

# Clinical Laboratory COVID-19 Response Call

Monday, December 13, 2021, at 3:00 PM EDT

- **Welcome**

- Jasmine Chaitram, CDC Division of Laboratory Systems (DLS)

- **Resources for Accurate and Reliable COVID-19 Testing at CLIA Certificate of Waiver Sites**

- Nancy Anderson, CDC Division of Laboratory Systems (DLS)

- **FDA Update**

- Tim Stenzel, US Food and Drug Administration (FDA)

- **SARS-CoV-2 Variants Update**

- John Barnes, CDC Laboratory and Testing Task Force for the COVID-19 Response



# Division of Laboratory Systems (DLS)

## Vision

Exemplary laboratory science and practice advance clinical care, public health, and health equity.

## Mission

Improve public health, patient outcomes, and health equity by advancing clinical and public health laboratory quality and safety, data and biorepository science, and workforce competency.

# Four Goal Areas



## Quality Laboratory Science

- Improve the quality and value of laboratory medicine and biorepository science for better health outcomes and public health surveillance



## Highly Competent Laboratory Workforce

- Strengthen the laboratory workforce to support clinical and public health laboratory practice



## Safe and Prepared Laboratories

- Enhance the safety and response capabilities of clinical and public health laboratories



## Accessible and Usable Laboratory Data

- Increase access and use of laboratory data to support response, surveillance, and patient care

# Omicron Variant: What You Need to Know

**Emergence of Omicron**

On November 24, 2021, a new variant of [SARS-CoV-2](#), B.1.1.529, was reported to the World Health Organization (WHO). This new variant was first detected in specimens collected on November 11, 2021 in Botswana and on November 14, 2021 in South Africa.

On November 26, 2021, WHO named the B.1.1.529 Omicron variant. On November 30, 2021, the United States designated Omicron as a [Variant of Concern](#). The first case of Omicron was identified in the United States on December 1, 2021.

CDC has been collaborating with global public health and industry partners to monitor its course. CDC has been using [genomic surveillance](#) to track the spread of SARS-CoV-2, the virus that causes COVID-19, and inform public health officials about the severity of illness it causes, or how well available vaccines protect against it.

Despite the increased attention of Omicron, [Delta](#) continues to be the dominant variant in the United States.

**Where has Omicron been Detected**

CDC is working with state and local public health officials to monitor the spread of Omicron in the United States.

**US COVID-19 Cases Caused by the Omicron Variant**

Legend: No (light green), Yes (dark green)

Territories: AS, GU, PR, VI, MP, FM, PW, MH

Data Table: +

<https://www.cdc.gov/coronavirus/2019-ncov/variants/omicron-variant.html>

# Updated Guidance for Waste Management

The screenshot shows the CDC COVID-19 website with the following content:

- Header: CDC Centers for Disease Control and Prevention, CDC 24/7: Saving Lives, Protecting People™. Search COVID-19.
- Navigation: Home, Your Health, Vaccines, Cases & Data, Work & School, Healthcare Workers, Health Depts, Science, More.
- Left Sidebar: More Resources (CDC in Action, Global COVID-19), Laboratories, Testing (Testing Strategies for SARS-CoV-2, Antigen Testing Guidelines, Antibody Testing Guidelines, Antibody Tests, Nucleic Acid Amplification Tests (NAATs), Point-of-Care & Rapid Testing, Pooling Testing), CDC COVID-19 Tests, CDC Lab Work, Lab FAQs.
- Main Content: 

## Guidance for SARS-CoV-2 Point-of-Care and Rapid Testing

Updated Dec. 10, 2021 [Print](#)

### Summary of Recent Changes

Updates as of December 10, 2021

  - Updated waste management guidance

[View Previous Updates](#)

### Key Points

  - This guidance provides information on the regulatory requirements for SARS-CoV-2 point-of-care and rapid testing, collecting specimens and performing point-of-care and 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 point-of-care testing and is not intended for specimen [self-collection and self-testing](#).

On this Page

Regulatory Requirements for Point-Of-Care and Rapid Testing

<https://www.cdc.gov/coronavirus/2019-ncov/lab/point-of-care-testing.html>

The screenshot shows the CDC COVID-19 website with the following content:

- Header: CDC Centers for Disease Control and Prevention, CDC 24/7: Saving Lives, Protecting People™. Search COVID-19.
- Navigation: Home, Your Health, Vaccines, Cases & Data, Work & School, Healthcare Workers, Health Depts, Science, More.
- Left Sidebar: More Resources (CDC in Action, Global COVID-19), Laboratories, Testing (CDC COVID-19 Tests, CDC Lab Work, Lab FAQs, Data and Reporting), Biosafety (Biosafety for Specimen Handling, Specimen Collection, Lab Workplace Safety), Data & Surveillance, Guidance for COVID-19.
- Main Content: 

## Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19)

Updated Dec. 10, 2021 [Print](#)

### Summary of Recent Changes

Updates as of December 10, 2021

  - Updated waste management guidance

[View Previous Updates](#)

### Key Points

  - This guidance is intended for clinical laboratory and support staff who handle or process specimens associated with COVID-19. For guidance on point-of-care testing, see the [Guidance for SARS-CoV-2 Point-of-Care and Rapid Testing](#)

<https://www.cdc.gov/coronavirus/2019-nCoV/lab/lab-biosafety-guidelines.html>

# CDC Preparedness Portal

<https://www.cdc.gov/csels/dls/preparedlabs/covid-19-clinical-calls.html>

Find CLCR call information,  
transcripts, and audio recordings on  
the CDC Preparedness Portal

The screenshot shows the 'Prepared Laboratories' section of the CDC website. The breadcrumb trail is 'Prepared Laboratories > Outbreak & Response'. The left sidebar has a menu with 'Preparedness Initiatives', 'Outbreak & Response' (selected), and 'Clinical Laboratory COVID-19 Response Calls'. Under 'Clinical Laboratory COVID-19 Response Calls', there is a list of months from June 2021 to November 2021. The main content area features a header 'Clinical Laboratory COVID-19 Response Calls' with a CDC logo and a background image of a virus particle. Below the header, there is a paragraph explaining that the CDC's Division of Laboratory Systems (DLS) convenes regular calls with clinical laboratories to discuss the nation's clinical laboratory response to COVID-19. It states that these calls take place every other Monday at 3:00 PM Eastern time and that audio and transcripts are posted online after each call. A final paragraph provides instructions on how to submit questions for consideration, either by email at [DLInquiries@cdc.gov](mailto:DLInquiries@cdc.gov) or by using the Q&A function in Zoom during the call. It notes that due to a large number of participants, not all questions can be addressed directly, but feedback will be noted and used to tailor future calls.

# Next Scheduled CLCR Call

The next call will be on **Monday, December 27**  
from **3:00 PM to 4:00 PM ET**



# We Want to Hear from You!

## Training and Workforce Development

Questions about education and training?

