COVID-19

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

Updated Feb. 5, 2021 Print

Summary of Recent Changes

Revisions were made on January 28, 2021 to reflect the following:

- Edited to add language about antibody testing.

Revisions were made on December 30, 2020 to reflect the following:

- Edited "Specimen Collection and Handling Point-of-Care Tests" section to add language which clarifies the personal protective equipment (PPE) recommended for personnel collecting point-of-care (POC) specimens versus the PPE recommended for personnel handling POC specimens but not directly involved in collection and not working within 6 feet of patients.

Revisions were made on December 26, 2020 to reflect the following:

- To whom staff at long-term care facilities (LCTFs) should report point-of-care antigen testing data under "Reporting Requirements for Point-of-Care Testing".

Revisions were made on December 10, 2020 to reflect the following:

- New "Help with Performing Point-of-Care Tests" section added, which includes training resources for performing POC tests.

Revisions were made on December 2, 2020 to reflect the following:

- Modified page to include Frequently Asked Questions about Point-of-Care Testing

Point-of-care 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 people residing in communities who cannot readily access care. POC tests are used to diagnose current or detect past SARS-CoV-2 infections 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 (see 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.

See How to Obtain a CLIA Certificate of Waiver for more information. POC testing can be performed after the laboratory or testing site has received a CLIA certificate number.

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

What tests can be used for POC?

See the US Food and Drug Administration (FDA) website for a list of the SARS-CoV-2 POC tests that have received Emergency Use Authorization (EUA) . 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 laboratory or 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 people who may be tested. All of the FDA-authorized tests for current SARS-CoV-2 infection are for use on symptomatic people. However, CMS has indicated that CLIA will temporarily allow CLIA laboratories and other CLIA testing sites to use SARS-CoV-2 POC antigen tests on asymptomatic people 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 certificate 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 can lead to inaccurate or unreliable test results.

For personnel collecting specimens or working within 6 feet of patients suspected to be infected with SARS-CoV-2, maintain proper infection control and use recommended personal protective equipment (PPE), which could include an N95 or higher-level respirator (or face mask if a respirator is not available), eye protection, gloves, and a lab coat or gown.

For personnel who are handling specimens but not directly involved in collection (e.g., self-collection) and not working within 6 feet of the patient, follow Standard Precautions. It is recommended that personnel wear a form of source control (face mask) at all times while in the facility.

For additional general information about the proper collection and handling of each of the specimen types, please refer to CDC's Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens for COVID-19.

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 in infectious material or touching contaminated objects and surfaces. Then
  - Decide what to do to prevent these potentially 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, as applicable, 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, swabs, lancets, or fingerstick collection devices.
- Discard tests and test components that have exceeded the expiration date or show signs of damage or discoloration (such as reagents showing any signs of alteration).
- Change gloves between specimen collection and after adding specimens to the testing device.
- Store reagents, specimens, kit contents, and test devices according to the manufacturer's instructions, found in the package insert.
- Reagents, test devices, and cassettes should not be opened until the test process is about to occur. Refer to the manufacturer's instructions to see how long a reagent, test device, or cassette can be used after opening.
- If an instrument allows for batch testing, develop a plan before testing begins to ensure that reagents, test device,

cassette, and specimens are used within time periods specified by the test manufacturer.

- 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 laboratory waste needs additional packaging or disinfection procedures.

Laboratories and 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.

Help with Performing Point-of-Care Tests

CDC has free training and tools to help you learn the basics about performing POC testing. The companies that make the tests and testing systems also have free training resources designed to help you use the machines. Find links in this section to resources and training that will help you get ready to test.

CDC Educational Materials for Point of Care Testing

CDC has resources to help you understand "waived tests," a category of tests that many COVID-19 POC tests fall into. Some of our free educational and training resources include:

- Ready? Set? Test!, an online training course that explains the waived testing process.
- A Ready? Set? Test! booklet that contains tips, reminders, and resources along with forms and examples for use in your testing site (also available in Spanish).
- A Self-Assessment Checklist you can use to help assure good testing practices and provide reliable, high-quality test results.
- For general batch testing tips, view the COVID-19 Point-of-Care Batch Testing Tips Infographic [2 MB, 2 Pages].

