Guidance for SARS-CoV-2 Rapid Testing Performed in Point-of-Care Settings

Updated Apr. 4, 2022

Summary of Recent Changes

Updates as of April 4, 2022

- HHS and CDC's new guidance [288 KB, 9 pages] no longer requires reporting of negative results for non-NAAT tests (rapid or antigen test results).
- This update also no longer requires reporting of antibody test results, positive or negative.

View Previous Updates

Key Points

- This guidance provides information on the regulatory requirements for SARS-CoV-2 rapid testing performed in point-of-care settings, collecting specimens and performing rapid tests safely and correctly, and information on reporting test results.
- This guidance is intended for individuals and facilities who are setting up and performing rapid testing in point-of-care settings and is not intended for use or reporting of self-tests performed by the individual being tested.

Point-of-care testing uses rapid diagnostic tests performed or interpreted by someone other than the individual being tested or their parent or guardian and can be performed in a variety of settings. Rapid tests used in point-of-care settings can be NAAT, antigen, or antibody tests.

These tests can be used to diagnose current or detect past SARS-CoV-2 infections in various point-of-care settings, including but not limited to:

- 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

Regulatory Requirements for Rapid Testing in Point-of-Care Settings

There are four different types of CLIA certificates , any one of which is appropriate for point-of-care testing. A CLIA certificate is required to perform point-of-care testing. A CLIA Certificate of Waiver is appropriate if SARS-CoV-2 point-of-care testing is the only testing being performed. It 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. Laboratories or point-of-care testing sites that have applied for a CLIA Certificate of Waiver to perform SARS-CoV-2 point-of-care testing can begin testing and reporting SARS-CoV-2 results as soon as they have submitted their application to the State Agency, as long as they meet any additional state licensure requirements that apply. A non-certified point-of-care testing site will be treated as operating under a Certificate of Waiver while their application is being processed. The point-of-care 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.

During the COVID-19 public health emergency, 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 CLIA-waived or FDA-authorized point-of-care tests for SARS-CoV-2 and must be under the direction of the existing laboratory or testing site director.

CMS has provided specific guidance for the use of FDA authorized OTC self-tests when these tests are either performed or the results are interpreted by someone other than the individual being tested or their parent or guardian. In these circumstances, the tests are not considered self-tests and the point-of-care testing site that performs the testing or interprets the test results needs a CLIA certificate and must report results as described below. See Over The Counter (OTC) Home Testing and CLIA Applicability for more information from CMS.

Tests That Can Be Used in Point-of-Care Settings

Refer to the U.S. Food and Drug Administration (FDA) website for a list of the SARS-CoV-2 point-of-care and rapid tests that have received Emergency Use Authorization (EUA) . Tests that have been authorized for use in a point-of-care 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 point-of-care use by the FDA and must follow the manufacturer's instructions for each 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.

OTC tests can be purchased and used in a point-of-care setting. However, when these tests are either performed or the results are interpreted by someone other than the individual being tested or their parent or guardian, then the CLIA reporting requirements for waived tests must be followed.

COVID-19 Viral Testing Tool

A tool to help you understand COVID-19 testing options.

Get Started About the Tool

Reporting Requirements for Rapid Testing in Point-of-Care Settings

A CLIA-certified laboratory or testing site must report all positive SARS-CoV-2 diagnostic and screening test results to the person who was tested or that person's healthcare provider. CLIA-certified laboratories or testing sites are no longer required to report negative results for non-NAAT tests (rapid or antigen test results) or antibody tests, positive or negative. Depending on the test manufacturer's instructions for use, which can be found on 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 positive SARS-CoV-2 test results to their respective state, tribal, localexternal icon , and territorial health department's website in accordance with the Coronavirus Aid, Relief, and Economic Security (CARES) Act; refer to the CMS interim final rule for regulatory reporting requirementspdf iconexternal icon . In addition, laboratories and testing sites can find out more about How to Report COVID-19 Laboratory Data. CLIA-certified laboratories or testing sites are no longer required to report negative results for non-NAAT tests (rapid or antigen test results) or antibody tests, positive or negative.

CMS-certified long-term care (LTC) facilities can submit point-of-care SARS-CoV-2 testing data, including antigen, antibody, and nucleic acid amplification test (NAAT) 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 LTC facilities. Test data submitted to NHSN will be reported to appropriate state, tribal, local, and territorial 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.

Specimen Collection & Handling of Rapid Tests in Point-of-Care Settings

Each point-of-care test has been authorized for use with certain specimen types and should only be used with those specimen types. Proper specimen collection and handling are critical for all COVID-19 testing, including those tests performed in point-of-care settings. A specimen that is not collected or handled correctly can lead to an inaccurate or unreliable test result.

Personnel collecting specimens or working within 6 feet of patients suspected to be infected with SARS-CoV-2 should 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.

Personnel handling specimens but not directly involved in the collection (e.g., self-collection) and not working within 6 feet of the patient should follow Standard Precautions. It is recommended that personnel wear well-fitting cloth masks, facemasks, or respirators at all times while at the point-of-care site where the testing is being performed.