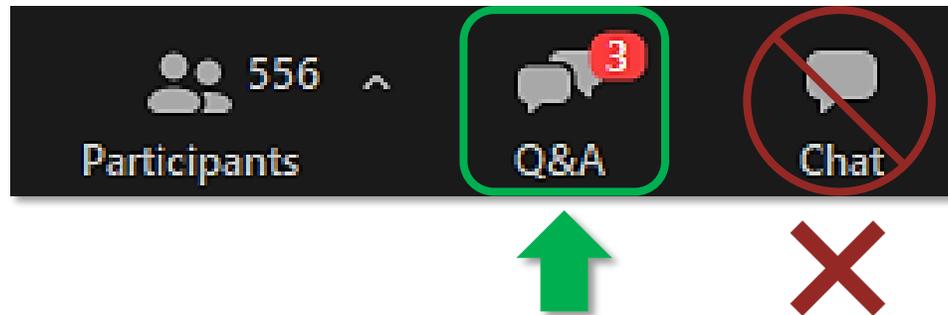
Contact [LabTrainingNeeds@cdc.gov](mailto:LabTrainingNeeds@cdc.gov)



# How to Ask a Question

- **Using the Zoom Webinar System**

- Click the **Q&A** button in the Zoom webinar system
- Type your question in the **Q&A** box and submit it
- **Please do not submit a question using the chat button**



- For media questions, please contact CDC Media Relations at [media@cdc.gov](mailto:media@cdc.gov)
- If you are a patient, please direct any questions to your healthcare provider



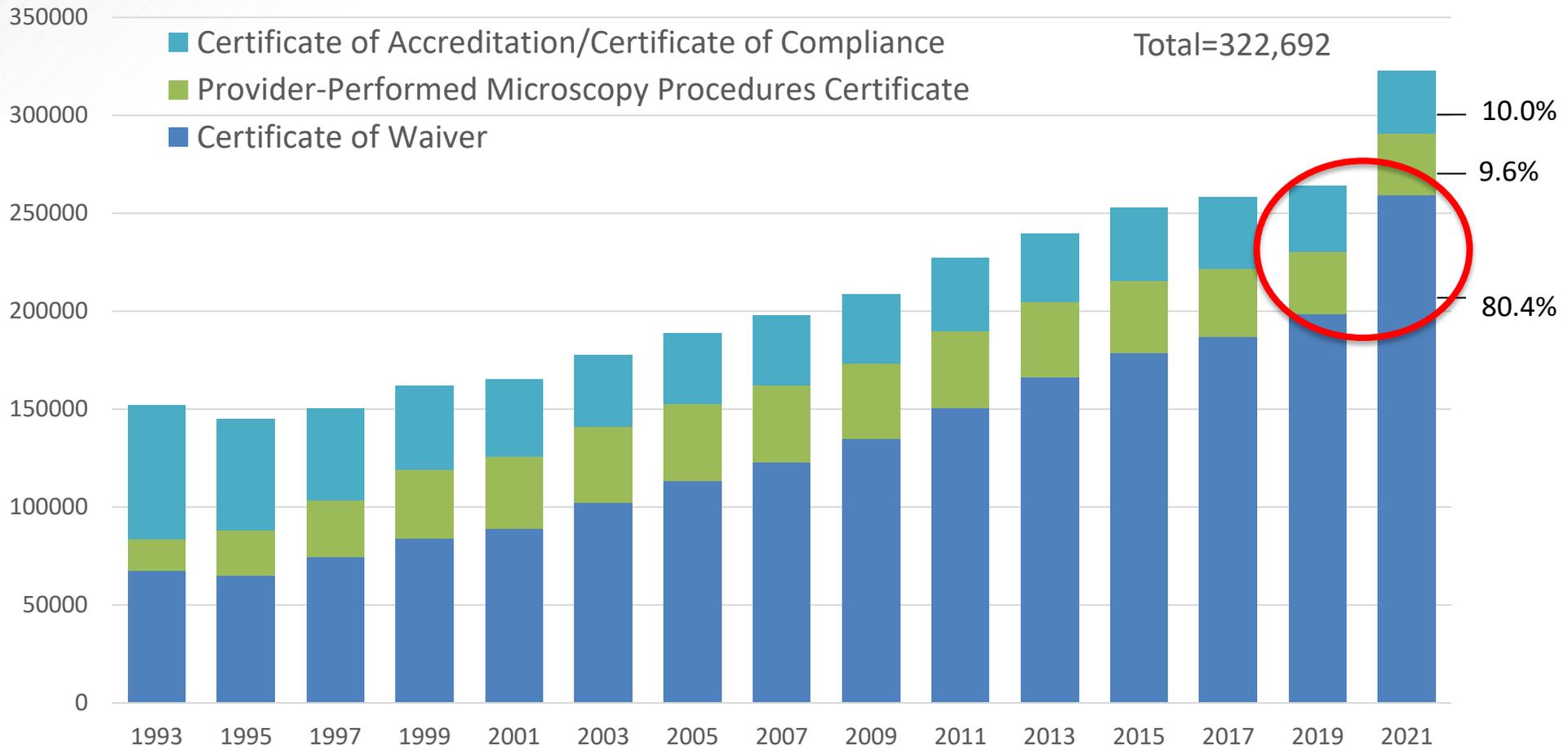
*Slide decks may contain presentation material from panelists who are not affiliated with CDC. Presentation content from external panelists may not necessarily reflect CDC's official position on the topic(s) covered.*

# Resources for Accurate and Reliable COVID-19 Testing at CLIA Certificate of Waiver Sites

Nancy Anderson, MMSc, MT(ASCP)  
Senior Advisor for Clinical Laboratories  
Division of Laboratory Systems

