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.

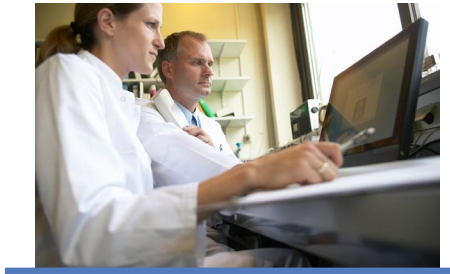
Four Goal Areas

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



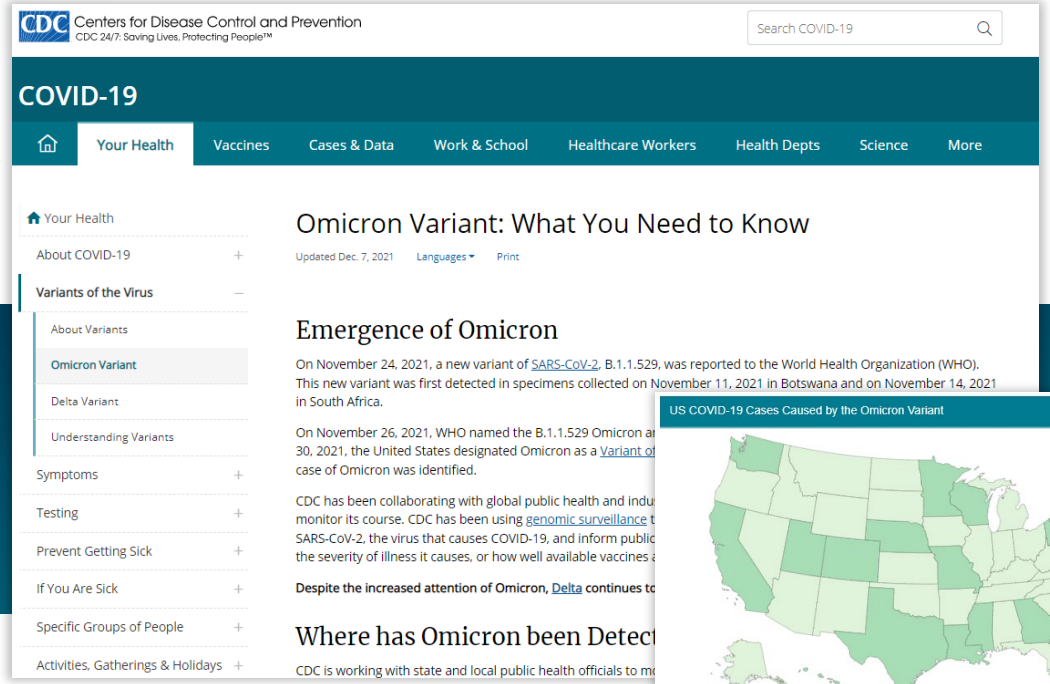
Safe and Prepared Laboratories

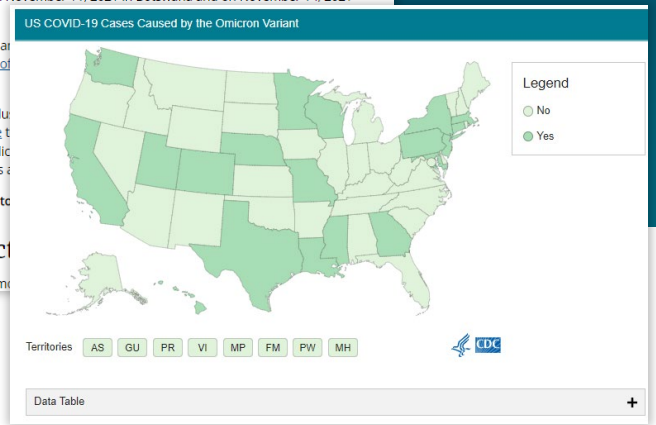
- Enhance the safety and response capabilities of clinical and public health laboratories

