



With the recent FDA final rule on the regulation of Laboratory Developed Tests (LDTs) we know that there will be a great deal for laboratories to grapple with, including how to navigate the FDA regulatory environment.

There is likely some uncertainty of how to meet the new regulations, as well as a sense of urgency to be ready when they phase in. **CLSI will be here for you.** When the current CLIA regulations began in 1988, CLSI had already developed much of the guidance laboratories needed to meet them, and we continue to provide guidance as those requirements evolve. We will do the same again now as the FDA rule comes into focus.

CLSI already has all the guidance needed to meet the FDA's LDT requirements with our Quality Management System (QMS) Standards, Evaluation Protocols (EP) Standards, Breakpoint Implementation Toolkit, and our Method Navigator Tool. But over the coming months you will hear more about new online training courses, webinars, and additional tools for performing the validations you will need for submissions. As always, CLSI is a trusted resource on your journey to provide the highest quality laboratory testing for all of the patients that you care for.

You can start your journey with these two FREE resources:

[**CLSI QSRLDT** Quality System Regulations for Laboratory Developed Tests: A Practical Guide for the Laboratory](#); and

[**CLSI EP19** A Framework for Using CLSI Documents to Evaluate Medical Laboratory Test Methods, 3rd Edition](#)

In spite of the angst that you might be feeling, there are real things to inspire optimism here. Because of your drive to meet the needs of patients, laboratory medicine continues to advance tremendously. So much so, that tests that are being developed in the laboratory are now more responsive to patient needs than ever before. And this spotlight on the medical laboratory, once again, shows how critical medical laboratory professionals are to clinical care of patients. That is worth celebrating!

No matter what comes our way – we are in this together. Since 1967, the expert volunteers of CLSI have provided the guidance that medical laboratories need to weather any storm...and we will weather this one together, again.

Warmest regards,

Barb