Visit CDC's Waived Tests page for more information and resources.

Training Resources from Test Manufacturers for COVID-19 POC Testing

Below are links to trainings developed by manufacturers of COVID-19 testing devices. Linking to these resources does not constitute an endorsement by the Department of Health and Human Services (HHS) or any of its employees of the sponsors or the information and products presented on the site.

This list of tests and associated resources will be updated as more manufacturer-specific training links become available.

Abbott ID NOW™

Learn about the Abbott ID NOW™ test and find training videos.

BD Veritor™ System for Rapid Detection of SARS-CoV-2

Learn about the BD Veritor™ System for Rapid Detection of SARS-CoV-2 and find training videos.

BinaxNOW™ COVID-19 Ag Card Test & NAVICA™ App

- Find BinaxNOW™ COVID-19 Ag Card and NAVICA™ App consumer videos, training videos, training materials, helpful documents, BinaxNOW™ frequently asked questions, NAVICA™ APP, support contacts, and other helpful documents and references at BinaxNOW™ COVID-19 Ag Card and NAVICA™ App Set-Up and Training .
- Find live webinars for this product.

The manufacturer provides additional product support through the Abbott Rapid Diagnostics Technical Services Team: 1-800-257-9525 (select option 2) between 8 a.m. – 8 p.m. EST Monday – Friday. or by emailing ts.scr@abbott.com.

Cepheid™ Xpert® Xpress

Learn how to run the Cepheid™ Xpert® Xpress SARS-CoV-2 test .

Cue™ COVID-19 Test

Find support for operating the Cue™ COVID-19 test .

Note: Users might have trouble accessing the Cue™ link with Internet Explorer. For the best experience, Chrome or Edge are recommended.

LumiraDx

Learn how to run a LumiraDx SARS-CoV-2 Ag Test .

Quidel Sofia® 2

- Find virtual training, live question and answer sessions for Sofia® SARS Antigen FIA (COVID-19) testing.
- Find on-demand training that consists of eight illustrations, a 45-second video on Sofia® 2 cleaning and maintenance, and a quiz.

Lessons Learned

Below are links to lessons learned documents for select COVID-19 specific antigen tests. These documents are meant to help ensure these tests are performed correctly.

- BD Veritor™ System for Rapid Detection of SARS-CoV-2
- BinaxNOW™ COVID-19 Ag Card Test
- Quidel Sofia® 2

Reporting Requirements for Point-of-Care Testing

A CLIA-certified laboratory or testing site must report all COVID-19 diagnostic and screening test results for current or past infections to the person who was tested or that person'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, laboratories and testing sites can find out more about How to Report COVID-19 Laboratory Data.

CMS-certified long-term care facilities can submit point-of-care SARS-CoV-2 testing data, including antigen testing data, to CDC's National Healthcare Safety Network (NHSN). This CDC- and CMS-preferred pathway to submit data to CDC's NHSN applies only to CMS-certified long-term care facilities. Test data submitted to NHSN will be reported to appropriate state and local health departments using standard electronic laboratory messages. Other types of LTC facilities can also report testing data in NHSN for self-tracking or to fulfill state or local reporting requirements, if any. While NHSN is the CDC- and CMS-preferred pathway, Medicare and Medicaid-certified LTC facilities can submit data through the other mechanisms described in the Current Methods of Submission section of HHS Laboratory Reporting Guidance to meet the reporting requirements.

Frequently Asked Questions about POC Testing

Understanding and Using Standard Precautions

What are the recommendations for safe and appropriate specimen collection and handling for SARS-CoV-2?

Use Standard Precautions when handling specimens that will be tested for SARS-CoV-2. Specimens should be labeled with appropriate information to definitively connect each specimen to a patient. When transferring specimens from a collection area to a testing area, follow the instructions for the POC test used.

Standard Precautions include:

- Performing hand hygiene
- Cleaning and disinfecting environmental surfaces
- Conducting site-specific risk assessments for the use of appropriate personal protective equipment (e.g., gloves, gowns, face masks or respirators, eye protection) based on activities being performed
- Minimizing potential exposures (e.g., respiratory hygiene and cough etiquette)

Standard Precautions are the basic practices that apply to all patient care, regardless of the patient's suspected or confirmed infectious status, and apply to all settings where care is delivered. These practices protect healthcare personnel and prevent healthcare personnel or the environment from transmitting infections to other patients.