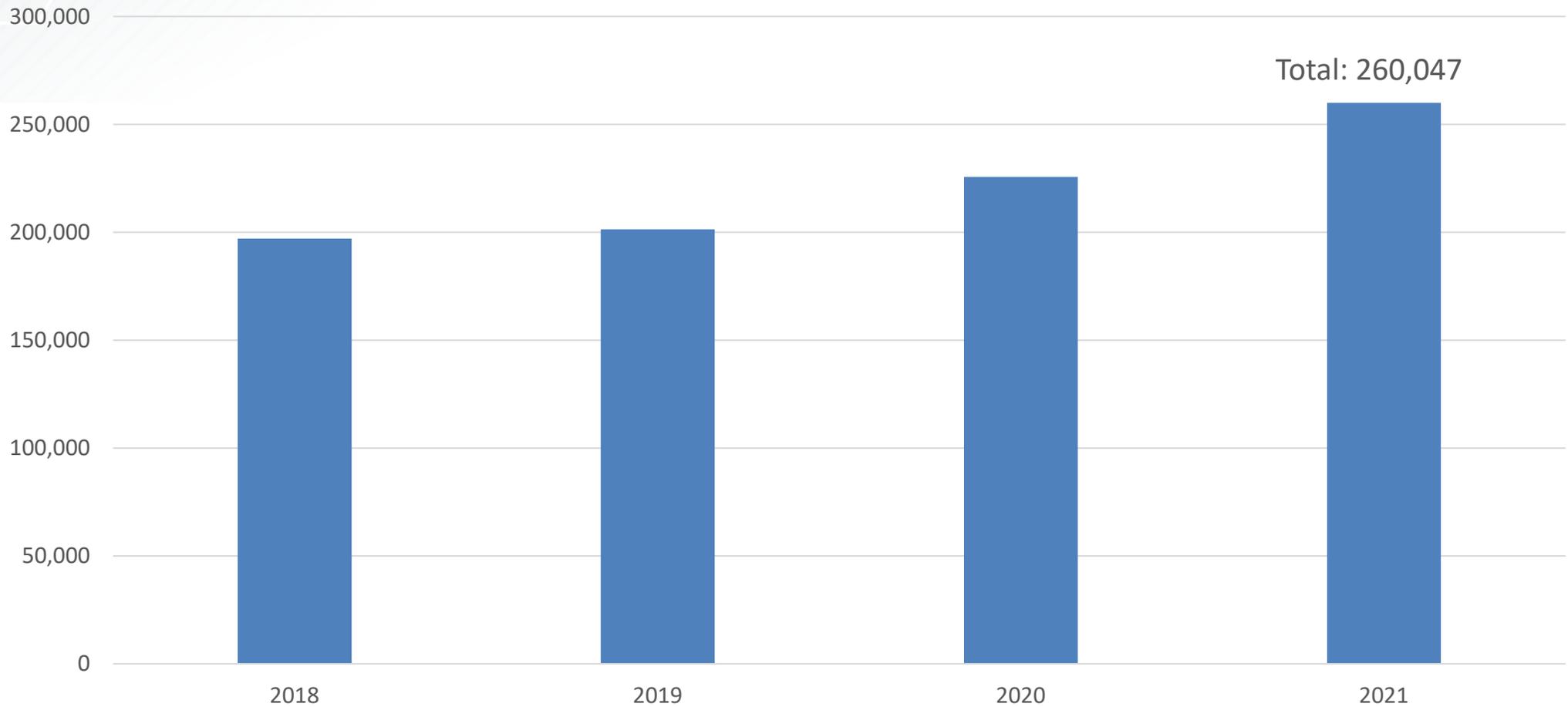


# Number of CLIA-Certified Laboratories: 1993 - 2021



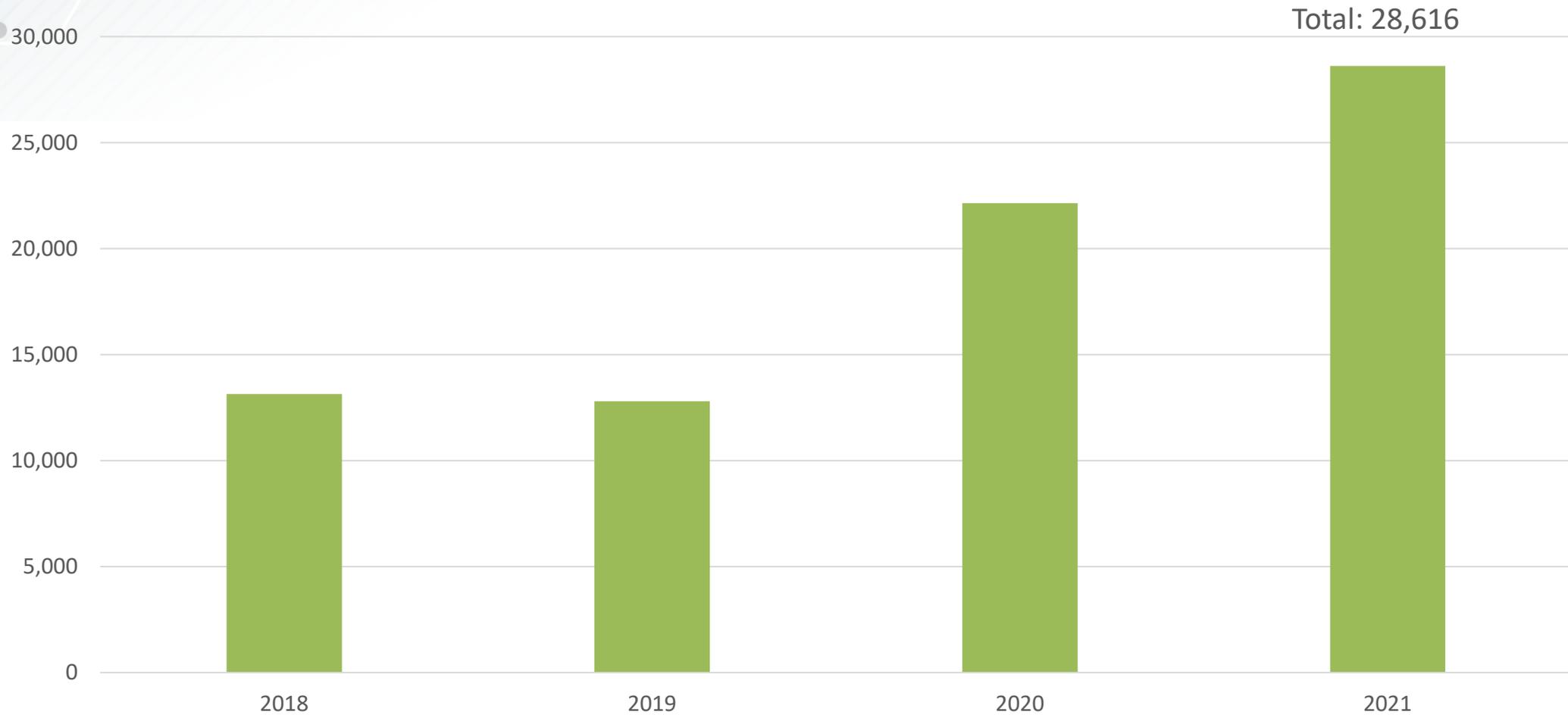
Data obtained from CMS QIES database, 11/23/2021. Lab types in QIES data are self-reported. Numbers include laboratories in CLIA-exempt states of NY and WA. Data does not include CLIA Certificate of Registration laboratories or US Department of Defense Laboratories.

# Number of Certificate of Waiver Laboratories: 2018-2021



Data obtained from CMS QIES database, 12/09/2021

# Number of New Certificate of Waiver Laboratories: 2018-2021



Data obtained from CMS QIES database, 12/09/2021

# Implications for Testing Quality in Point-of-Care Sites Under Certificates of Waiver

- CLIA requirements for waived testing are minimal
  - Obtain a Certificate of Waiver
  - Follow the manufacturer's instructions for testing
- Certificate of Waiver sites are not routinely inspected



# CDC Free Educational Resources

**PATIENT TESTING IS IMPORTANT.**  
Get the right results.

**READY? SET? TEST!**

- Have the latest instructions for ALL of your tests.
- Know how to do tests the right way.
- Know how and when to do quality control.
- Make sure you do the right test on the right patient.
- Make sure the patient has prepared for the test.
- Collect and label the sample the right way.
- Follow instructions for quality control and patient tests.
- Keep records for all patient and quality control tests.
- Follow rules for discarding test materials.
- Report all test results to the doctor.

