CLINICAL AND LABORATORY STANDARDS INSTITUTE®

1st Edition

EP35

Assessment of Equivalence or Suitability of Specimen Types for Medical Laboratory Measurement Procedures

This guideline provides recommendations for assessing clinically equivalent performance for additional similar-matrix specimen types and suitable performance for dissimilar-matrix specimen types, such that the laboratory does not necessarily need to repeat the full measurement procedure validation for each specimen type. The recommendations in this guideline apply to both quantitative measurement procedures and qualitative examinations.

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

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EP35, 1st ed.
December 2019

Assessment of Equivalence or Suitability of Specimen Types for Medical Laboratory Measurement Procedures

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Abstract

Clinical and Laboratory Standards Institute guideline EP35—*Assessment of Equivalence or Suitability of Specimen Types for Medical Laboratory Measurement Procedures* provides information for assessing clinically equivalent performance for additional similar-matrix specimen types and suitable performance for dissimilar-matrix specimen types. During development, medical laboratory measurement procedures are typically validated for the most common specimen type. However, it can be clinically useful to test the measurand in multiple specimen types, including different fluids (eg, serum, plasma, whole blood, urine, cerebrospinal fluid, saliva), anticoagulants, and collection devices. By following the recommendations in this guideline, developers of laboratory measurement procedures do not necessarily need to repeat the full measurement procedure validation for each specimen type. EP35 applies to both quantitative measurement procedures and qualitative examinations. This guideline is useful to developers of commercial and laboratory-developed tests and medical laboratory personnel.

Clinical and Laboratory Standards Institute (CLSI). *Assessment of Equivalence or Suitability of Specimen Types for Medical Laboratory Measurement Procedures*. 1st ed. CLSI guideline EP35 (ISBN 978-1-68440-062-1 [Print]; ISBN 978-1-68440-063-8 [Electronic]). Clinical and Laboratory Standards Institute, 950 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2019.

CLINICAL AND LABORATORY STANDARDS INSTITUTE®

Suggested Citation

CLSI. *Assessment of Equivalence or Suitability of Specimen Types for Medical Laboratory Measurement Procedures*. 1st ed. CLSI guideline EP35. Wayne, PA: Clinical and Laboratory Standards Institute; 2019.

ISBN 978-1-68440-062-1 (Print)

ISBN 978-1-68440-063-8 (Electronic)

ISSN 1558-6502 (Print)

ISSN 2162-2914 (Electronic)

Volume 39, Number 13

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Foreword

For measurement procedures whose performance characteristics have previously been validated with a primary specimen type, this guideline provides recommendations for assessing clinically equivalent performance for other similar-matrix specimen types and suitable performance for dissimilar-matrix specimen types. These assessments provide verification options that do not repeat full measurement procedure validation for the additional specimen types, which include different fluids (eg, serum, plasma, whole blood, urine, cerebrospinal fluid, saliva), anticoagulants (eg, EDTA, citrate, oxalate), and collection devices (eg, gel barrier, plain tube). To date, there is no general guidance on requirements or protocols for demonstrating multiple specimen type equivalence or suitability for use on measurement procedure performance. Multiple sources provide guidance (eg, anticoagulant testing in CLSI document EP07,[1] discussion of alternate body fluids in CLSI document C49,[2] specimen collection tube evaluation in CLSI document GP34[3]), but no CLSI documents provide the information as a cohesive whole. EP35 provides guidance on verifying clinically equivalent or suitable performance for additional specimen types without necessarily having to repeat the full measurement procedure validation for each specimen type. EP35 applies to both quantitative measurement procedures and qualitative examinations and is useful to developers of commercial and laboratory-developed tests and medical laboratory personnel.

Because measurement procedure performance characteristics can change when specimen types have substantially different matrix characteristics, evaluation of performance often needs to be based on suitability of the observed performance to the clinical requirements for the specific specimen type matrix rather than strict numerical equivalence. Therefore, access to the necessary clinical information is key to establishing equivalent or suitable performance for multiple specimen types, including the expected interval of measurand concentrations, inherent biological variability, medical decision levels, and any other relevant information for each specimen type. These characteristics can vary considerably between specimen types for the same measurand (eg, creatinine in serum vs urine). Once the necessary clinical information is available, the desirable measurement procedure performance attributes can be characterized for each specimen type based on risk assessment. After the performance requirements are established for each specimen type, the protocols described in this guideline can be used to document clinically equivalent or suitable performance.

NOTE: The content of this guideline is supported by the CLSI consensus process and does not necessarily reflect the views of any single individual or organization.

