

CLSI Documents Helpful for COVID-19 Testing



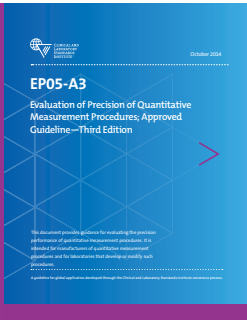
This list of documents have been identified as helpful for the laboratory community's use during the current pandemic. Click the document covers below to view sample pages and learn more.

NOTE: Most COVID-19 devices (current or near future) will have an internal signal; therefore, CLSI documents EP05, EP07, EP12, EP17, EP18, EP25, and EP35 are recommended. If a signal is not available, the same CLSI documents are recommended but additional data analysis may be required.

CLSI Document Title and Information

How is this helpful for COVID-19?

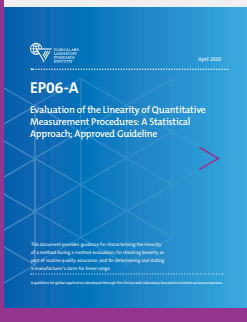
Method Evaluation



EP05 | *Evaluation of Precision of Quantitative Measurement Procedures, 3rd Edition*

This document provides guidance for evaluating the precision performance of quantitative measurement procedures. It is intended for manufacturers of quantitative measurement procedures and for laboratories that develop or modify such procedures.

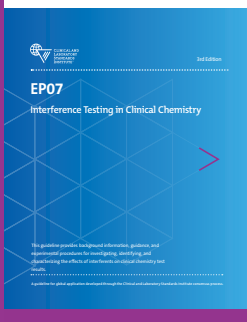
EP05 provides study design of precision studies with regard to testing conditions. If the test has an internal signal, then analysis of the internal signal described in CLSI document EP05 is also recommended.



EP06 | *Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach, 1st Edition*

This document provides guidance for characterizing the linearity of a method during a method evaluation; for checking linearity as part of routine quality assurance; and for determining and stating a manufacturer's claim for linear range.

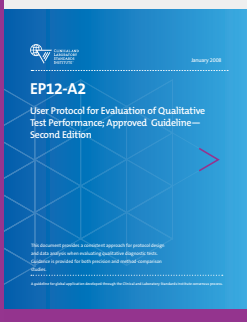
Serologic assays can provide quantitative results (for example, to monitor a patient's immune system). EP06 may apply in such cases.



EP07 | *Interference Testing in Clinical Chemistry, 3rd Edition*

This guideline provides background information, guidance, and experimental procedures for investigating, identifying, and characterizing the effects of interferents on clinical chemistry test results.

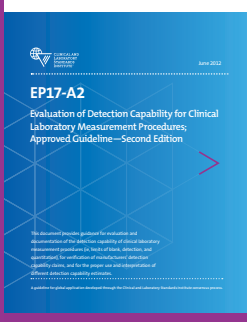
EP07 provides study design of interference studies. If the test has an internal signal, then analysis of the internal signal described in EP07-A3 is also recommended.



EP12 | *User Protocol for Evaluation of Qualitative Test Performance, 2nd Edition*

This document provides a consistent approach for protocol design and data analysis when evaluating qualitative diagnostic tests. Guidance is provided for both precision and method-comparison studies.

EP12 is recommended for all types of assays (regardless of whether the internal signal is available or not).



EP17 | *Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures, 2nd Edition*

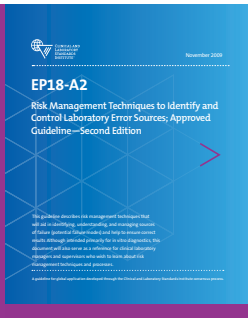
This document provides guidance for evaluation and documentation of the detection capability of clinical laboratory measurement procedures (ie, limits of blank, detection, and quantitation), for verification of manufacturers' detection capability claims, and for the proper use and interpretation of different detection capability estimates.

EP17 is also recommended for all types of COVID-19 assays.

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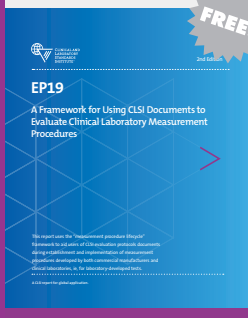
Method Evaluation



EP18 | *Risk Management Techniques to Identify and Control Laboratory Error Sources, 2nd Edition*

This guideline describes risk management techniques that will aid in identifying, understanding, and managing sources of failure (potential failure modes) and help to ensure correct results. Although intended primarily for *in vitro* diagnostics, this document will also serve as a reference for clinical laboratory managers and supervisors who wish to learn about risk management techniques and processes.

