An Introduction from the Special Issue Guest Editors

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Dear Fellow Scientists and Concerned Citizens,

This special issue of the *Journal of Mass Spectrometry and Advances in the Clinical Lab* focuses on the integral role of laboratory developed tests (LDTs) in patient care. LDTs are designed, validated, and used within a single clinical laboratory to meet specific and unmet medical needs. Traditionally, these tests have been overseen by qualified laboratory directors who have the necessary expertise to develop, validate, and implement them. Over the last several decades, and most recently last year with the 2021 VALID Act, legislation has been proposed to shift oversight of LDTs to the United States Food and Drug Administration (FDA). There are significant negative implications for the LDT landscape under an FDA-oversight mechanism, which would result in less access to critically needed tests. While the VALID Act did not move forward during the December 2022 congressional meeting, the topic of FDA oversight is likely to resurface. The threat of the VALID Act provides motivation to reflect on current LDT oversight and identify opportunities for improvement within the existing framework.

In this special issue, we have engaged leaders in the field to provide their perspectives on current best practices and how to improve LDT oversight while maintaining the flexibility required to adapt to emerging clinical needs. Of note, there are several case reports illustrating the importance of LDTs in various sectors of healthcare, including those on mass spectrometry-based therapeutic drug monitoring to ensure transplant success, and the application of microbial pathogen identification to manage urinary tract infections. Further, there are thoughtful reviews that illustrate the importance of mass spectrometry in therapeutic drug monitoring, toxicology, endocrinology, as well as the growing role of protein-based testing in patient care. Additionally, there are research articles demonstrating the need for the flexibility offered by LDTs.

This special issue is meant to serve as evidence of the critical role these tests play in patient care, and a call to action for medical professionals to advocate for continued access to LDTs.

Sincerely,

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