Resources

- Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19)
- Frequently Asked Questions about Coronavirus (COVID-19) for Laboratories
- Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic
- APHL Risk Assessment Best Practices
- 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings
- CDC Isolation Precautions
- Using Personal Protective Equipment (PPE)
- Core Infection Prevention and Control Practices for Safe Healthcare Delivery in All Settings

Wearing Personal Protective Equipment (PPE)

How often should gloves be changed while collecting and processing specimens?

Use a new pair of gloves each time a specimen is collected from a different person. If specimens are tested in batches, also change gloves before putting a new specimen into a testing device. Doing so will help to avoid cross-contamination.

Disinfecting Work Surfaces

What disinfectant should be used to disinfect work surfaces?

Use an Environmental Protection Agency (EPA)-registered disinfectant from List N: Disinfectants for Coronavirus (COVID-19) . Follow the manufacturer's recommendations for use, such as dilution, contact time, and safe handling.

For general instructions about using EPA-registered disinfectants, refer to EPA's 6 Steps for Safe & Effective Disinfectant Use .

One of the most commonly available disinfectants is bleach. Use bleach containing 5.25%–8.25% sodium hypochlorite and prepare a 1:10 diluted bleach solution. Follow the manufacturer's application instructions for the surface, ensuring a contact time of at least 1 minute.

For more general instructions about using diluted bleach solutions, refer to the resources below.

Resources

- Cleaning and Disinfecting Your Facility
- Cleaning and Disinfection for Households
- Cleaning and Disinfecting Your Home

How should a 1:10 diluted bleach solution be prepared to disinfect surfaces?

1. Check the label to ensure the bleach contains **5.25%–8.25% sodium hypochlorite**. If there is no label or the bleach is past the expiration date, don't use it.
2. For every 9 parts of water, add 1 part of bleach.
3. Keep the solution in a closed container when not in use.
4. Label the container with the time and date the solution was made.
5. After 24 hours, discard the remaining diluted bleach solution and make a new batch.
6. Never mix household bleach with ammonia or any other cleaner as the resulting fumes can cause serious harm.

Resource

Cleaning and Disinfection for Households

When should surfaces near a specimen collection and handling site be disinfected?

Disinfect surfaces within 6 feet of the specimen collection and handling area at these times:

- Before testing begins each day
- Between each specimen collection
- At least hourly during testing
- When visibly soiled
- In the event of a specimen spill or splash
- At the end of every testing day

Disinfect surfaces before, during, and after testing.

- Ensure proper ventilation during and after application of disinfectant, so no one inhales fumes from the disinfectant.
- Always wear gloves appropriate for the chemicals being used when you are cleaning and disinfecting. Additional personal protective equipment (PPE) might be needed based on setting and product. For more information, see CDC's website on Cleaning and Disinfection for Community Facilities.
- Use an Environmental Protection Agency (EPA)-registered disinfectant when disinfecting surfaces where specimens are collected and processed. Follow the manufacturer's application instructions for use, such as dilution, contact time, and safe handling.
- Disinfect surfaces where specimen collection, handling, and testing occur. Examples include tables, chairs, and bed frames.

It is important to follow these recommendations to avoid cross-contamination and keep workers safe.

Resources

- List N: Disinfectants for Coronavirus (COVID-19)
- Frequently Asked Questions about Coronavirus (COVID-19) for Laboratories
- Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic
- Detailed Disinfection Guidance
- Performing Facility-wide SARS-CoV-2 Testing in Nursing Homes

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) (6th edition)
- Ready? Set? Test! poster
- Ready? Set? Test! Booklet – Good Laboratory Practices for Waived Testing
- Self-Assessment Checklist for Good Testing Practices for Sites that Perform Patient Testing under a CLIA Certificate of Waiver
- Performing Broad-Based Testing for SARS-CoV-2 in Congregate Settings

Last Updated Feb. 5, 2021
Content source: National Center for Immunization and Respiratory Diseases (NCIRD), Division of Viral Diseases