<http://www.cdc.gov/dls/waivedtests>

**Realizar pruebas al paciente es importante.**  
Obtenga los resultados correctos.

**¿Preparado? ¿Listo? ¡Ya!**

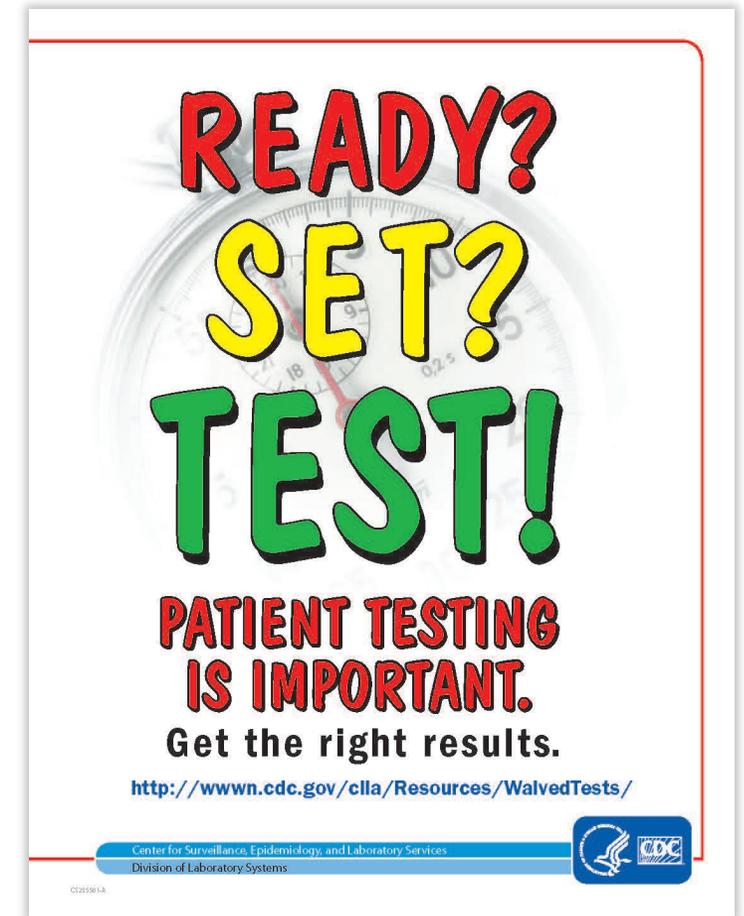
- Obtenga las instrucciones más recientes para TODAS sus pruebas.
- Sepa cómo realizar las pruebas de manera correcta.
- Sepa cómo y cuándo hacer un control de calidad.
- Asegúrese de realizar la prueba correcta al paciente correcto.
- Asegúrese de que el paciente se haya preparado para la prueba.
- Recolecte y etiquete la muestra de manera correcta.
- Siga las instrucciones para las pruebas de control de calidad y del paciente.
- Lleve registros de todas las pruebas del paciente y de las pruebas de control de calidad.
- Siga las reglas para la eliminación de los materiales de las pruebas.
- Informe al médico de todos los resultados de las pruebas.

<http://www.cdc.gov/dls/waivedtests>

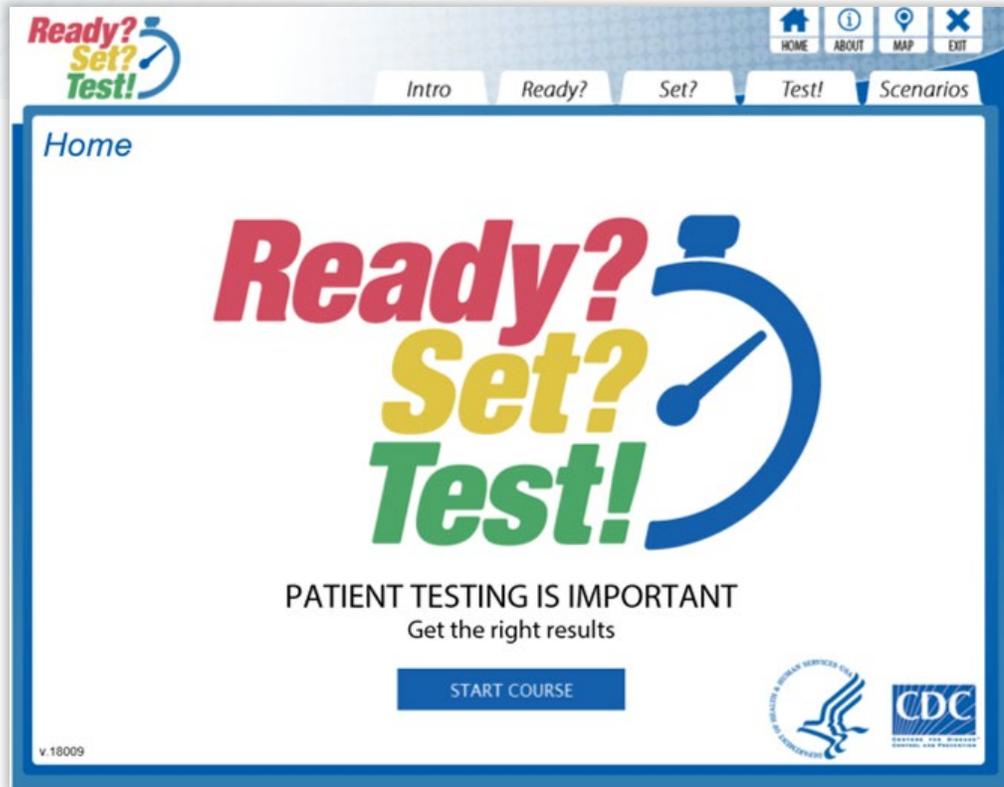
[www.cdc.gov/waivedtesting](http://www.cdc.gov/waivedtesting)

# Ready? Set? Test!

- Explains the waived testing process and how to help ensure accurate and reliable testing
- Intended to assist those who perform CLIA-waived testing
- Booklet and poster available in English and Spanish



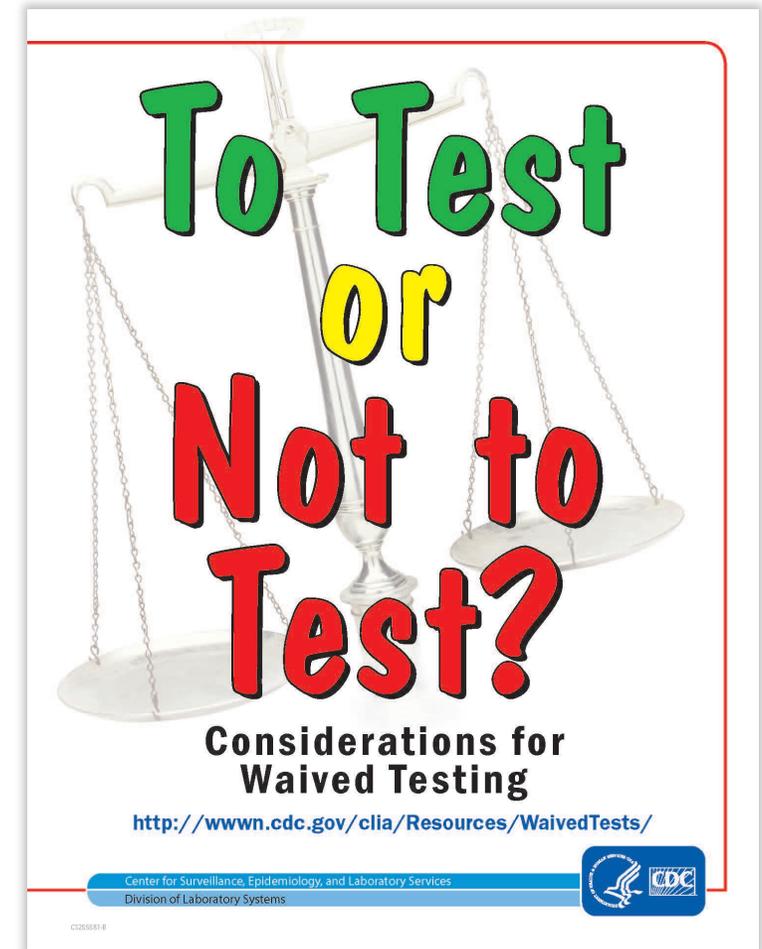
# Ready? Set? Test! Online Course: New Update Available



