<table>
<thead>
<tr>
<th>CLSI Document Title and Information</th>
<th>How is this helpful for COVID-19?</th>
</tr>
</thead>
<tbody>
<tr>
<td>EP05</td>
<td>Evaluation of Precision of Quantitative Measurement Procedures, 3rd Edition</td>
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<tr>
<td>EP06</td>
<td>Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach, 1st Edition</td>
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<tr>
<td>EP07</td>
<td>Interference Testing in Clinical Chemistry, 3rd Edition</td>
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<tr>
<td>EP12</td>
<td>User Protocol for Evaluation of Qualitative Test Performance, 2nd Edition</td>
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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.
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.

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 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 provides guidance for establishing shelf-life and in-use reagents.

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.

Creating a risk assessment for the new test will help you decide the extent of the validation or verification testing needed.
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.
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.
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<tr>
<td>**M40</td>
<td>Quality Control of Microbiological Transport Systems, 2nd Edition**&lt;br&gt;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.</td>
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<tr>
<td>**POCT04</td>
<td>Essential Tools for Implementation and Management of a Point-of-Care Testing Program, 3rd Edition**&lt;br&gt;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.</td>
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<tr>
<td>**POCT07</td>
<td>Quality Management: Approaches to Reducing Errors at the Point of Care, 1st Edition**&lt;br&gt;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.</td>
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<tr>
<td>**POCT15</td>
<td>Point-of-Care Testing for Infectious Diseases, 1st Edition**&lt;br&gt;This report summarizes current knowledge of rapid and point-of-care testing practices used worldwide for infectious diseases.</td>
</tr>
<tr>
<td>**GP17</td>
<td>Clinical Laboratory Safety, 3rd Edition**&lt;br&gt;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.</td>
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</table>
**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.

**How is this helpful for COVID-19?**

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

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**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.

**How is this helpful for COVID-19?**

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

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**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.

**How is this helpful for COVID-19?**

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

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

**How is this helpful for COVID-19?**

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

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**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 that your training and competence assessment program are adequate.