Accessible and Usable Laboratory Data

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

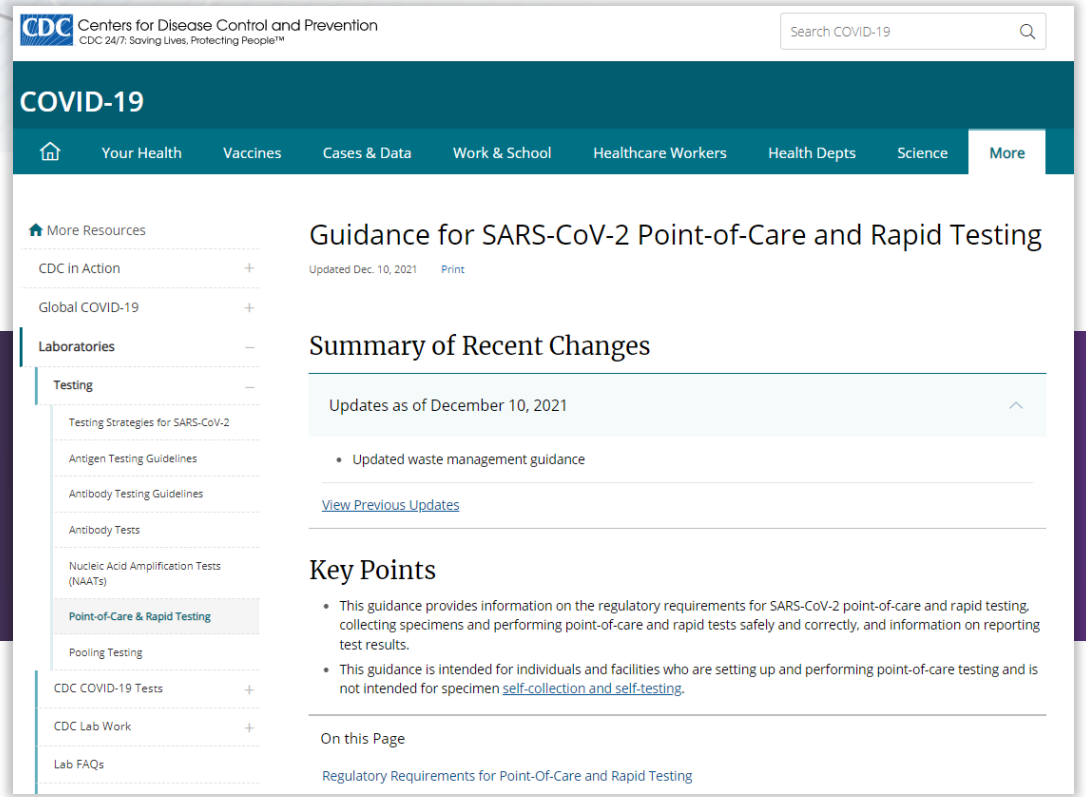
Omicron Variant: What You Need to Know



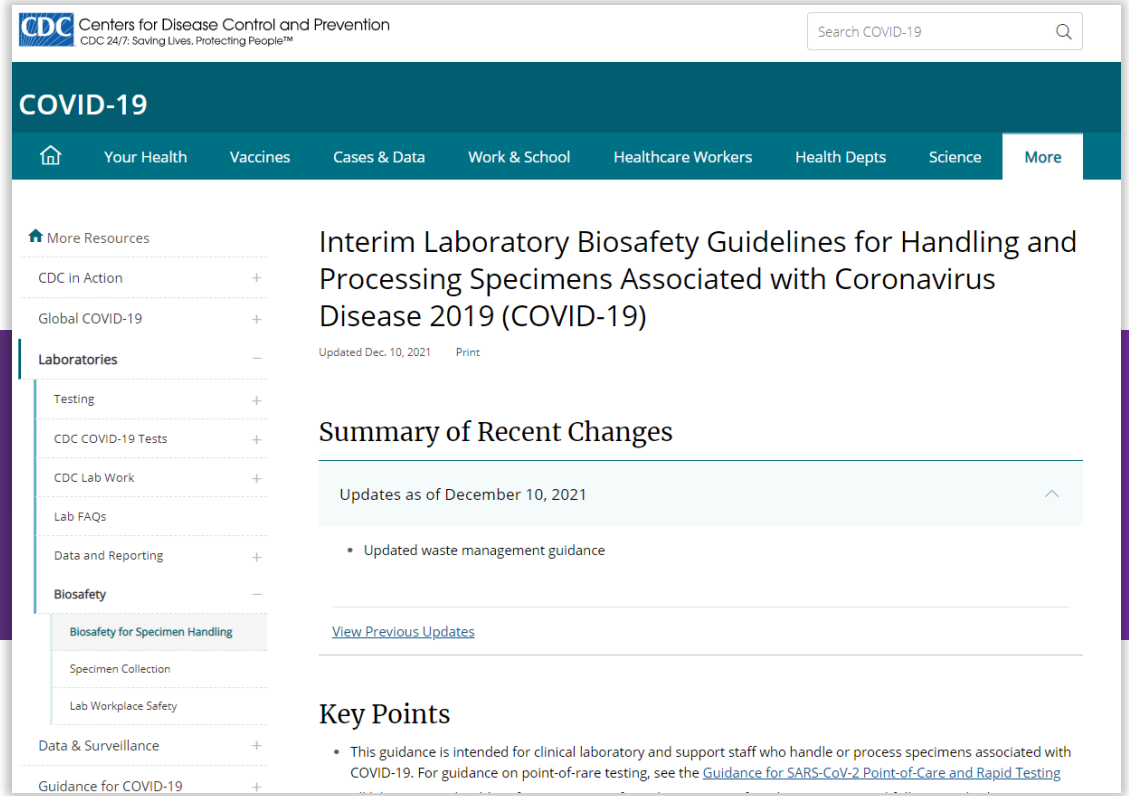


https://www.cdc.gov/coronavirus/2019-ncov/variants/omicron-variant.html

Updated Guidance for Waste Management