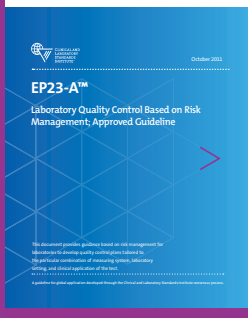
Creating a risk assessment for the new test will help you decide the extent of the validation or verification testing needed.



EP19 | *A Framework for Using CLSI Documents to Evaluate Clinical Laboratory Measurement Procedures, 2nd Edition*

This report uses the “measurement procedure lifecycle” framework to aid users of CLSI evaluation protocols documents during establishment and implementation of measurement procedures developed by both commercial manufacturers and clinical laboratories, ie, for laboratory-developed tests (LDTs).

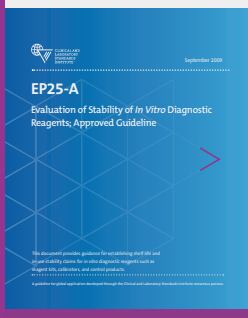
EP19 explains when you need to validate a test and when you need to verify a test. It also lists all CLSI documents that can help you either verify or validate a new test in your laboratory.



EP23 | *Laboratory Quality Control Based on Risk Management, 1st Edition*

This document provides guidance based on risk management for laboratories to develop quality control plans tailored to the particular combination of measuring system, laboratory setting, and clinical application of the test.

This document addresses individual quality control plans.



EP25 | *Evaluation of Stability of In Vitro Diagnostic Reagents, 1st Edition*

This document provides guidance for establishing shelf-life and in-use stability claims for *in vitro* diagnostic reagents such as reagent kits, calibrators, and control products.

EP25 is recommended for checking shelf life and in-use reagents. Study design described in EP25 is recommended for all types of COVID-19 assays. The analysis of the internal signal for the samples included in the stability of reagent studies described in EP25 is also recommended.



EP35 | *Assessment of Equivalence or Suitability of Specimen Types for Medical Laboratory Measurement Procedures, 1st Edition*

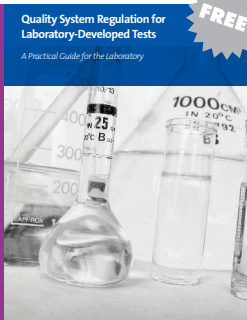
This guideline provides recommendations for assessing clinically equivalent performance for additional similar-matrix specimen types and suitable performance for dissimilar-matrix specimen types, such that the laboratory does not necessarily need to repeat the full measurement procedure validation for each specimen type. The recommendations in this guideline apply to both quantitative measurement procedures and qualitative examinations.

EP35 is recommended for the evaluation of different types of specimens.

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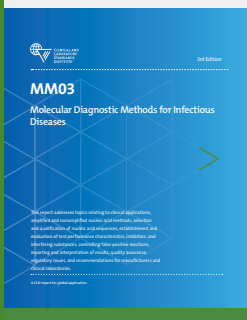


QSRLDT | *Quality System Regulation for Laboratory-Developed Tests: A Practical Guide for the Laboratory*

This practical guide, compiled with the help of experts from the *in vitro* diagnostics industry, is intended for the laboratory that is creating laboratory developed tests that may be subject to the US Food and Drug Administration (FDA) regulations, specifically the Quality System Regulation (QSReg), 21 CFR part 820.

This guide will help you meet FDA requirements for a laboratory developed test.

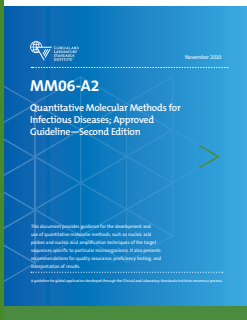
Molecular Diagnostics



MM03 | *Molecular Diagnostic Methods for Infectious Diseases, 3rd Edition*

This report 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.

This document includes verification and validation information.



MM06 | *Quantitative Molecular Methods for Infectious Diseases, 2nd Edition*

This document provides guidance for the development and use of quantitative molecular methods, such as nucleic acid probes and nucleic acid amplification techniques of the target sequences specific to particular microorganisms. It also presents recommendations for quality assurance, proficiency testing, and interpretation of results.

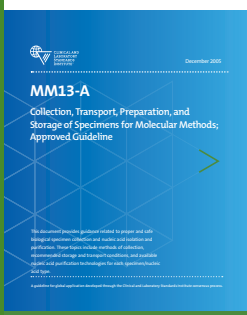
This document includes verification and validation information.