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

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

CDC recommends the following practices when performing tests in point-of-care settings:

Before the Test

- Perform a risk assessment to identify what could go wrong, such as breathing in infectious material or touching contaminated objects and surfaces. Then
  - Implement appropriate control measures to prevent these potentially negative outcomes from happening.
  - Find more information at CDC's Biological Risk Management for Point-of-Care Testing Sites.
  - Find more information on Risk Assessment Best Practices and Risk Assessment templates .
  - Learn more about CDC's Guidelines for Handling and Processing Specimens Associated with COVID-19.
- 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.
- Do not reuse used test devices, reagent tubes, solutions, swabs, lancets, or fingerstick collection devices.
- Store reagents, specimens, kit contents, and test devices according to the manufacturer's instructions found in the package insert.
- 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).
- Do not open reagents, test devices, and cassettes 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.
- Label each specimen with appropriate information to definitively connect that specimen to the correct person being tested.
- When transferring specimens from a collection area to a testing area, follow the instructions for the point-of-care test used.

During the Test

- Follow all 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 before proceeding with patient testing.
- When processing multiple specimens successively in batches, ensure proper timing for each specimen and each step of the testing process, as specified by the test manufacturer. To avoid cross-contamination, change gloves before putting a new specimen into a testing device.

After the Test

- 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.
- Decontaminate the instrument after each use. Follow the manufacturer's recommendations for using an approved disinfectant, including proper dilution, contact time, and safe handling.
- Always discuss used and unused COVID-19 test kit waste with your facility leadership, facility waste management contractor, your State Department of Public Health, and the test manufacturer's technical support. All waste disposal must comply with your local, tribal, regional, state, national, and/or international regulations. Waste disposal regulations may vary at the state and local levels; see Environmental Protection Agency Regulations and State Universal Waste Programs in the United States for more information.

Learn More About Performing Rapid Tests in Point-of-Care Settings

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

CDC Educational Materials for Rapid Testing in Point-of-Care Settings

Many COVID-19 point-of-care and rapid tests fall into a category called waived tests, which are tests performed in a laboratory or at a testing site under a CLIA Certificate of Waiver. CDC has free educational and training resources for waived point-of-care testing, including:

Ready? Set? Test! is an online training course that explains the waived testing process and how to help ensure that test results are accurate and reliable.

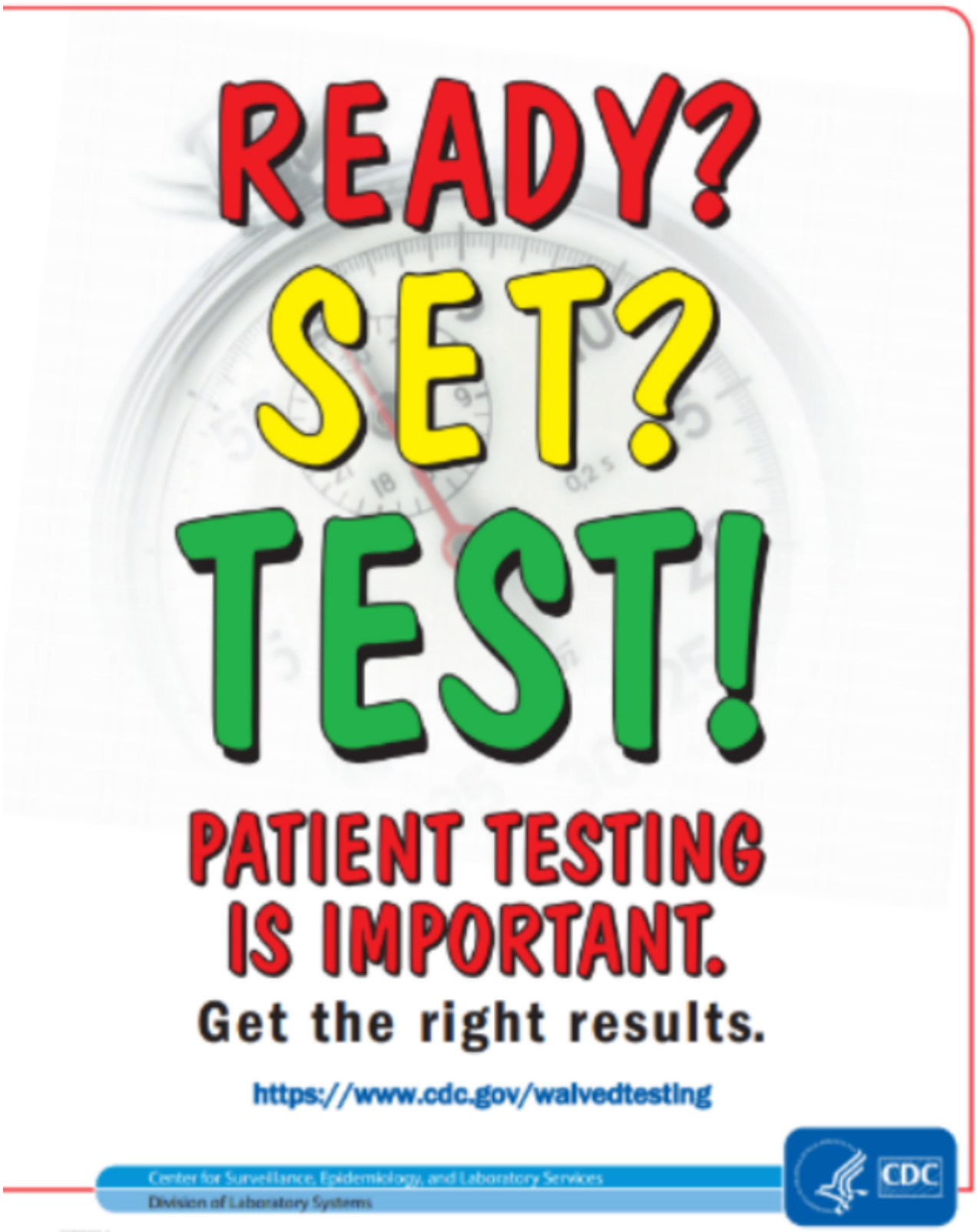
A Ready? Set? Test! booklet that contains tips, reminders, and resources along with forms and examples for use in your testing site (also available in Spanish).