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

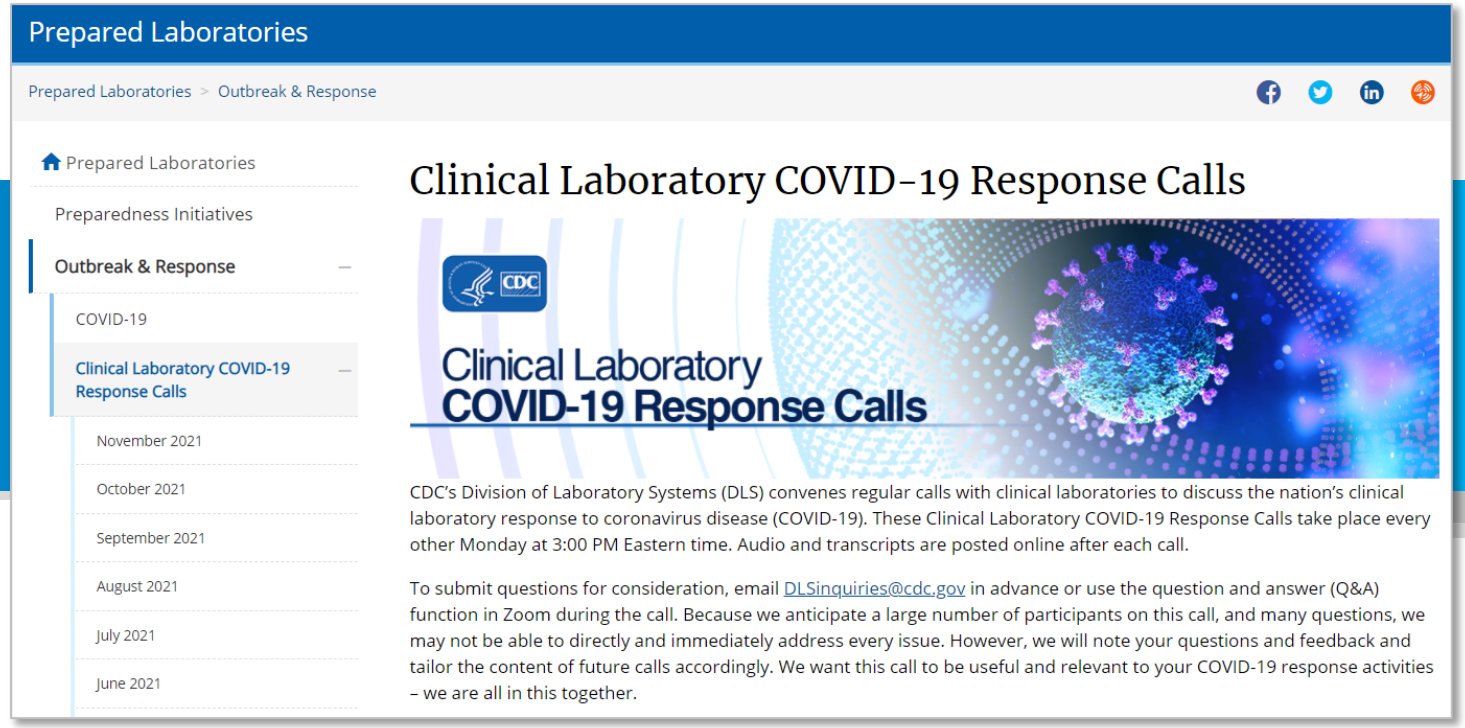


https://www.cdc.gov/coronavirus/2019-nCoV/lab/lab-biosafety-guidelines.html

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



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

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
