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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.
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.

This document addresses individual quality control plans.

This document provides guidance for establishing 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.

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.

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

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.

This document provides guidance for developing quality control plans tailored to the particular combination of measuring system, laboratory setting, and clinical application of the test.

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 is recommended for the evaluation of different types of specimens.
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 document includes verification and validation information.

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

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 guide will help you meet FDA requirements for a laboratory developed test.
This guideline will help you understand how to validate or verify a new microarray test.
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.

How is this helpful for COVID-19?

This document provides information on viral specimen collection and transport.

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.

How is this helpful for COVID-19?

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.

How is this helpful for COVID-19?

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.

How is this helpful for COVID-19?

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

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.

How is this helpful for COVID-19?

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

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.

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.

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.

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

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

How is this helpful for COVID-19?

- This document will help you ensure accurate patient and specimen identification.
- This document will help you develop and implement emergency preparedness plans.
- Contains specific information (in Subchapter 5.4.1) on collection from patients in isolation.
- This document will help you ensure that your samples are being processed properly.
- This document will help you ensure that your training and competence assessment program are adequate.