<table>
<thead>
<tr>
<th>CLSI Document Title and Information</th>
<th>How is this helpful for COVID-19?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>EP05</strong></td>
<td>Evaluation of Precision of Quantitative Measurement Procedures, 3rd Edition</td>
</tr>
<tr>
<td><strong>EP06</strong></td>
<td>Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach, 1st Edition</td>
</tr>
<tr>
<td><strong>EP07</strong></td>
<td>Interference Testing in Clinical Chemistry, 3rd Edition</td>
</tr>
<tr>
<td><strong>EP12</strong></td>
<td>User Protocol for Evaluation of Qualitative Test Performance, 2nd Edition</td>
</tr>
<tr>
<td>CLSI Document Number</td>
<td>CLSI Document Title and Information</td>
</tr>
<tr>
<td>----------------------</td>
<td>------------------------------------</td>
</tr>
<tr>
<td><strong>EP18</strong></td>
<td>Risk Management Techniques to Identify and Control Laboratory Error Sources, 2nd Edition</td>
</tr>
<tr>
<td><strong>EP19</strong></td>
<td>A Framework for Using CLSI Documents to Evaluate Clinical Laboratory Measurement Procedures, 2nd Edition</td>
</tr>
<tr>
<td><strong>EP23</strong></td>
<td>Laboratory Quality Control Based on Risk Management, 1st Edition</td>
</tr>
<tr>
<td><strong>EP25</strong></td>
<td>Evaluation of Stability of In Vitro Diagnostic Reagents, 1st Edition</td>
</tr>
<tr>
<td><strong>EP35</strong></td>
<td>Assessment of Equivalence or Suitability of Specimen Types for Medical Laboratory Measurement Procedures, 1st Edition</td>
</tr>
</tbody>
</table>
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.

**How is this helpful for COVID-19?**
This document will help you understand how to perform, validate, and verify nucleic acid sequencing tests.

---

**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.

**How is this helpful for COVID-19?**
This guide will help you meet FDA requirements for a laboratory developed test.
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 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 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 will help you understand how to validate or verify a new microarray test.

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.
CLSI Document Title and Information

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.

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.