- If you are a patient, please direct any questions to your healthcare provider

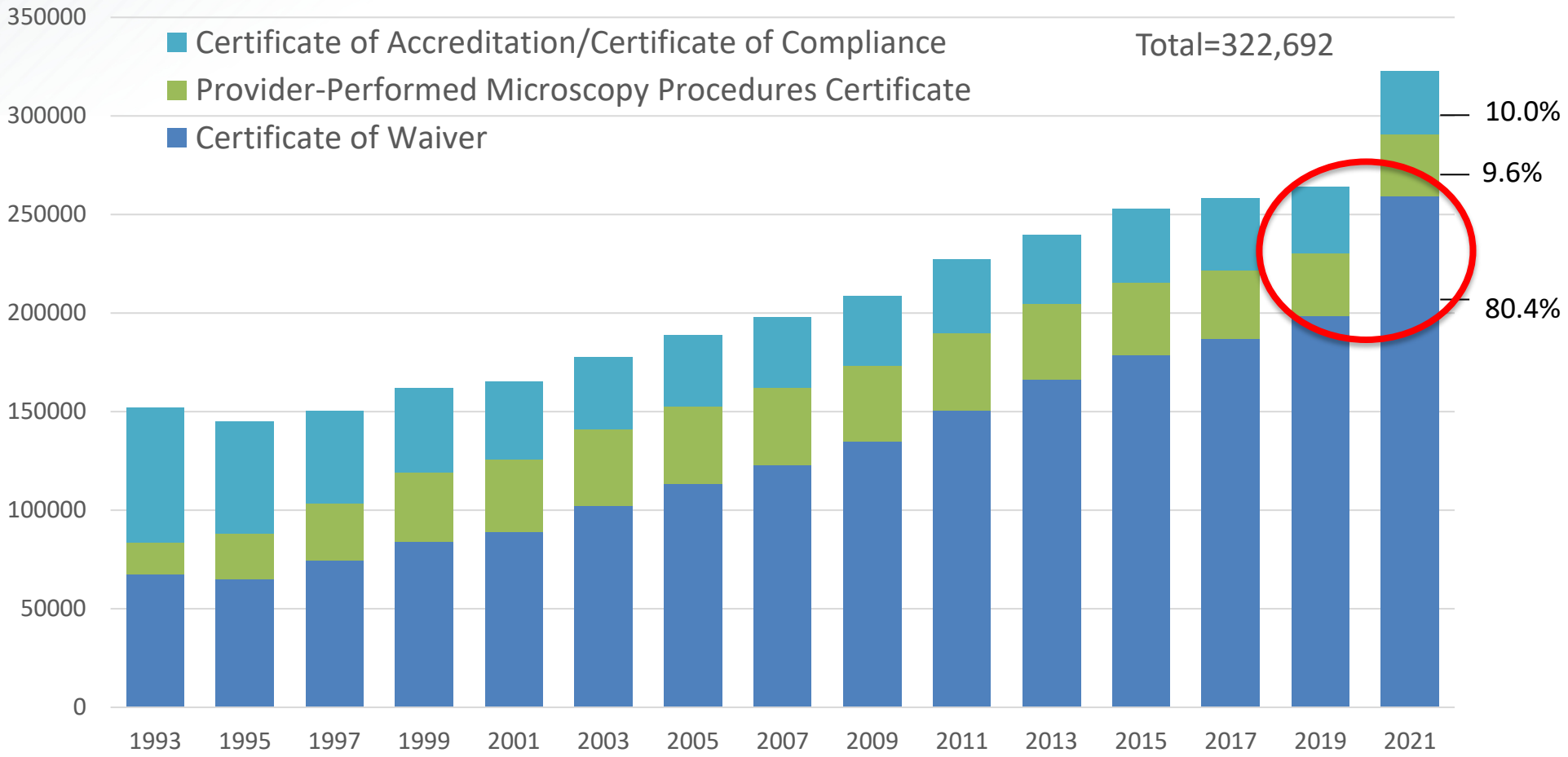
Slide decks may contain presentation material from panelists who are not affiliated with CDC. Presentation content from external panelists may not necessarily reflect CDC's official position on the topic(s) covered.

