CLINICAL AND LABORATORY STANDARDS INSTITUTE®

4th Edition

CLSI EP10™

Preliminary Evaluation of Quantitative Medical Laboratory Measurement Procedures

CLSI EP10 provides experimental design and data analysis for preliminary evaluation of the performance of a measurement procedure or device.

A guideline for global application developed through the Clinical and Laboratory Standards Institute consensus process.

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Preliminary Evaluation of Quantitative Medical Laboratory Measurement Procedures

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Abstract

Clinical and Laboratory Standards Institute EP10—*Preliminary Evaluation of Quantitative Medical Laboratory Measurement Procedures* is intended to facilitate a limited, preliminary evaluation of the performance of a measurement procedure or device. Using the experimental design and data analysis procedure described, determination of whether a device has problems that require further evaluation or referral to the manufacturer can be done with a minimum expenditure of time and material. Included in Appendixes A and B are sample data sheets that should facilitate the analysis of the data. Appendix C contains a more sophisticated, powerful statistical method for determining the possible causes of imprecision.

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Committee Membership

Consensus Council

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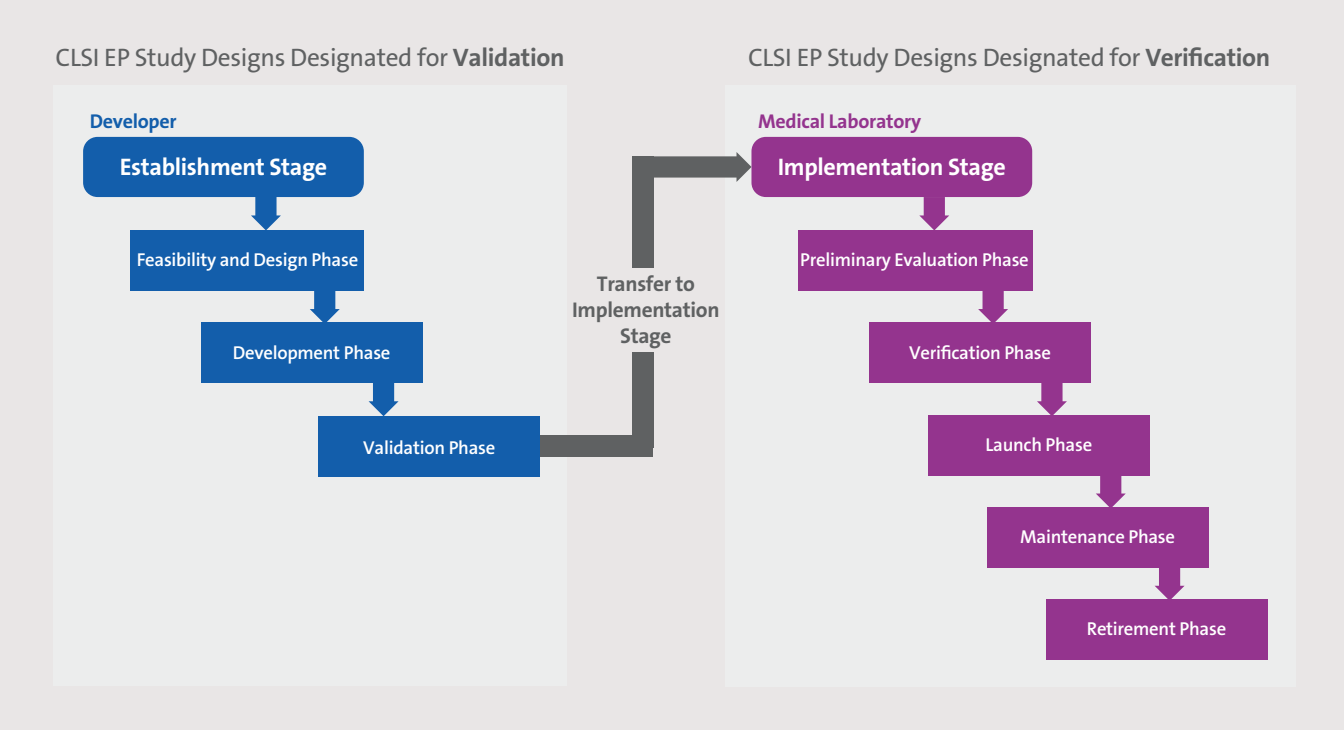
Contents

