

CLSI Publishes 3rd Edition of EP19—A Framework for Using CLSI Documents to Evaluate Medical Laboratory Test Methods

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Standards Institute ([CLSI](#)) has published the 3rd Edition of [EP19](#), A Framework for Using CLSI Documents to Evaluate Medical Laboratory Test Methods. The 3rd Edition of the EP19 Report is available free, and introduces the Test Life Phases Model, which points users to CLSI evaluation



EP19 guides the reader through the test life phases and calls out all the relevant CLSI documents that can be used as guidance along the way.”

*Jennifer Rychert, PhD,
D(ABMM)*

protocol documents to establish and implement commercially manufactured or laboratory-developed test (LDT) methods.

This edition of EP19 includes an introduction to CLSI's new electronic product [Method Navigator](#), updates to the figures and flow chart, discussion of the concept of risk management as an integral part of the Test Life Phases Model, and an update to the Special Cases section. It is intended for use by medical laboratories, commercial manufacturers, and government agencies.

“CLSI document EP19 has recently been updated and refreshed,” said Paula Ladwig, MS, MT(ASCP), Co-Chairholder of the EP19 Document Development Committee and Chairholder of CLSI’s Expert Panel for Evaluation Protocols. “The new version is still an invaluable resource for developers of new or changed test methods to establish performance characteristics and for the laboratory end user for implementation of these test methods utilizing the Test Life Phases Model. The revised version introduces CLSI’s electronic Method Navigator to be used in conjunction with EP19; to help users provide the needed information for their Quality Management System. EP19 also contains an enhanced discussion of the concept of risk management as an integral part of the Test Life Phases Model.”

Method Navigator is designed to be used with EP19, and includes links to requirements, guidance tables and evidence tables, and fillable and downloadable checklists. Method Navigator provides users with quick and easy access to specific guidance from CLSI documents. This new product was designed to help test developers—whether they are test manufacturers or laboratories developing tests—fulfill FDA, CLIA, ISO, and other requirements.

“Developing and implementing an LDT in a high-complexity clinical laboratory often requires a considerable amount of technical and statistical knowledge. EP19 guides the reader through the test life phases and calls out all the relevant CLSI documents that can be used as guidance along the way. It is very useful to see all of the relevant EP and QMS documents in this context,” said Jennifer Rychert, PhD, D(ABMM), Co-Chairholder of the EP19 Document Development Committee.

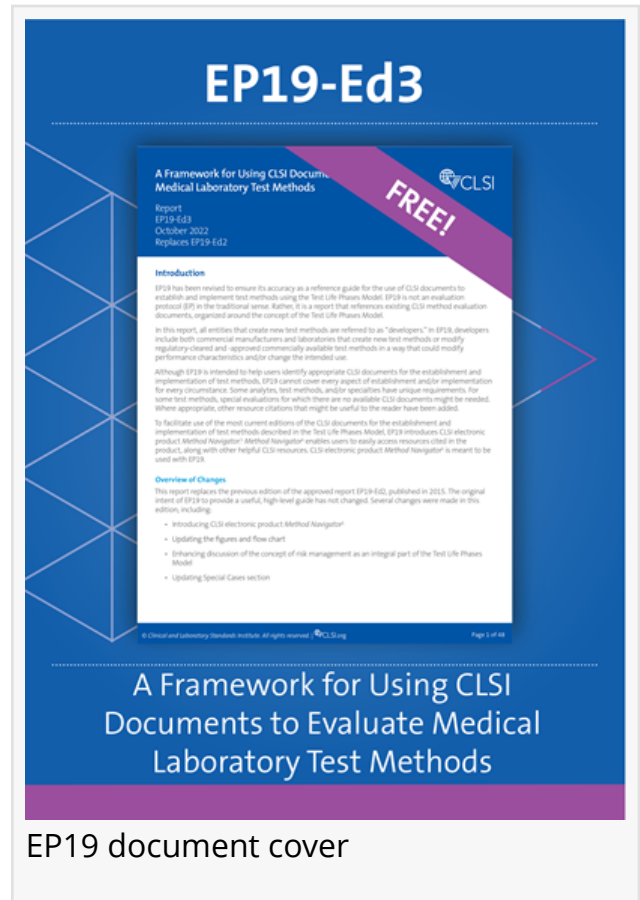
CLSI sets the standard for quality in medical laboratory testing. A not-for-profit membership organization, CLSI brings together the global laboratory community for the advancement of a common cause: to foster excellence in laboratory medicine. For over 50 years, our members, volunteers, and customers have made CLSI a respected, transformative leader in the development and implementation of medical laboratory testing standards. Through our unified efforts, we will continue to set and uphold the standards that drive quality test results, enhance patient care delivery, and improve health care around the world. By using CLSI standards, laboratorians can improve process quality, speed the development of standard operating procedures, and implement safer practices with greater ease and efficiency.

For more information about EP19 or Method Navigator, contact Joanne Christopher.

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