
Overview
Certain diagnostic tests may be performed at the point-of-care, or POC, meaning that the process of medical diagnostic testing occurs at the time and place of patient care, e.g. bedside, physician’s office, etc. POC testing offers additional benefits including speed of diagnosis, and simplicity of use (push button, single cassette, etc.). They can include both nucleic acid amplification (molecular) tests that detect the presence of a pathogen, and serological tests that can determine whether or not an individual has immunological evidence of exposure to a pathogen. This type of diagnostic test is a useful component of the diagnostic strategy in response to the SARS-CoV-2 (COVID-19) outbreak.

Nucleic Acid Amplification POC Tests
Mobile platforms
Mobile platforms are small and portable, and are optimal for deployment to remote, outbreak and crisis situations. These POC instruments are lower throughput (i.e., process less samples in a specified timeframe) than other platforms (instruments), and typically run one sample at a time in 5-30 minutes. For this reason, it may not be feasible to test, for example, an entire manufacturing facility of thousands of employees for COVID-19 with a POC platform. In such a situation, the POC instrument could be used to test prioritized (symptomatic) individuals, while results for asymptomatic individuals could be sent out for processing at an offsite laboratory using high throughput platforms. The Abbott ID NOW is an example of a mobile molecular POC device for COVID-19.

Facility-based platforms
Larger POC platforms, such as the Cepheid GeneXpert® Xpress, another example of a POC device that can be used for COVID-19, are often based in hospitals and medical centers. They have higher throughput than the mobile platforms, but still return results in less than an hour. The components are often self-contained, requiring fewer laboratory resources (i.e., hands-on personnel) than other laboratory-based instruments. Using a rapid, facility-based POC platform to test healthcare providers and symptomatic patients enables maintenance of workforce (rapid return to work), lessens PPE usage, and rapid diagnosis for critically ill patients.

Serological POC Tests
POC serologic testing technologies include single-use, low through-put lateral flow tests where the presence of antibody is demonstrated by a color change on a paper strip. Samples for this type of test are commonly collected through the use of a finger stick.

There are different types of antibodies. IgM is one of the first types of antibody to be produced after a pathogen has entered the body, and is most useful for determining recent infection. In most infections, IgG generally develops after IgM, and may remain detectable for months or years. These are the types of antibodies that are often targeted by serological tests.

CDC, NIH and FDA and other parts of the federal government are evaluating the performance of commercially manufactured antibody tests for SARS-CoV-2 (COVID-19). FDA has authorized emergency use of several of these antibody tests.

Presently, a positive test result from a POC serological test for SARS-CoV-2 (COVID-19) shows that an individual has antibodies that likely resulted from an infection with SARS-CoV-2, or possibly a related coronavirus. It is unclear if those antibodies can provide protection (immunity) against re-infection.

 Appropriately validated serology tests, when used broadly as part of seroprevalence studies, can be useful in understanding how many people have been infected and how far the pandemic has progressed. These tests can also be useful to examine demographics and geographic patterns, to determine which
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Communities may have had more cases, suggesting more ‘herd immunity’ which reflects the degree of resistance to infection in a population.

Proposed Uses of Point-of-Care Diagnostic Tests for SARS-CoV-2 (COVID-19)
POC rapid tests are envisioned to supplement laboratory testing, enabling testing to be available for communities and populations that cannot readily access laboratory testing or need to quickly address emerging outbreaks. Laboratory testing remains the primary testing mechanism for the nation because of the ability to perform a high volume of tests at one time.

Examples of potential uses for POC instruments for COVID-19 diagnostic purposes include:

- Deployment to rural hospitals or other critical care sites that lack widely available testing.
- Use at public health department testing sites performing CLIA-waived testing for other purposes.
- Deployment to long-term care facilities or correctional institutions. Regulatory requirements and necessary CLIA documentation need to be considered when deploying instruments to these settings if they are not currently performing other POC testing.
- Rapid deployment to aid in the investigation of a newly identified case cluster. This potential use would require careful consideration to ensure the feasibility of rapidly standing up testing.
- Placement in public health laboratories to test high-priority specimens requiring a rapid result.

Regulatory Considerations
There are regulatory considerations that must guide the use of POC instruments for SARS-CoV-2 diagnostic purposes. Testing sites operating a POC diagnostic instrument must have a current certificate via the Clinical Laboratory Improvement Amendments of 1988 (CLIA). During the COVID-19 public health emergency, the Centers for Medicare & Medicaid Services (CMS) will permit a Certificate of Waiver laboratory to extend its existing certificate to operate a temporary COVID-19 testing site in an off-site location, such as a long-term care facility. The temporary COVID-19 testing site is only permitted to perform waived tests, consistent with the laboratory's existing certificate and must be under the direction of the existing lab director. Frequently Asked Questions (FAQs) concerning CLIA Guidance during the COVID-19 Emergency is available here.

For Additional Information

CDC Coronavirus Disease 2019 (COVID-19) – Test for Past Infection -

CDC Coronavirus Disease 2019 (COVID-19) – COVID-19 Serology Surveillance Strategy

CMS Frequently Asked Questions (FAQs), CLIA Guidance During the COVID-19 Emergency -