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

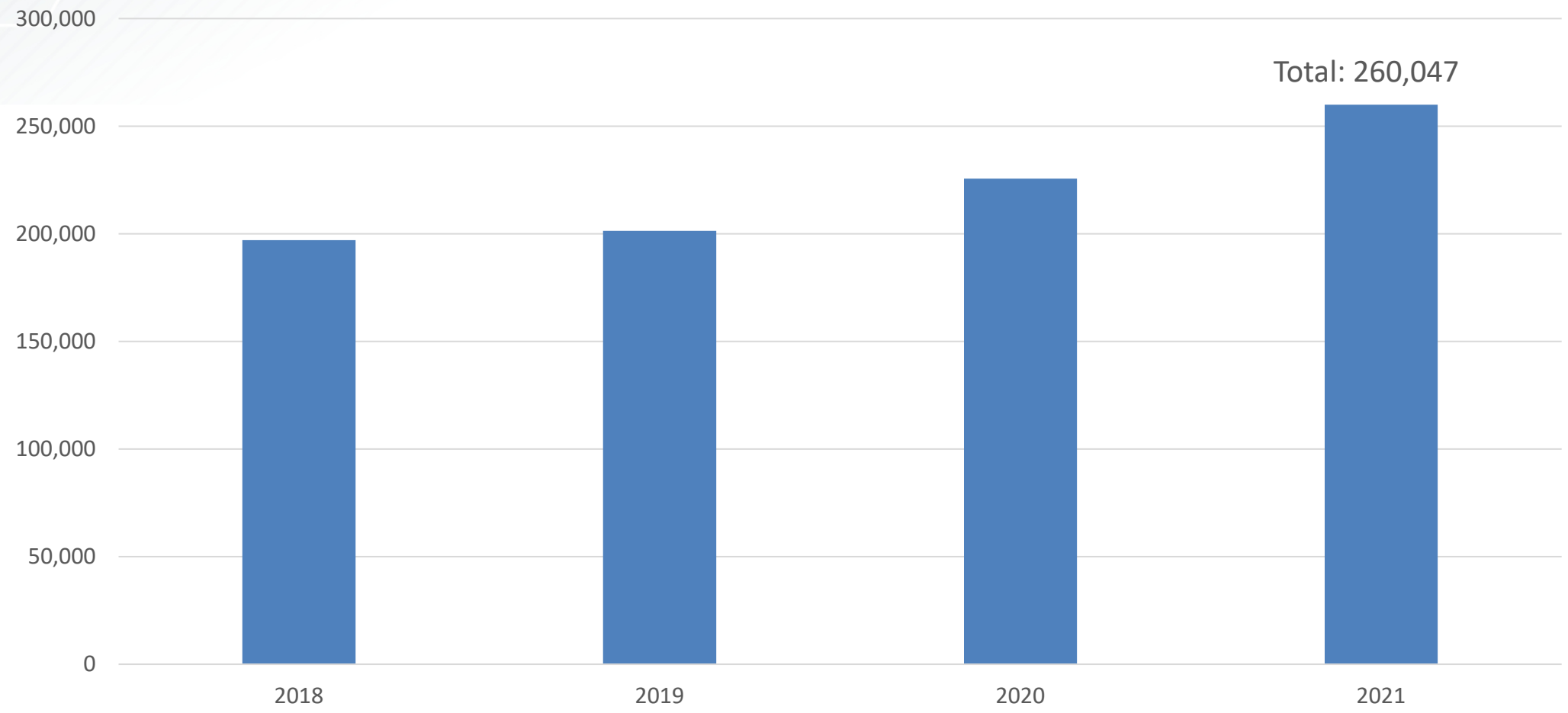
U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Number of CLIA-Certified Laboratories: 1993 - 2021