- Free course with continuing education credit available on CDC TRAIN
- Knowledge check questions throughout the course to reinforce learning
- Templates, checklists, resources to save/download
- Scenarios – nursing home, hospital, doctor's office
- [www.cdc.gov/labtraining/training-courses/ready-set-test.html](http://www.cdc.gov/labtraining/training-courses/ready-set-test.html)

# To Test or Not to Test?

- Booklet describes considerations when beginning to test or adding a test to your menu
- Intended to assist those who want to initiate or direct CLIA-waived testing
- Contains helpful information for physician offices and all point-of-care settings



# Waived Testing Self-Assessment Checklist

- Voluntary checklist tool to help ensure good testing practices and reliable, high quality test results when performing CLIA-waived testing
- Designed to supplement the *Ready? Set? Test!* and *To Test or Not to Test?* booklets

<b>REGULATORY REQUIREMENTS</b>		YES	NO	N/A
Do you have a current CLIA Certificate for Waived Testing? <a href="https://www.cms.gov/Regulations">https://www.cms.gov/Regulations</a>				
Do you renew the Certificate every 3 years?	<b>READY</b>	YES	NO	N/A
Do you clean work surfaces and equipment before and after testing?				
Do you perform only CLIA-waived tests?	<b>SET</b>	YES	NO	N/A
Do you follow any additional state or local regulations? <a href="https://www.cms.gov/Regulations">https://www.cms.gov/Regulations</a>				
Do you check and record lot numbers for reagents and controls?	<b>TEST</b>	YES	NO	N/A
Do you check inventory levels for reagents and controls?				
Do you follow the manufacturer's instructions for the volume needed for testing?				
Do you follow instructions for the order of testing?				
Do you only use unprocessed samples?				
Do you check patient identifiers?				
Do you document that all staff have satisfactorily completed initial training before performing temperature checks, blood collection, sample testing, and reporting patient results?				
Do you test samples that are properly collected or handled?				
Do you have the current manufacturer's instructions or a quick reference guide at the work station?				
Do you follow the manufacturer's instructions in the exact order?				

# Guidance for Point-of-Care and Rapid Testing

## Purpose

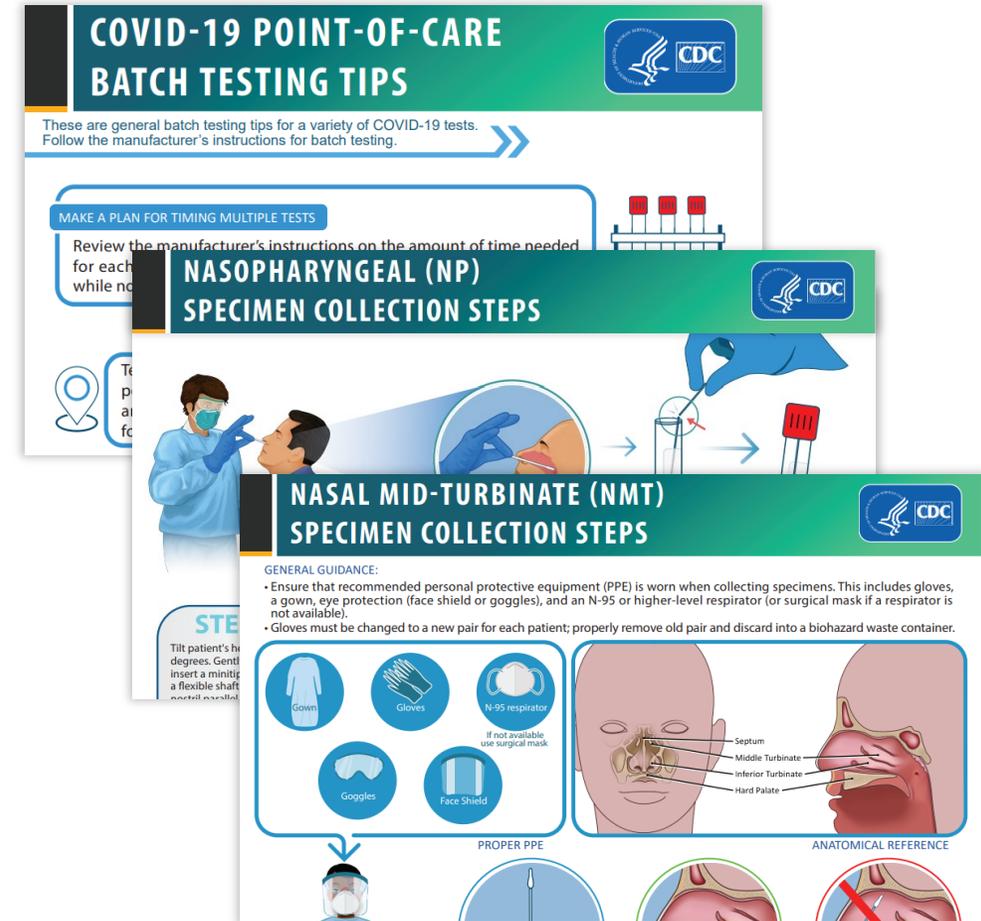
To provide guidance on the regulatory requirements for SARS-CoV-2 point-of-care (POC) testing, using POC tests safely, and information on reporting POC test results

<https://www.cdc.gov/coronavirus/2019-ncov/lab/point-of-care-testing.html>

The screenshot shows the CDC COVID-19 website. The header includes the CDC logo and the tagline "Centers for Disease Control and Prevention, CDC 24/7: Saving Lives, Protecting People™". A search bar for "Search COVID-19" is in the top right. The main navigation bar includes links for "Your Health", "Vaccines", "Cases & Data", "Work & School", "Healthcare Workers", "Health Depts", "Science", and "More". The page title is "COVID-19". A left sidebar menu lists "More Resources" with expandable sections: "CDC in Action", "Global COVID-19", "Laboratories", "Testing" (expanded), "Pooling Testing", "CDC COVID-19 Tests", and "CDC Lab Work". The "Testing" section includes links for "Testing Strategies for SARS-CoV-2", "Antigen Testing Guidelines", "Antibody Testing Guidelines", "Antibody Tests", "Nucleic Acid Amplification Tests (NAATs)", "Point-of-Care & Rapid Testing" (highlighted), and "Pooling Testing". The main content area features the article title "Guidance for SARS-CoV-2 Point-of-Care and Rapid Testing", updated on July 8, 2021. A "Summary of Recent Changes" section notes revisions made on March 8, 2021, including updates to regulatory requirements, new training resources, and a link to biological risk management sites. A "Key Points" section states that the guidance provides regulatory requirements and reporting information, and is intended for individuals and facilities setting up and performing point-of-care testing, but not for self-collection and self-testing.

