

Method evaluation standards, 11/15

November 2015—CLSI released new and revised standards on method evaluation titled “A Framework for Using CLSI Documents to Evaluate Clinical Laboratory Measurement Procedures (EP19-Ed2).”

EP19 is intended to serve as a reference guide for the use of CLSI documents in method evaluations, especially when developing or implementing new clinical laboratory tests. This report references existing CLSI method evaluation documents, explaining which CLSI documents are useful for validating newly developed tests and when implementing new tests in the laboratory. EP19 is intended for use by clinical laboratory professionals, manufacturers, and governmental agencies.

The document provides a roadmap to help the laboratory establish each new test’s performance characteristics. Laboratories using EP19 will learn which CLSI documents to turn to for understanding a test’s linearity interval, precision, stability, quality control, and more. Also, when implementing a new test, EP19 will help the laboratory understand which CLSI documents contain procedures for verifying the manufacturer’s performance claims.

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