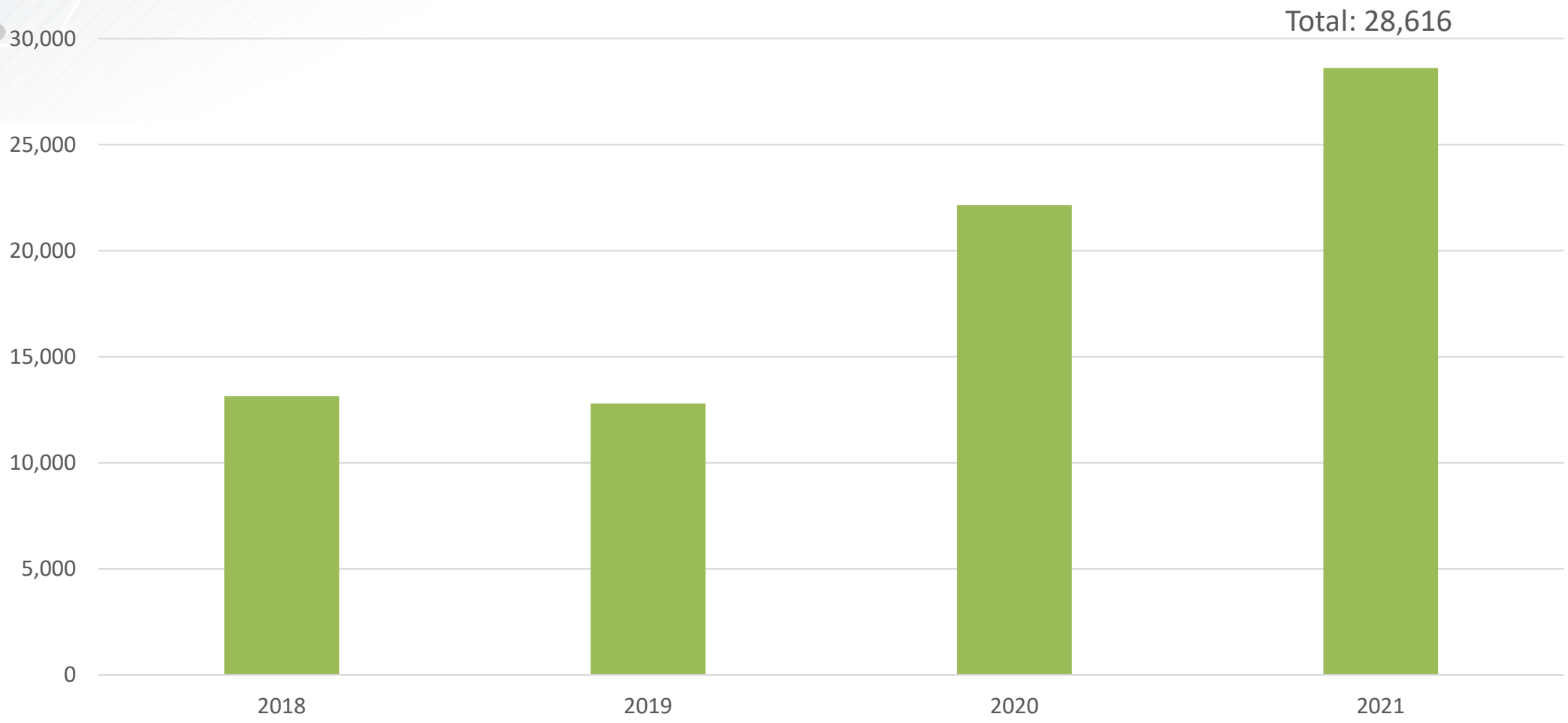
Data obtained from CMS QIES database, 11/23/2021. Lab types in QIES data are self-reported. Numbers include laboratories in CLIA-exempt states of NY and WA. Data does not include CLIA Certificate of Registration laboratories or US Department of Defense Laboratories.