# CDC Point-of-Care Testing Infographics

- COVID-19 Point-of-Care Batch Testing Tips
  - <https://www.cdc.gov/coronavirus/2019-ncov/downloads/lab/COVID-19-batch-testing-tips.pdf>
- Nasal Mid-Turbinate (NMT) Specimen Collection Steps
  - [https://www.cdc.gov/coronavirus/2019-ncov/downloads/lab/NMT Specimen Collection Infographic FINAL 508.pdf](https://www.cdc.gov/coronavirus/2019-ncov/downloads/lab/NMT_Specimen_Collection_Infographic_FINAL_508.pdf)
- Nasopharyngeal (NP) Specimen Collection Steps
  - [https://www.cdc.gov/coronavirus/2019-ncov/downloads/lab/NP Specimen Collection Infographic FINAL 508.pdf](https://www.cdc.gov/coronavirus/2019-ncov/downloads/lab/NP_Specimen_Collection_Infographic_FINAL_508.pdf)



# Guidance for Antigen Testing

## Purpose

To support effective use of antigen tests for different testing situations

<https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html>

The screenshot shows the CDC website's COVID-19 section. The header includes the CDC logo and the tagline 'CDC 24/7: Saving Lives. Protecting People™'. A search bar is located in the top right corner. The main navigation menu includes 'Your Health', 'Vaccines', 'Cases & Data', 'Work & School', 'Healthcare Workers', 'Health Depts', 'Science', and 'More'. The left sidebar contains a 'More Resources' section with links to 'CDC in Action', 'Global COVID-19', 'Laboratories', 'Testing', 'CDC COVID-19 Tests', and 'CDC Lab Work'. The 'Testing' link is expanded, showing sub-links for 'Testing Strategies for SARS-CoV-2', 'Antigen Testing Guidelines', 'Antibody Testing Guidelines', 'Antibody Tests', 'Nucleic Acid Amplification Tests (NAATs)', 'Point-of-Care & Rapid Testing', and 'Pooling Testing'. The main content area displays the title 'Interim Guidance for Antigen Testing for SARS-CoV-2' with a date of 'Updated Sept. 9, 2021' and a 'Print' option. Below the title is a 'Summary of Recent Changes' section, which includes a date 'Updates as of September 9, 2021' and a bullet point: 'Updated footnotes for the Antigen Test Algorithm for Congregate Living Settings.' A link for 'View Previous Updates' is provided. The 'Key Points' section contains three bullet points: 'This interim guidance is intended for healthcare providers who order antigen tests, receive antigen test results, or perform point-of-care testing, as well as for laboratory professionals who perform antigen testing in a laboratory setting or at the point-of-care and report those results.', 'The purpose of this interim technical guidance is to support effective clinical and public health use of antigen tests for different testing situations.', and 'This guidance applies to all clinical and culturally responsive, accessible, and available consumer uses of antigen tests and is not specific to any particular age group.'

# Tips for Rapid Antigen Tests

## ABBOTT BINAXNOW™ COVID-19 AG CARD TEST HELPFUL TESTING TIPS



This document is a supplement to the manufacturer's instructions and is intended to provide helpful testing tips when using the Abbott BinaxNOW™ COVID-19 Ag Card test.

To ensure accurate performance of this test, please refer to the package insert or Instructions for Use for complete details on how to perform the test. Additional instructions can be found at [www.fda.gov/media/141570/download](http://www.fda.gov/media/141570/download).

For information on the Abbott BinaxNOW™ COVID-19 Ag Card Test, please view the manufacturer's website at <https://www.globalpointofcare.abbott/en/support/product-installation-training/navica-brand/navica-binaxnow-ag-training.html>.



\* Use of trade names and commercial sources is for identification only and does not imply endorsement by the Centers for Disease Control and Prevention, the Public Health Service, or the U.S. Department of Health and Human Services.

## BD VERITOR™ PLUS SYSTEM FOR RAPID DETECTION OF SARS-COV-2 HELPFUL TESTING TIPS



### BD Veritor™ Plus System

This document is a supplement to the manufacturer's instructions and is intended to provide helpful testing tips when using the BD Veritor™ Plus System for Rapid Detection of SARS-CoV-2. To ensure accurate performance of this test, please refer to the package insert or Instructions for Use for complete details on how to perform the test. Additional instructions can be found at <https://www.fda.gov/media/139755/download>.

For information on the BD Veritor™ system please view the manufacturer's website here <https://www.bdveritor.com>.\*



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## QUIDEL® SOFIA® SARS ANTIGEN FLUORESCENT IMMUNOASSAY (FIA) AND QUIDEL® SOFIA2® FLU + SARS ANTIGEN FIA HELPFUL TESTING TIPS



### Sofia® & Sofia2®

This document is a supplement to the manufacturer's instructions and is intended to provide helpful testing tips when using the Quidel® Sofia® Antigen Immunoassays. This document has been developed specifically for the Quidel® Sofia® point-of-care (POC) tests. To ensure accurate performance of these tests, please refer to the package insert or Instructions for Use. Additional instructions can be found at [www.fda.gov/media/137885/download](http://www.fda.gov/media/137885/download).

For information on the Quidel® Sofia® POC tests, please view the manufacturer's website at [www.quidel.com](http://www.quidel.com).\*



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<https://www.cdc.gov/coronavirus/2019-ncov/lab/point-of-care-testing.html>

# Laboratory Biosafety Guidelines for Handling and Processing Specimens

## Purpose

To provide support to public health and clinical laboratories through development of laboratory biosafety guidance

<https://www.cdc.gov/coronavirus/2019-nCoV/lab/lab-biosafety-guidelines.html>

**CDC** Centers for Disease Control and Prevention  
CDC 24/7: Saving Lives, Protecting People™

Search COVID-19

## COVID-19

Home Your Health Vaccines Cases & Data Work & School Healthcare Workers Health Depts Science More

More Resources

- CDC in Action +
- Global COVID-19 +
- Laboratories -
- Testing +
- CDC COVID-19 Tests +
- CDC Lab Work +
- Lab FAQs
- Data and Reporting +
- Biosafety -
- Biosafety for Specimen Handling
- Specimen Collection
- Lab Workplace Safety
- Data & Surveillance +
- Guidance for COVID-19 +
- Communication Resources +

### Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19)

Updated Oct. 28, 2021 [Print](#)

### Summary of Recent Changes

Updates as of Oct 26, 2021

- Added definition for aerosols and droplets
- Added pneumatic tube guidance
- Added shipping instructions

[View Previous Updates](#)

### Key Points

- This guidance is intended for clinical laboratory and support staff who handle or process specimens associated with COVID-19. Guidance for Point-Of-Care Testing can be found [here](#).

# Biological Risk Management for Point-of-Care Testing Sites

## Purpose

To explain how to conduct a risk management and focus on the risks of working with specimens that contain harmful biological material while performing POC testing

<https://www.cdc.gov/csels/dls/point-of-care-testing.html>

The screenshot shows the CDC website for the Division of Laboratory Systems (DLS). The page title is "Biological Risk Management for Point-of-Care Testing Sites". The main content area is titled "Point-of-Care Testing Staff Support Health and Reduce Risk" and contains the following text: "As someone who delivers point-of-care (POC) testing, you help people understand their health status. You collect specimens that contain biological material, such as blood or saliva, from people to test and determine what is making them sick. The results from these tests can help the people you serve make informed decisions about what to do next. From the time you start each testing process until you finish, there are risks involved. Use this guidance to help make sure you reduce those risks as much as possible to keep you and your coworkers, patients, customers, family, and community safe and healthy while you perform POC tests. Learn how to evaluate and reduce risks using the information below; learn why risk assessment is important in your role [here](#)."

