Clinical Laboratory Improvement Advisory Committee (CLIAC)

The Clinical and Laboratory Standards Institute (CLSI) is the only US-based, accredited, not-for-profit standards development organization in the field of laboratory medicine. CLSI’s standards and guidelines are developed through a highly structured, open, and inclusive voluntary consensus process that balances stakeholder participation and approval among government, industry, and health care professionals. For over 50 years, CLSI has been creating and revising the standards and guidelines that drive quality test results, support regulatory and accreditation requirements, and improve patient care globally.

CLSI offers a number of consensus guidelines for molecular diagnostic methods, including infectious diseases identification, oncological applications, quality management, and proficiency testing. CLSI also publishes guidelines on specimen collection, transport, preparation, and storage.

Of note, CLSI is currently revising MM09, Nucleic Acid Sequencing Methods in Diagnostic Laboratory Medicine. This revision, titled Human Genetic and Genomic Testing Using Traditional and High-Throughput Nucleic Acid Sequencing Methods, will focus on next-generation sequencing (NGS). In particular, the guideline will describe how to perform activities in the NGS testing lifecycle, including test design, optimization, validation, as well as cover quality management. MM09 will provide necessary guidance for industry and laboratories to implement current best practices and facilitate standardization of NGS test development and validation procedures. In addition to providing guidance that can be formally recognized and used by regulatory organizations such as the US Food and Drug Administration, the revision of MM09 will harmonize US-focused best practices with global standards.

Molecular diagnostics is one of the most rapidly developing disciplines in laboratory medicine, and CLSI has specifically identified NGS as a high-growth area. As such, it is expected to be an important focus of CLIAC for the foreseeable future. CLSI is pleased CLIAC has commissioned the Next Generation Sequencing Workgroup and eagerly looks forward to evaluating its output as a resource for consensus guidance that will improve laboratory medicine practice and patient care.

Submitted by,

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