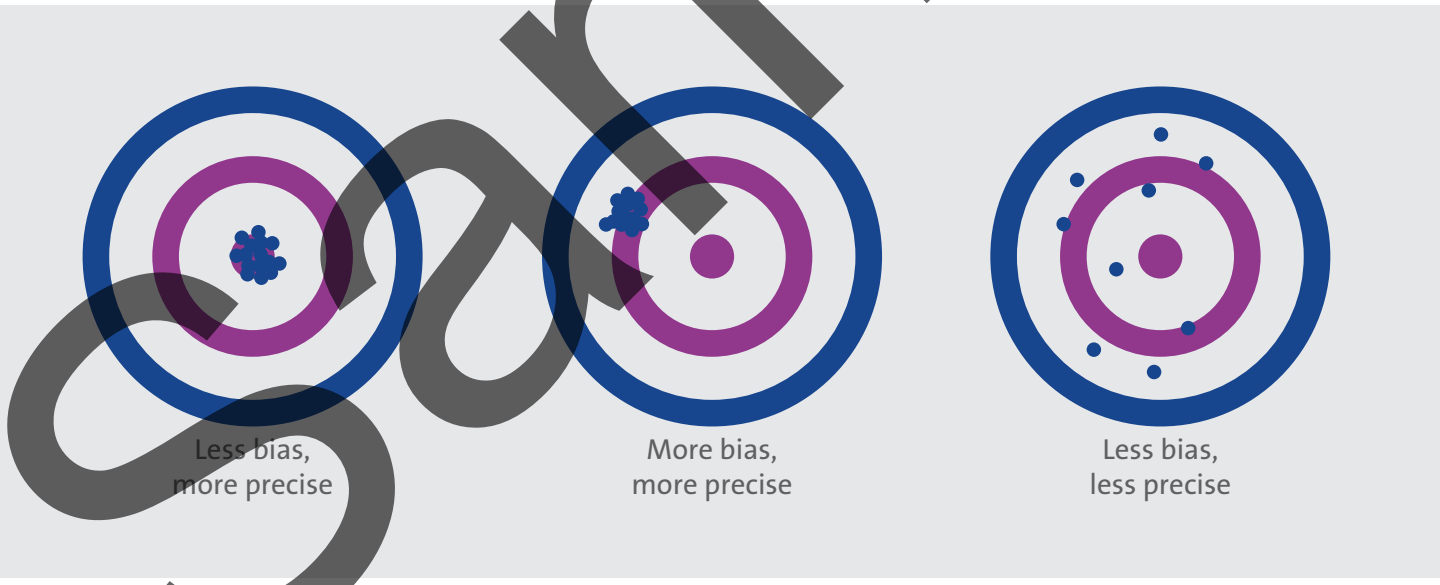
This implementation guide describes the minimum procedures necessary for a medical laboratory to estimate bias (trueness) of a laboratory measurement procedure. For additional information on estimating bias, see CLSI document EP15.[1]

NOTE: The study described in this implementation guide uses the data and statistics generated from the precision study described in CLSI document EP15.[1] The instructions provided in CLSI document EP15-Ed3-IG1[2] should be used for running the precision study.

IMPORTANT NOTE: The study described in CLSI document EP15[1] is not intended for use by a test developer to establish or validate bias claims for a new commercial or laboratory-developed test. Instead, test developers should use CLSI document EP09[3] for guidance on establishing bias claims. Laboratories and commercial manufacturers are collectively referred to as "developers" in this implementation guide.

Accuracy: A Combination of Precision and Bias

It is important that measurement procedures provide accurate results. In order to do so, they must both be precise and have low bias as shown in the figure below.



While CLSI document EP15[1] contains instructions for studying both precision and bias, this implementation guide focuses only on bias. CLSI document EP15-Ed3-IG1[2] focuses on precision.

Having low or no bias means that when a sample is run, its results are very close to the true value (actual concentration or activity) for the sample.

Preparing for the Study

The bias goal should be determined by asking the question, "What is the maximum allowable bias (units or %) at each analyte concentration to be tested?"

The Study

Designing the Study

The table below shows an example study design for verifying precision.

Samples	Replicates	Runs	Days	QC	Daily Results Review
2	5	1 per day	5	2 levels with each run	Yes

Abbreviation: QC, quality control.

Running the Study

The bias study uses the data and statistics from the precision study. The laboratory should follow all instructions for running the precision study as presented in CLSI document EP15-Ed3-IG1.[2]

In the precision study, all samples are tested in one run per day, with five replicates for each sample. This testing is repeated for four additional days (or five days total). The precision study should include quality control (QC) materials in the run to ensure the test has worked properly.

Analyzing the Data

When analyzing the data, the laboratory should:

1. Open CLSI document EP15-Ed3-WB[4] (https://clsidocuments.s3.amazonaws.com/EP15-Ed3-WB.xlsm).
2. On the tab labeled "Instructions," enter the requested information in the blue highlighted cells.
3. On the tab labeled "Design," enter the requested information in the blue highlighted cells.
4. On the tab labeled "Data Entry," enter the testing results into the data entry cells that are highlighted in blue indicated for each sample and each day.

   NOTE 1: If data already appear in the data entry cells, click the "Reset Data" button to clear the data, and then proceed with data entry.

   NOTE 2: When data are transferred from a different spreadsheet, the formatting of the data cells may change. Therefore, it is recommended to either enter each individual data point or paste the data as "values."

   NOTE 3: Data cannot be moved within the spreadsheet. If data are entered into the wrong cell, click the "Reset Data" button and re-enter the data.
5. When all results have been entered, the worksheet automatically calculates:
   - n (total number of measurements for each day)
   - Mean (average of the results for each day)