
Molecular Diagnostic Methods for Infectious Diseases; Approved Guideline— Second Edition

This guideline addresses topics relating to clinical applications, amplified and nonamplified nucleic acid methods, selection and qualification of nucleic acid sequences, establishment and evaluation of test performance characteristics, inhibitors, and interfering substances, controlling false-positive reactions, reporting and interpretation of results, quality assurance, regulatory issues, and recommendations for manufacturers and clinical laboratories.

A guideline for global application developed through the Clinical and Laboratory Standards Institute consensus process.



**CLINICAL AND
LABORATORY
STANDARDS
INSTITUTE**

*(Formerly NCCLS)
Preceding NCCLS standards and guidelines,
ISO/TC 212 standards, and ISO/TC 79 standards*

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JL Elias



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