Below this text is a section titled "Perform Risk Management Using these Five Steps" with the text: "Risk management is a five-step process of identifying and analyzing risks and taking steps to reduce or eliminate them." A circular diagram illustrates the five steps:

- Step 1: Identify hazards and risks
- Step 2: Assess the risks
- Step 3: Choose controls that reduce the risks
- Step 4: Put the controls into practice
- Step 5: Evaluate whether the controls are effective

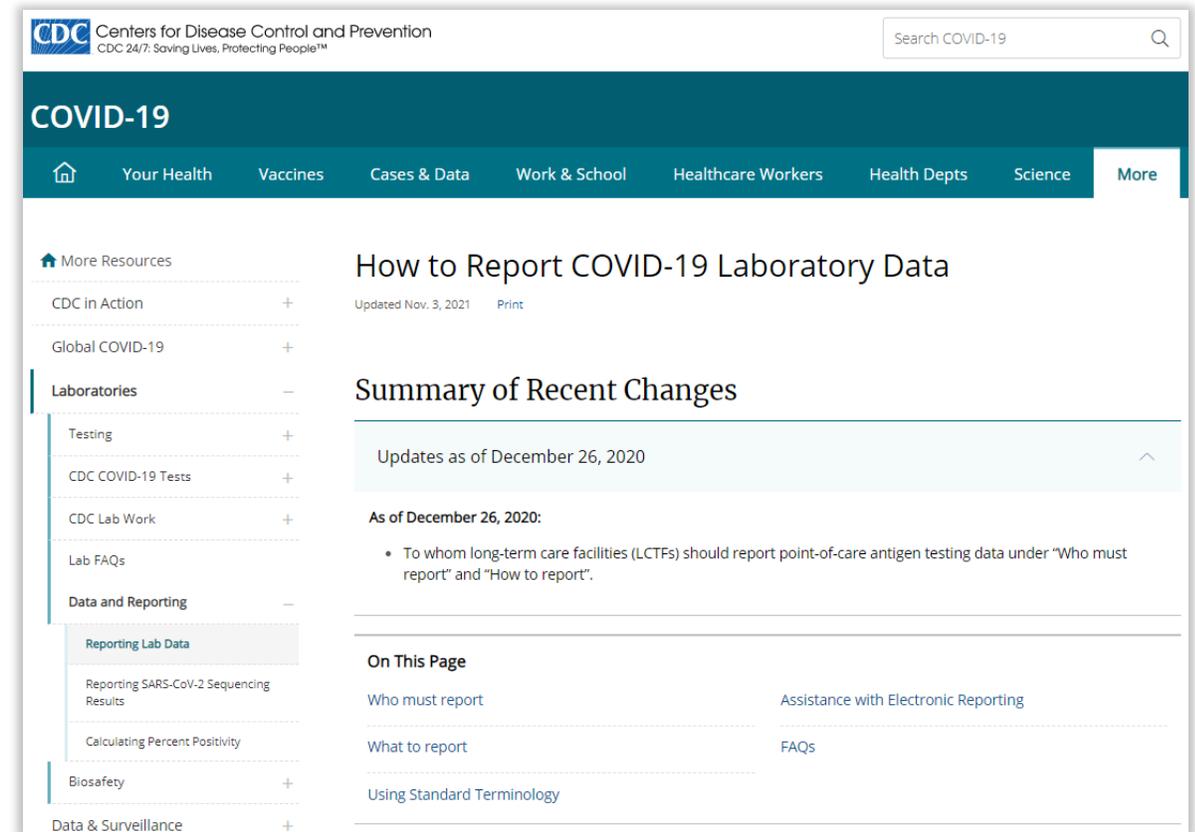
The left sidebar of the website lists various resources such as "DLS Home", "About Us", "LIVD Mapping Tool for SARS-CoV-2 Tests", "Strengthening Clinical Laboratories", "CDC's Laboratory Outreach Communication System (LOCS)", "Laboratory Communicators' Network", "Free Educational Materials for Public Health and Clinical Laboratories", "Competency Guidelines for Laboratory Professionals", "CDC Biorepository", "Biological Risk Assessment: General Considerations for Laboratories", and "Lab Week". There is also a "Get Email Updates" button at the bottom of the sidebar.

# Reporting COVID-19 Laboratory Data

## Purpose

To provide guidance on the reporting requirements for laboratories

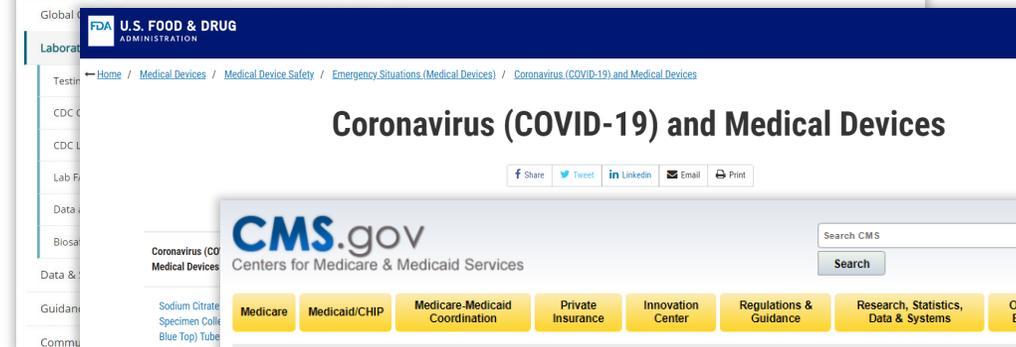
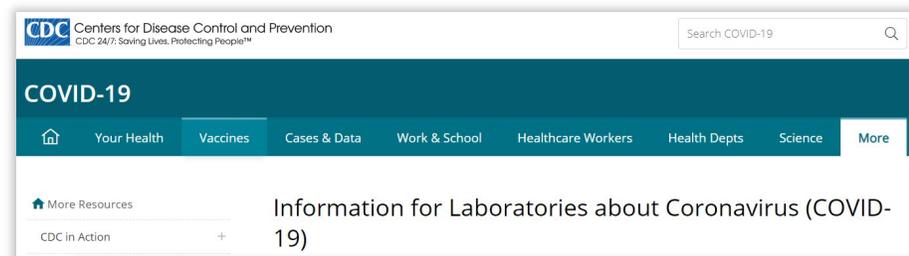
<https://www.cdc.gov/coronavirus/2019-ncov/lab/reporting-lab-data.html>



The screenshot shows the CDC website's COVID-19 reporting page. The header includes the CDC logo and the tagline "Centers for Disease Control and Prevention, CDC 24/7: Saving Lives, Protecting People™". A search bar is located in the top right corner. The main navigation bar features links for "Your Health", "Vaccines", "Cases & Data", "Work & School", "Healthcare Workers", "Health Depts", "Science", and "More". The page title is "COVID-19". The left sidebar contains a "More Resources" section with expandable categories: "CDC in Action", "Global COVID-19", "Laboratories" (expanded), "Testing", "CDC COVID-19 Tests", "CDC Lab Work", "Lab FAQs", "Data and Reporting", "Reporting Lab Data" (selected), "Reporting SARS-CoV-2 Sequencing Results", "Calculating Percent Positivity", "Biosafety", and "Data & Surveillance". The main content area is titled "How to Report COVID-19 Laboratory Data" and includes a "Summary of Recent Changes" section with updates as of December 26, 2020. A bullet point states: "To whom long-term care facilities (LCTFs) should report point-of-care antigen testing data under 'Who must report' and 'How to report'". The "On This Page" section lists links for "Who must report", "Assistance with Electronic Reporting", "What to report", "FAQs", and "Using Standard Terminology".