KEY WORDS

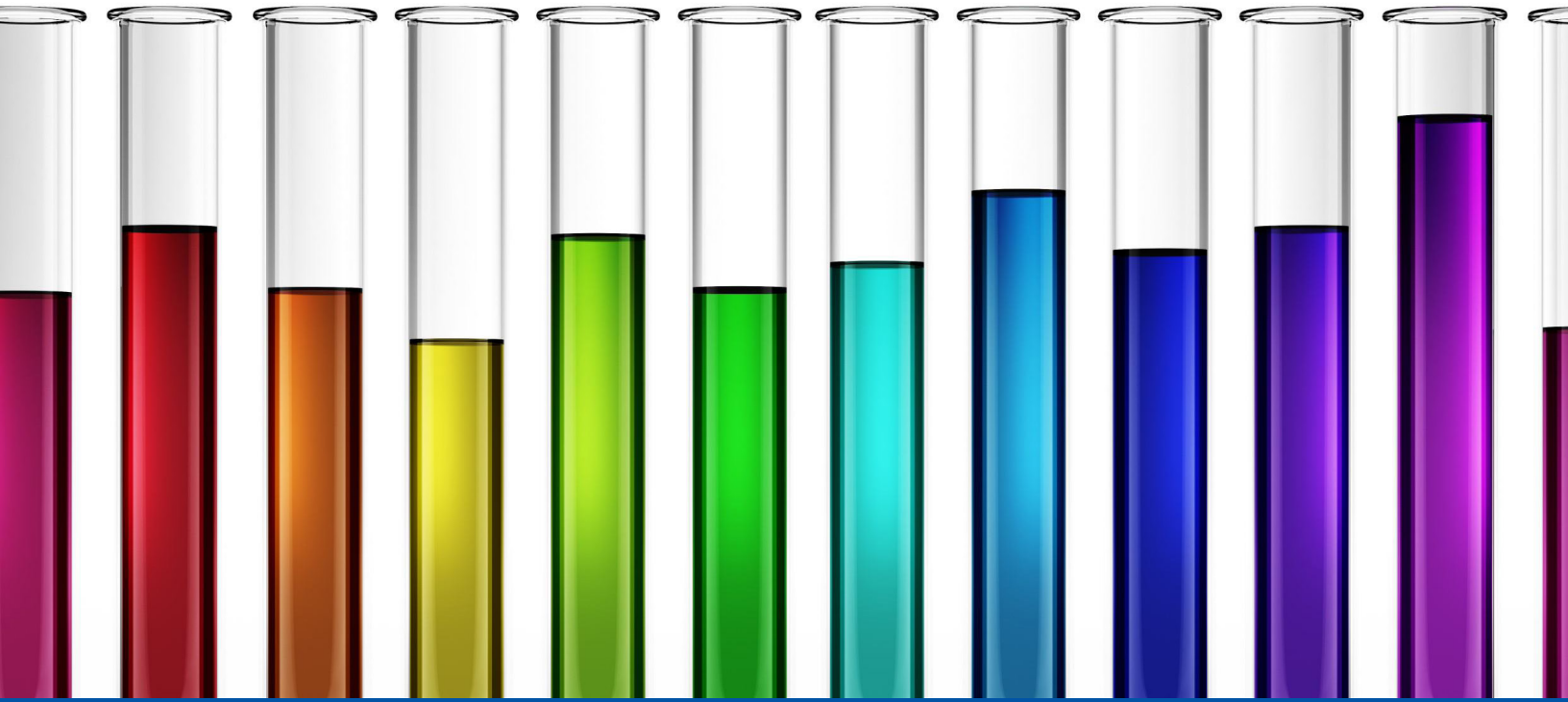
Candidate specimen type
Clinical equivalence
Clinical suitability
Equivalence
Primary specimen type
Specimen type
Suitable

Chapter 1

Introduction

This chapter includes:

- Guideline's scope and applicable exclusions
- Background information pertinent to the guideline's content
- Standard precautions information
- "Note on Terminology" that highlights particular use and/or variation in use of terms and/or definitions
- Terms and definitions used in the guideline
- Abbreviations and acronyms used in the guideline



Assessment of Equivalence or Suitability of Specimen Types for Medical Laboratory Measurement Procedures

1 Introduction

1.1 Scope

This guideline provides a protocol for assessing equivalence or suitability for use of a different specimen type compared with the established primary specimen type for a medical laboratory measurement procedure or qualitative examination. This guideline provides a general framework for studies that establish equivalence among similar-matrix specimen types and clinical suitability among dissimilar-matrix specimen types. It also includes instructions for laboratory verification of alternate specimen types for commercial measurement procedures. This guideline applies to both quantitative measurement procedures and qualitative examinations. The intended users of this guideline are manufacturers, developers of medical laboratory measurement procedures, and laboratorians verifying alternate specimen types.

EP35 is intended to be used for specimen types for which the desired measurand has a known clinical indication and for which adequate clinical information is available to establish risk-based clinical performance goals. Establishing clinically based performance goals is beyond this guideline's scope.

EP35 focuses on the effect of specimen type on the analytical measurement procedure. There may also be preexamination factors between specimen types that can affect results. These differences may require additional studies to characterize their effect on the results. Such preexamination factors are outside of the scope of EP35.

1.2 Background

Medical laboratory measurement procedure performance characteristics are generally established and validated for use for the most commonly used specimen type for the measurand, which is designated as the primary specimen type. However, there is often a clinical need to measure the same measurand in a different specimen type (eg, urine rather than serum). Changing the specimen type can alter both the measurement procedure performance and the performance characteristics desirable for clinical use, so it is important to document that the measurement procedure performance characteristics are clinically acceptable with the candidate specimen type.

For specimen types with a similar matrix (eg, serum and plasma), the measurement procedure's performance can be tested for equivalence among specimen types. When the matrixes are dissimilar (eg, serum and urine), it might not be possible to establish equivalence (eg, because of different measuring intervals), but the new specimen type can still be shown to be clinically acceptable or suitable for use.

To assess specimen type equivalence or suitability, a definition of what constitutes equivalent or suitable performance is needed. Typically, equivalence is defined as the condition of being equal in value, worth, function, etc. In the context of establishing specimen types' equivalence or suitability for a measurement procedure, there are two primary scenarios.