MM09 | *Nucleic Acid Sequencing Methods in Diagnostic Laboratory Medicine, 2nd Edition*

This document addresses diagnostic sequencing using both automated capillary-based sequencers and massively parallel sequencing instruments. Topics 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.

This document will help you understand how to perform, validate, and verify nucleic acid sequencing tests.



MM13 | *Collection, Transport, Preparation, and Storage of Specimens for Molecular Methods, 1st Edition*

This document provides guidance related to proper and safe biological specimen collection and nucleic acid isolation and purification. These topics include methods of collection, recommended storage and transport conditions, and available nucleic acid purification technologies for each specimen/nucleic acid type.

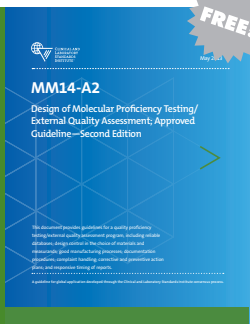
This document provides information on specimen collection, handling, and transport for molecular testing.

CLSI Document Title and Information

How is this helpful for COVID-19?

Molecular Diagnostics

Microbiology



MM14 | *Design of Molecular Proficiency Testing/External Quality Assessment, 2nd Edition*

This document provides guidelines for a quality proficiency testing/external quality assessment program, including reliable databases; design control in the choice of materials and measurands; good manufacturing processes; documentation procedures; complaint handling; corrective and preventive action plans; and responsive timing of reports.

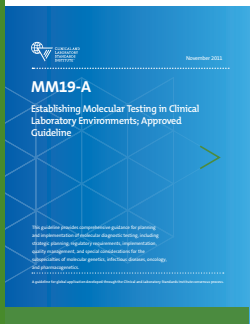
This document will help you understand when you need proficiency testing/external quality assessment, and how to perform the testing.



MM17 | *Validation and Verification of Multiplex Nucleic Acid Assays, 2nd Edition*

This guideline includes recommendations for analytical validation and verification of multiplex assays, as well as a review of different types of biological and synthetic reference materials.

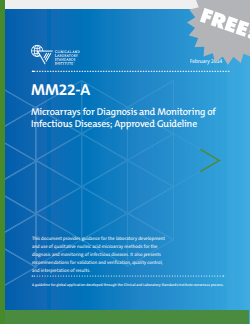
This document includes verification and validation information.



MM19 | *Establishing Molecular Testing in Clinical Laboratory Environments, 1st Edition*

This guideline provides comprehensive guidance for planning and implementation of molecular diagnostic testing, including strategic planning, regulatory requirements, implementation, quality management, and special considerations for the subspecialties of molecular genetics, infectious diseases, oncology, and pharmacogenetics.

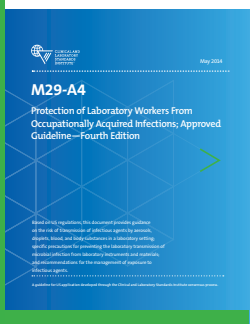
This document includes detailed verification and validation information.



MM22 | *Microarrays for Diagnosis and Monitoring of Infectious Diseases, 1st Edition*

This document provides guidance for the laboratory development and use of qualitative nucleic acid microarray methods for the diagnosis and monitoring of infectious diseases. It also presents recommendations for validation and verification, quality control, and interpretation of results.

This guideline will help you understand how to validate or verify a new microarray test.



M29 | *Protection of Laboratory Workers From Occupationally Acquired Infections, 4th Edition*

Based on US regulations, this document provides guidance on the risk of transmission of infectious agents by aerosols, droplets, blood, and body substances in a laboratory setting; specific precautions for preventing the laboratory transmission of microbial infection from laboratory instruments and materials; and recommendations for the management of exposure to infectious agents.

Information on biological risk assessment is included.

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Microbiology

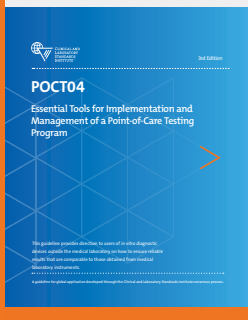


M40 | *Quality Control of Microbiological Transport Systems, 2nd Edition*

This document provides criteria to assist manufacturers and end users of transport devices in providing and selecting dependable products for the transport of microbiological clinical specimens.

This document provides information on viral specimen collection and transport.

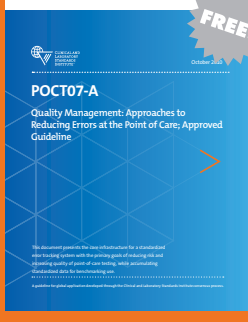
Point-of-Care Testing



POCT04 | *Essential Tools for Implementation and Management of a Point-of-Care Testing Program, 3rd Edition*

This guideline provides direction to users of *in vitro* diagnostic devices outside the medical laboratory on how to ensure reliable results that are comparable to those obtained from medical laboratory instruments.

