

New molecular methods standards, 7/14

July 2014—The Clinical and Laboratory Standards Institute released *Nucleic Acid Sequencing Methods in Diagnostic Laboratory Medicine; Approved Guideline—Second Edition* (MM09-A2) and published a new document, *Microarrays for Diagnosis and Monitoring of Infectious Diseases; Approved Guideline* (MM22-A).



MM09-A2 addresses diagnostic sequencing using both automated capillary-based sequencers and massively parallel sequencing instruments. Topics in this guideline include specimen collection and handling; isolation and extraction of nucleic acid; template preparation; sequence generation, alignment, and assembly; validation and verification; ongoing quality assurance; and reporting results.

MM22-A focuses on the use of nucleic acid microarrays in microbiology and immunology labs. It provides recommendations for assay performance validation and verification processes unique to microarrays, and includes recommended target types and numbers for diagnosis and monitoring of infectious diseases. The guideline contains information for clinical laboratories performing qualitative, multiplexed nucleic acid-based testing, including bacteriology, mycobacteriology, mycology, parasitology, and virology. It also helps users select and validate commercially available microarray-based diagnostic devices and assays.

[CLSI](http://www.clsi.org), 610-688-0100