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


The New York Times

Nevada Halts Use of Rapid Coronavirus Tests in Nursing Homes, Citing Inaccuracies


March 31, 2021

Currently: 69° -- Complete Forecast

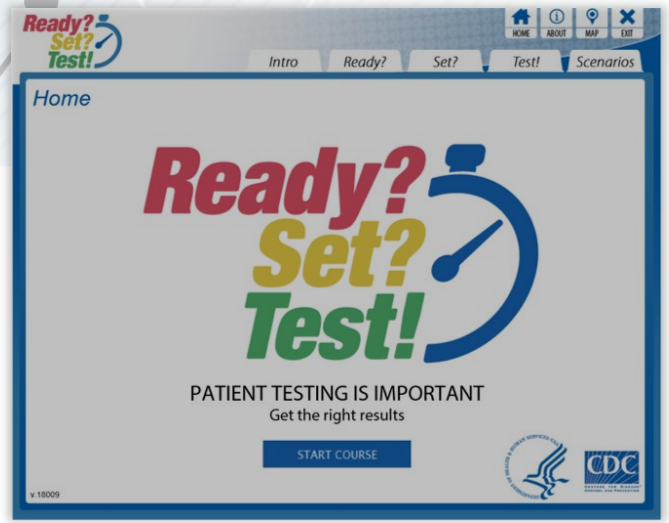
LAS VEGAS SUN

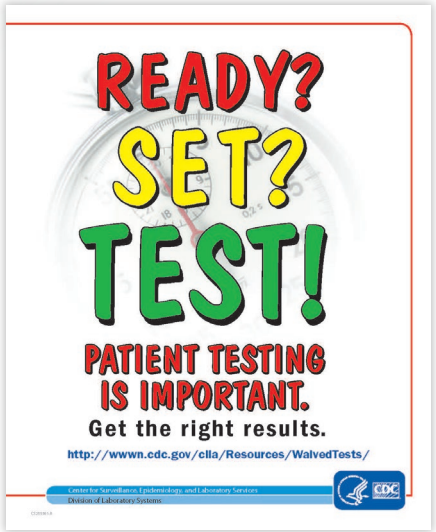
NEWS | BUSINESS | SPORTS | POLITICS | OPINION | ENTERTAINMENT | CALENDAR

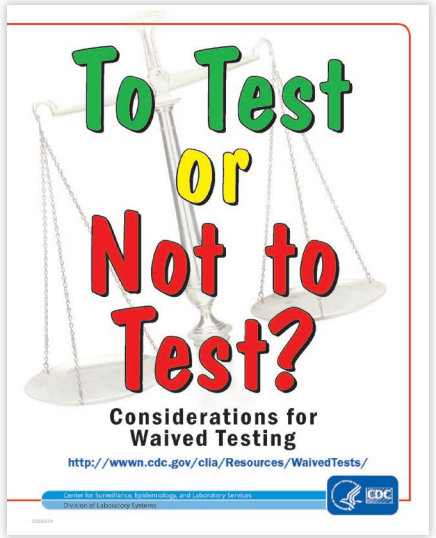
Betting | Las Vegas Raiders | UNLV Sports | Marijuana Laws | Gaming | Golden Knights | Smith's World

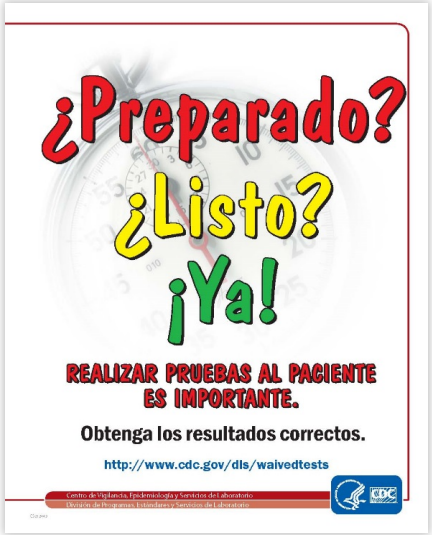
Why Nevada halted the use of rapid coronavirus tests in nursing homes