Foreword

Before acquiring or adopting a new measurement procedure or instrument for *in vitro* diagnostic use, the laboratory must make a preliminary decision about its acceptability. CLSI EP10 is useful for the initial evaluation of a measurement procedure or instrument performance through assessment of several analytical performance characteristics in a simple experiment in the Establishment Stage or Preliminary Evaluation Phase (ie, before the Validation or Verification Phases, respectively) of the Test Life Phases Model (see Figure 1 and CLSI EP19[1]). The primary purpose of CLSI EP10 is to help detect performance problems that would warrant immediate correction, referral to the manufacturer, or expanded investigation before a new device is placed into service. This initial performance check is neither a rigorous characterization of long-term performance nor an evaluation of all factors that can affect results produced by the device. Rather, this experiment is a quick check to rule out major problems and a starting point for accumulating data and experience that will enable the user to make a final decision. Additionally, developers of such measurement procedures and instruments may want to perform a brief evaluation of analytical performance before proceeding with more thorough, time-consuming, and costly studies.



Abbreviation: EP, evaluation protocols.
[a] The eight phases separate into the two stages, ie, the Establishment Stage (blue), performed by a developer, and the Implementation Stage (purple), performed by the end-user laboratory.

Figure 1. The Test Life Phases Model[a]

Overview of Changes

This guideline was revised in 2024 under the Limited Revision Process and replaces CLSI EP10-A3, which was published in 2010. Several changes were made in this edition, including:

- Reformatting and condensing sections to improve readability
- Adding information on the Test Life Phases Model (see CLSI EP19[1]) and at which phases CLSI EP10 may be applicable to users
- Providing additional guidance in Chapter 2 on reference procedures and/or materials
- Clarifying Subchapter 7.2 on visual inspection for outliers
- Referencing related CLSI documents for guidance on validation or verification of described analytical performance characteristics, when applicable
- Updating figures

KEY WORDS

carryover
comparison of methods
evaluation protocol
experimental design
linearity
multiple regression
outlier
precision

Use of Microsoft® Excel in this guideline is not an endorsement on the part of CLSI. With each use of the trade name, "or the equivalent" is added to indicate that this guideline also applies to any equivalent products.

Chapter 1

Introduction

Preliminary Evaluation of Quantitative Medical Laboratory Measurement Procedures

1 Introduction

1.1 Scope

Before starting an extensive evaluation of a new measurement procedure, kit, or instrument for *in vitro* diagnostic use, or when screening one or more candidate methods for additional consideration, it is often necessary to make a preliminary decision about its acceptability. This can be accomplished through a preliminary performance check to determine the feasibility and general analytical performance characteristics of a new method. This initial performance check is neither a rigorous investigation into the procedure's long-term performance nor an evaluation of all factors that can affect results produced by the device. The primary purpose of this document is to help detect problems that would cause the end user to disqualify a candidate measurement procedure or require immediate correction, referral to the manufacturer, or expanded investigation. Accreditation organizations may have requirements for validation or verification that exceed the procedures in this document.

Developers can also benefit by performing this protocol either as assays are developed or before they are validated. By performing more than five runs, developers can detect trends in the effects estimated by CLSI EP10 or document their absence.

1.2 Background

This document describes a procedure for the preliminary evaluation of linearity, proportional and constant bias, linear drift, sample carryover, and precision of a medical laboratory measurement procedure. Preliminary evaluations can be performed before acquisition or purchase of a new measurement procedure or instrument. The experiment is intended primarily for evaluating automated instruments but may be appropriate for kits, manual procedures, or other *in vitro* diagnostic devices. By repeating a sequence of only ten samples, performance characteristics are estimated by plotting the data and performing some simple calculations. Using a statistical technique called multiple linear regression analysis, further information about the factors influencing accuracy (such as sample carryover, linear drift, and nonlinearity) can be obtained. Instructions are given for simple data analysis, in case a computer is not available.

CLSI EP10 is intended to provide preliminary estimates of several analytical performance characteristics of the device. The results should be used only to determine whether the device has grossly unacceptable performance.

The following chapters outline the materials and procedures to be used. Many variations on this basic experiment are possible (such as extending the number of days or eliminating the priming samples, when appropriate). Variations should be dictated by the complexities of the device, the particular characteristics of the measurement procedure, and the resources available to the user, as well as the performance characteristics deemed to be most important to the user.