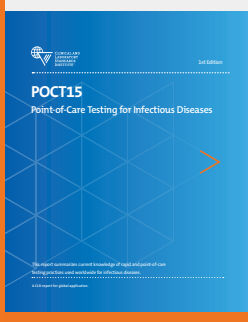
This guideline will help you ensure that your point-of-care testing is being performed correctly.



POCT07 | *Quality Management: Approaches to Reducing Errors at the Point of Care, 1st Edition*

This document presents the core infrastructure for a risk management and standardized error tracking system for reducing risk at the point of care, as well as for benchmarking purposes. POCT07-A proposes a set of indicators for each analytical process for incorporation into a point-of-care quality program. It also presents the user with predefined common causes of error and respective error prevention mechanisms for a more standardized reporting mechanism.

This document will help you identify and eliminate errors in your point-of-care testing programs.

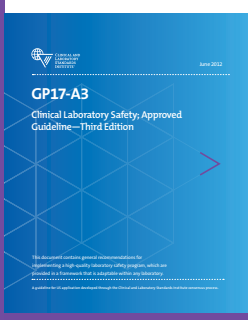


POCT15 | *Point-of-Care Testing for Infectious Diseases, 1st Edition*

This report summarizes current knowledge of rapid and point-of-care testing practices used worldwide for infectious diseases.

This document will help you understand current practices in point-of-care testing for infectious diseases.

General Laboratory



GP17 | *Clinical Laboratory Safety, 3rd Edition*

This document contains general recommendations for implementing a high-quality laboratory safety program, which are provided in a framework that is adaptable within any laboratory.

This document will help you understand the safety practices that need to be in place in your laboratory.

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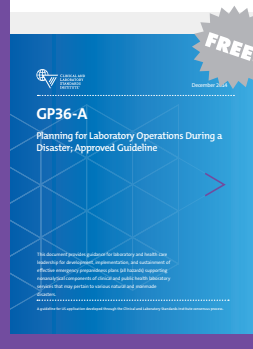
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GP33 | *Accuracy in Patient and Sample Identification, 2nd Edition*

This standard specifies the processes required to ensure accurate patient and specimen identification in manual and electronic systems across the health care organization. Processes include system design considerations, differences in requirements for patients with or without identification bands, and provisions for patients with communication barriers.

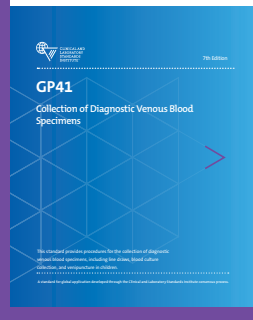
This document will help you ensure accurate patient and specimen identification.



GP36 | *Planning for Laboratory Operations During a Disaster, 1st Edition*

This document provides guidance for laboratory and health care leadership for development, implementation, and sustainment of effective emergency preparedness plans (all hazards) supporting nonanalytical components of clinical and public health laboratory services that may pertain to various natural and manmade disasters.

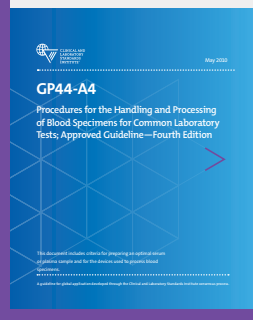
This document will help you develop and implement emergency preparedness plans.



GP41 | *Collection of Diagnostic Venous Blood Specimens, 7th Edition*

This standard provides procedures for the collection of diagnostic venous blood specimens, including line draws, blood culture collection, and venipuncture in children.

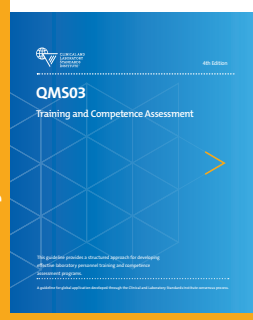
Contains specific information (in Subchapter 5.4.1) on collection from patients in isolation.



GP44 | *Procedures for the Handling and Processing of Blood Specimens for Common Laboratory Tests, 4th Edition*

This document includes criteria for preparing an optimal serum or plasma sample and for the devices used to process blood specimens.

This document will help you ensure that your samples are being processed properly.



QMS03 | *Training and Competence Assessment, 4th Edition*

This guideline provides a structured approach for developing effective laboratory personnel training and competence assessment programs.

This document will help you ensure that your training and competence assessment program are adequate.