Guidance for SARS-CoV-2 Point-of-Care Testing

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Point-of-care (POC) tests, such as some rapid tests for diagnosing an infectious disease, provide results within minutes of the test being administered, allowing for rapid decisions about patient care. POC tests can also extend testing to communities and populations that cannot readily access care. POC tests are used to diagnose COVID-19 in various settings, such as:

- Physician offices
- Urgent care facilities
- Pharmacies
- School health clinics
- Long-term care facilities and nursing homes
- Temporary locations, such as drive-through sites managed by local organizations

Summary: This CDC Web resource provides guidance on the regulatory requirements for SARS-CoV-2 POC testing, using POC tests safely, and information on reporting POC test results.

Regulatory Requirements for POC Testing

Who can do POC testing?

Sites that perform POC testing are required to have a Clinical Laboratory Improvement Amendments (CLIA) certificate; find information in this brochure . There are four different types of CLIA certificates, any one of which is appropriate for POC testing. See this Centers for Medicare & Medicaid Services (CMS) document that describes the different types of CLIA certificates. A CLIA Certificate of Waiver is appropriate for POC testing and can be obtained as follows:

1. Complete an application (Form CMS-116), available on the CMS CLIA website or from a local State Agency.
2. Send the completed application to the address of the local State Agency for the state where testing will be performed.
3. Pay the CLIA Certificate of Waiver fee, following instructions provided by the State Agency.

Further information on obtaining a CLIA Certificate of Waiver may be found here . POC testing may be performed after the testing site has received a CLIA certificate number.

The testing site must keep its certificate information current. The State Agency should be notified of any changes in ownership, name, address, or director within 30 days.

What tests can be used for POC?

A list of the SARS-CoV-2 POC tests that have received US Food & Drug Administration (FDA) Emergency Use Authorization (EUA) is here . Tests that have been authorized for use in a POC setting will have a W, for Waived, in the Authorized Settings column of the FDA table. The testing site must use a test authorized for POC use by FDA and must follow the manufacturer's instructions for each POC test. The instructions for use provide specific information on how to perform the test, which specimens can be used, and the individuals who may be tested. All of the currently authorized tests are authorized for use on symptomatic individuals. However, CMS has indicated here that CLIA will temporarily allow CLIA testing sites to use SARS-CoV-2 POC antigen tests on asymptomatic individuals for the duration of the COVID-19 public health emergency.

For more information and additional resources for POC testing, see CDC's Waived Tests Web page.

Expedited Review of CLIA Applications

On March 26, 2020, CMS issued a memorandum for surveyors and laboratories, providing guidance that included expedited review of CLIA applications during the COVID-19 public health emergency.

Temporary COVID-19 Testing Sites

During the COVID-19 public health emergency, the Centers for Medicare & Medicaid Services (CMS) allows a laboratory or testing site to use its existing Certificate of Waiver to operate a temporary COVID-19 testing site in an off-site location, such as a nursing home or drive-through location. A temporary COVID-19 testing site can only perform waived COVID-19 tests and must be under the direction of the existing laboratory or testing site director.

Specimen Collection & Handling of Point-of-Care Tests

There are many different FDA-authorized SARS-CoV-2 tests for POC settings. Each has been authorized for use with certain specimen types. Each POC test should only be used with its authorized specimen type. Proper specimen collection and handling is critical for all COVID-19 testing, including those tests performed at POC settings. A specimen that is not collected or handled correctly may lead to inaccurate or unreliable test results. For additional general information about the proper collection of each of the specimen types, please refer to CDC's Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens for COVID-19.

It is also important to use proper infection control practices when collecting and handling specimens for POC testing. Whenever possible, after collecting the specimen, maintain at least six feet of separation from the person whose specimen was collected. CDC recommends using Standard Precautions when collecting and handling specimens for POC testing. Standard Precautions include, but are not limited to, personal protective equipment (PPE), such as a laboratory coat, surgical mask or face shield, disposable gloves, and eye protection.

In addition, CDC recommends the following practices when performing POC tests:

- Perform a risk assessment before testing to identify what could go wrong, such as breathing infectious material or touching contaminated objects and surfaces. Then
  - Decide what to do to prevent these negative outcomes from happening, and implement appropriate control measures.
  - Find more information on Risk Assessment Best Practices and Risk Assessment templates .
  - Learn more about CDC's guidelines for safe handling and processing of COVID-19 samples.
- Follow all of the manufacturer's instructions for performing the test in the exact order specified.
- Perform regular quality control and instrument calibration according to the manufacturer's instructions. If quality control or calibration fails, identify and correct issues prior to proceeding with patient testing.
- Do not reuse used test devices, reagent tubes, solutions, or swabs.
- Discard tests and test components that have exceeded the expiration date or show signs of damage or discoloration.
- Change gloves between specimen collection and after adding specimens to the testing device.
- Store reagents, specimens, kit content, and test devices according to the manufacturer's recommendations, found in the package insert.
- If using an instrument to perform testing, decontaminate the instrument after each use; follow the manufacturer's recommendations for using an approved disinfectant, including proper dilution, contact time, and safe handling.
- Read and record results only within the amount of time specified in the manufacturer's instructions. Do not record results from tests that have not been read within the manufacturer's specified timeframe.
- Handle laboratory waste from testing suspected or confirmed COVID-19 patient specimens as all other biohazardous waste in the laboratory. Currently, there is no evidence to suggest that this laboratory waste needs additional packaging or disinfection procedures.

or disinfection procedures.

Testing sites can find free, online training courses relevant to working with COVID-19 specimens on CDC's Preparing and Supporting Laboratories Responding to COVID-19 Web page.

Reporting Requirements for Point-of-Care Testing

A CLIA-certified laboratory or testing site must report all COVID-19 diagnostic and screening test results to the individual who was tested or that individual's healthcare provider. Depending on the test manufacturer's instructions for use, which can be found at FDA's EUA website, the laboratory or testing site may be required to report a negative test result as a "presumptive negative."

A CLIA-certified laboratory or testing site must also report all COVID-19 test results to their respective state, local, tribal, or territorial health department in accordance with the Coronavirus Aid, Relief, and Economic Security (CARES) Act; refer to the CMS interim final rule for regulatory reporting requirements. In addition, testing sites can find out more about How to Report COVID-19 Laboratory Data.

More Point-of-Care Resources

- Diagnostic, Screening, and Surveillance Testing for SARS-CoV-2
- Interim Guidance for Rapid Antigen Testing for SARS-CoV-2
- Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19)
- Considerations for Use of SARS-CoV-2 Antigen Testing in Nursing Homes
- Performing Facility-wide SARS-CoV-2 Testing in Nursing Homes
- SARS-CoV-2 (COVID-19) Fact Sheet: Guidance – Proposed Use of Point-of-Care (POC) Testing Platforms for SARS-CoV-2 (COVID-19)
- CMS COVID-19 FAQs on Medicare Fee-for-Service Billing
- CMS Guidance on SARS-CoV-2 Laboratory Testing
- CMS FAQs on SARS-CoV-2 Surveillance Testing
- S. Food and Drug Administration (FDA) FAQs on Testing for SARS-CoV-2
- FDA COVID-19 Emergency Use Authorizations (EUAs) for Medical Devices
- FDA Medical Device Reporting (MDR) Information
- Biosafety in Microbiological and Biomedical Laboratories (BMBL) (5th edition)

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