# Additional Guidance for CLIA Certificates of Waiver and Point-of-Care Testing

- CDC Information for Laboratories about COVID-19
  - <https://www.cdc.gov/coronavirus/2019-nCoV/lab/index.html>
- FDA COVID-19 and Medical Devices
  - <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/coronavirus-covid-19-and-medical-devices>
- CMS Clinical Laboratory Improvement Amendments (CLIA)
  - <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA>





For more information, please contact Centers for Disease Control and Prevention

1600 Clifton Road NE, Atlanta, GA 30333

Telephone: 1-800-CDC-INFO (232-4636)/TTY: 1-888-232-6348

E-mail: [cdcinfo@cdc.gov](mailto:cdcinfo@cdc.gov) | Web: [www.cdc.gov](http://www.cdc.gov)

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

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# FDA Update

Tim Stenzel

US Food and Drug Administration (FDA)



U.S. Department of  
Health and Human Services  
Centers for Disease  
Control and Prevention

# U.S. Food and Drug Administration (FDA)

- **COVID-19 Emergency Use Authorization (EUA) Information for Medical Devices**  
<https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>
- **COVID-19 In Vitro Diagnostic EUAs**  
<https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas>
- **COVID-19 Frequently Asked Questions**  
<https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/coronavirus-disease-2019-covid-19-frequently-asked-questions>
- **COVID-19 Updates**  
<https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#2019-ncov>
- **FDA Townhall Meetings**  
<https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/virtual-town-hall-series-immediately-effect-guidance-coronavirus-covid-19-diagnostic-tests-06032020>
- **Independent Evaluations of COVID-19 Serological Tests**  
<https://open.fda.gov/apis/device/covid19serology/>

# U.S. Food and Drug Administration (FDA)

- **COVID-19 Diagnostic Development**

[CDRH-EUA-Templates@fda.hhs.gov](mailto:CDRH-EUA-Templates@fda.hhs.gov)

- **Spot Shortages of Testing Supplies: 24-Hour Support Available**

1. Call 1-888-INFO-FDA (1-888-463-6332)

2. Then press star (\*)

- **FDA MedWatch**

<https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program>

# SARS-CoV-2 Variants Update

John Barnes

CDC Laboratory and Testing Task Force for the COVID-19 Response



U.S. Department of  
Health and Human Services  
Centers for Disease  
Control and Prevention

# CDC Social Media

<https://www.facebook.com/CDC>



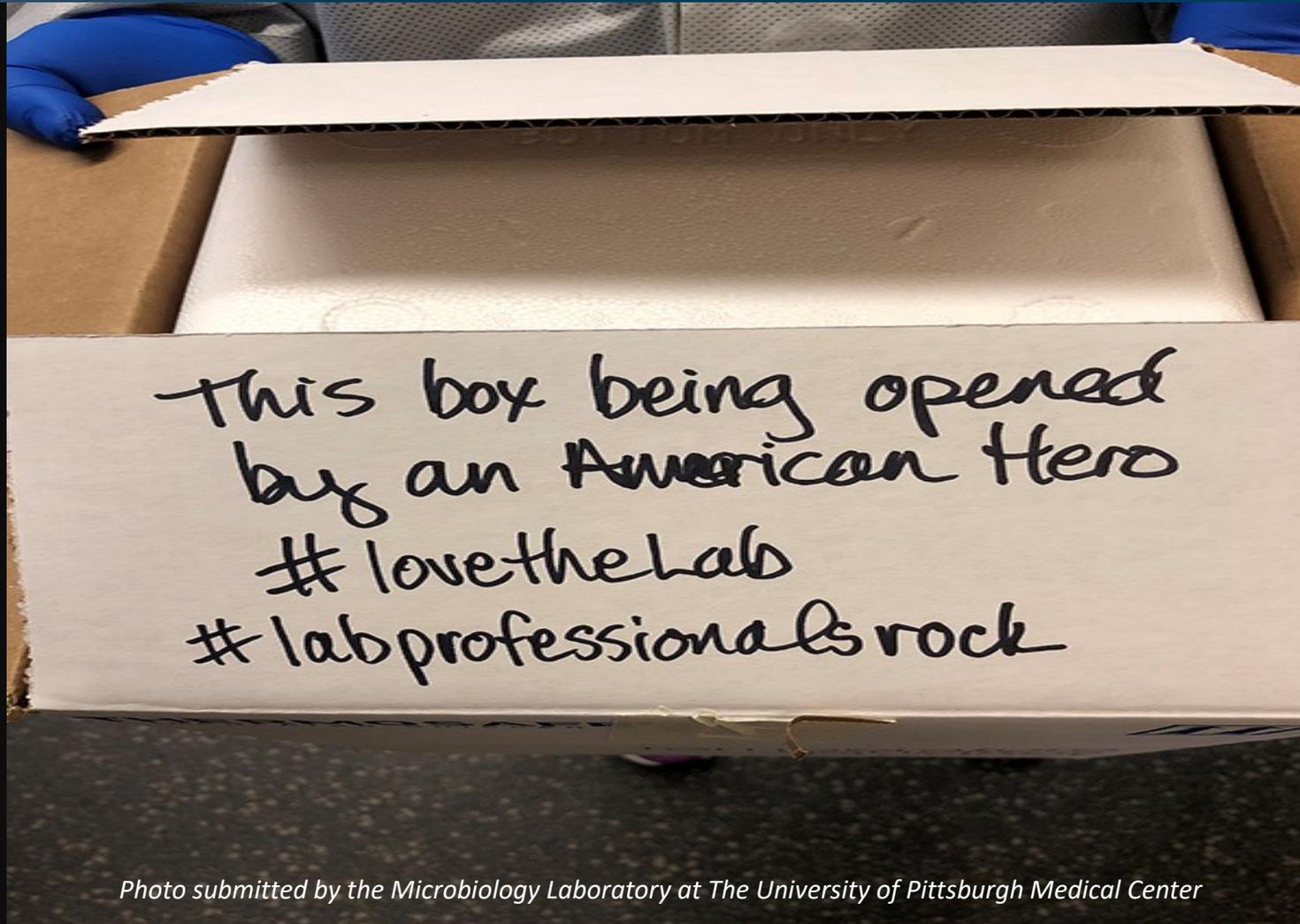
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<https://www.instagram.com/cdcgov>



<https://www.linkedin.com/company/cdc>

# Thank You For Your Time!



*Photo submitted by the Microbiology Laboratory at The University of Pittsburgh Medical Center*