A Self-Assessment Checklist you can use to help ensure good testing practices and provide reliable, high-quality test results.

The COVID-19 Point-of-Care Batch Testing Tips Infographic [2 MB, 2 Pages] gives advice for performing batch testing.

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

Laboratories and testing sites can find additional free, online training courses relevant to working with SARS-CoV-2 specimens on CDC's Preparing and Supporting Laboratories Responding to COVID-19 web page.



Training Resources from Test Manufacturers for COVID-19 Rapid Testing in Point-of-Care Settings

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, the test manufacturers listed below, 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.

ADVAITE

- RapCov™ Rapid COVID-19 Test
  - Training Video

Abbott

- ID NOW™ COVID-19 test

Cepheid™

- Xpert® Xpress SARS-CoV-2
  - Test Resources

Cue™ Health*

- Cue™ COVID-19 Test

    - Training Videos
- BinaxNOW™ COVID-19 Ag Card
    - App Set-Up and Training

Becton, Dickinson and Company (B.D.)

- Veritor™ System for Rapid Detection of SAR-CoV-2
    - Training Videos

LumiraDx

- LumiraDx SARS-CoV-2 Ag Test
    - Training Resources

Quidel

- QuickVue® SARS Antigen Test
    - Product Training
- Sofia® 2 Flu + SARS Antigen FIA
    - Online Training

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

Tips for Using Rapid Antigen Tests

Below are links to documents for select SARS-CoV-2 specific antigen tests procured in large numbers by the U.S. government. Based on CDC experience with these tests, following these tips will help to ensure the tests are performed correctly.

- Cue® Professional Antigen Test [12 MB, 6 pages]
- BD Veritor™ System for Rapid Detection of SARS-CoV-2 [7MB, 4 Pages]
- BinaxNOW™ COVID-19 Ag Card Test [6MB, 4 Pages]
- Quidel Sofia® 2 [6.9MB, 4 Pages]

More Point-of-Care Resources

CDC

- Performing Broad-Based Testing for SARS-CoV-2 in Congregate Settings
- Performing Facility-wide SARS-CoV-2 Testing in Nursing Homes
- SARS-CoV-2 (COVID-19) Fact Sheet: Guidance – Proposed Use of Point-of-Care Testing Platforms for SARS-CoV-2 (COVID-19)
- Frequently Asked Questions about Coronavirus (COVID-19) for Laboratories
- CDC Isolation Precautions
- Using Personal Protective Equipment (PPE)
- Core Infection Prevention and Control Practices for Safe Healthcare Delivery in All Settings

CMS

- 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

FDA

- U.S. Food and Drug Administration (FDA) FAQs on Testing for SARS-CoV-2

U.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

Updates from Previous Content

As of January 19, 2022

- Added language about reporting results of over-the-counter (OTC) tests when used in a point-of-care setting.

As of December 31, 2021

COVID-19

- Edited “Regulatory Requirements for Point-of-Care and Rapid Testing” section to add updated Centers for Medicare & Medicaid Services (CMS) guidance for SARS-CoV-2 point-of-care tests and Clinical Laboratory Improvement Amendments (CLIA) Certificates of Waiver.
- Added new training resources from manufacturers of SARS-CoV-2 point-of-care and rapid tests.
- Added a link to CDC’s Biological Risk Management for Point-of-Care Testing Sites.

As of January 28, 2021

- Edited to add language about antibody testing.

As of December 30, 2020

- 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.

As of December 26, 2020

- Added 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” section

As of December 10, 2020

- Added a new “Help with Performing Point-of-Care Tests” section, which includes training resources for performing POC tests.

As of December 2, 2020

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

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