A Framework for Using CLSI Documents to Evaluate Medical Laboratory Test Methods

Report
EP19-Ed3
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Replaces EP19-Ed2

Introduction

EP19 has been revised to ensure its accuracy as a reference guide for the use of CLSI documents to establish and implement test methods using the Test Life Phases Model. EP19 is not an evaluation protocol (EP) in the traditional sense. Rather, it is a report that references existing CLSI method evaluation documents, organized around the concept of the Test Life Phases Model.

In this report, all entities that create new test methods are referred to as "developers." In EP19, developers include both commercial manufacturers and laboratories that create new test methods or modify regulatory-cleared and -approved commercially available test methods in a way that could modify performance characteristics and/or change the intended use.

Although EP19 is intended to help users identify appropriate CLSI documents for the establishment and implementation of test methods, EP19 cannot cover every aspect of establishment and/or implementation for every circumstance. Some analytes, test methods, and/or specialties have unique requirements. For some test methods, special evaluations for which there are no available CLSI documents might be needed. Where appropriate, other resource citations that might be useful to the reader have been added.

To facilitate use of the most current editions of the CLSI documents for the establishment and implementation of test methods described in the Test Life Phases Model, EP19 introduces CLSI electronic product *Method Navigator*.[1] *Method Navigator*[1] enables users to easily access resources cited in the product, along with other helpful CLSI resources. CLSI electronic product *Method Navigator*[1] is meant to be used with EP19.

Overview of Changes

This report replaces the previous edition of the approved report EP19-Ed2, published in 2015. The original intent of EP19 to provide a useful, high-level guide has not changed. Several changes were made in this edition, including:

- Introducing CLSI electronic product *Method Navigator*[1]
- Updating the figures and flow chart
- Enhancing discussion of the concept of risk management as an integral part of the Test Life Phases Model
- Updating Special Cases section

Scope

EP19 is organized around the Test Life Phases Model, which is the concept that all test methods undergo establishment by a developer, followed by implementation by the end user, all sequentially. For the purposes of EP19, the term "test method" includes the processes, reagents, supplies, calibrators, control material, hardware, software, and any other components that make up a test. EP19 describes the considerations and processes for planning, performing, and documenting test method evaluations by referring users to the appropriate CLSI EP documents, along with other related documents and resources when applicable. Effective use of EP19 is based on the premise that both the developer and the end user have a QMS in place with appropriate controls over all essential processes, including personnel, environment, general processes, and documentation. Users should refer to CLSI electronic product *Method Navigator*[1] in conjunction with EP19.

Because CLSI documents are regularly updated, the EP documents can be considered generally accepted good practice for how test methods should be evaluated. EP19 provides general reference on the specific CLSI documents that are useful for test method evaluations and provides considerations for how users could most effectively benefit from this information. EP19 users should refer to the referenced CLSI documents for sufficient details to plan, perform, and interpret the evaluations correctly.

Intended User

EP19 is intended for use by medical laboratories, commercial manufacturers, and government agencies. The term "developer" is used in this report to include not only commercial manufacturers of regulatory-cleared and -approved test methods but also laboratories that develop their own test methods for implementation, which are commonly referred to as laboratory-developed tests (LDTs). Although commercial manufacturers are likely to have well-documented and approved protocols, EP19 is a resource for them, as well as for start-up companies. Laboratories that modify regulatory-cleared and -approved commercial test methods, eg, by changing reagents, sample volumes, or patient sample types or by adding analyte-specific reagents, are essentially creating a new test method. In these cases, the laboratory acting as the developer needs to establish acceptable performance characteristics, and the laboratory as the end user must verify performance as part of test method implementation.

The laboratory needs to establish performance characteristics when it is acting as a test method developer, regardless of whether it has recognized research and development facilities or is a medical laboratory that incorporates minor modifications to a test method or measuring system. Laboratories that create new test methods and those that make relatively minor changes to regulatory-cleared and -approved commercial test methods are considered developers and are responsible for establishing test method performance. EP19 is an especially useful resource for laboratories that are just beginning to use CLSI documents and those that use non–regulatory-approved or modified regulatory-cleared and -approved commercial test methods.

Background

The Test Life Phases Model as shown in the figure below categorizes test method evaluations into two major **stages:**

- Establishment of a test method by a developer
- Implementation of that established test method by an end user