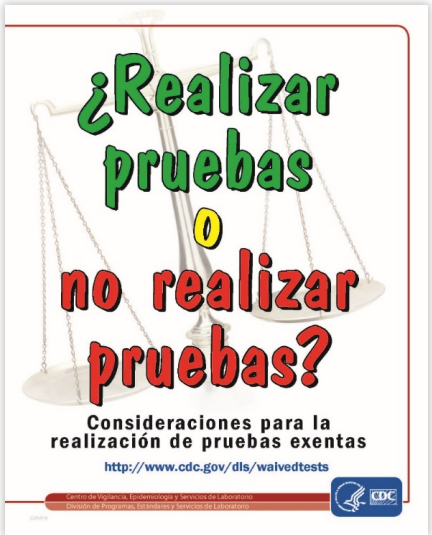
CDC Free Educational Resources

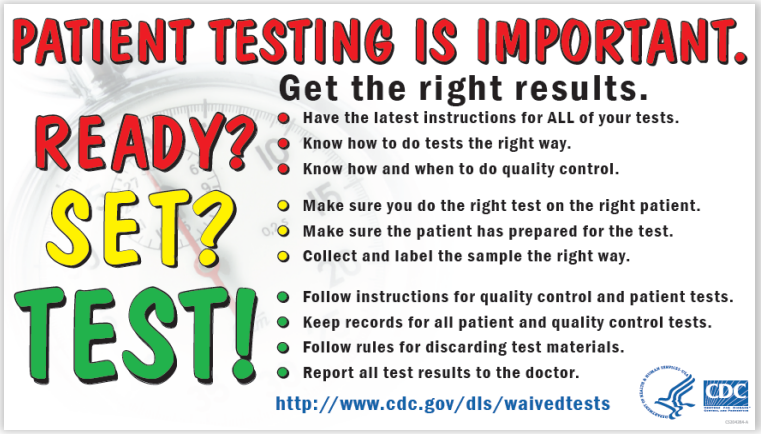








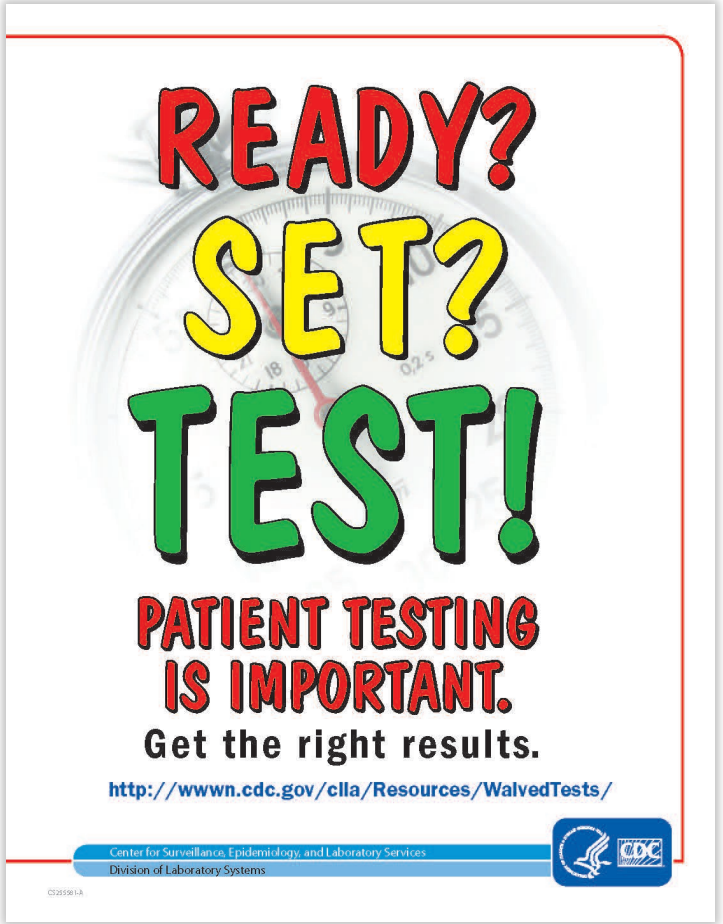




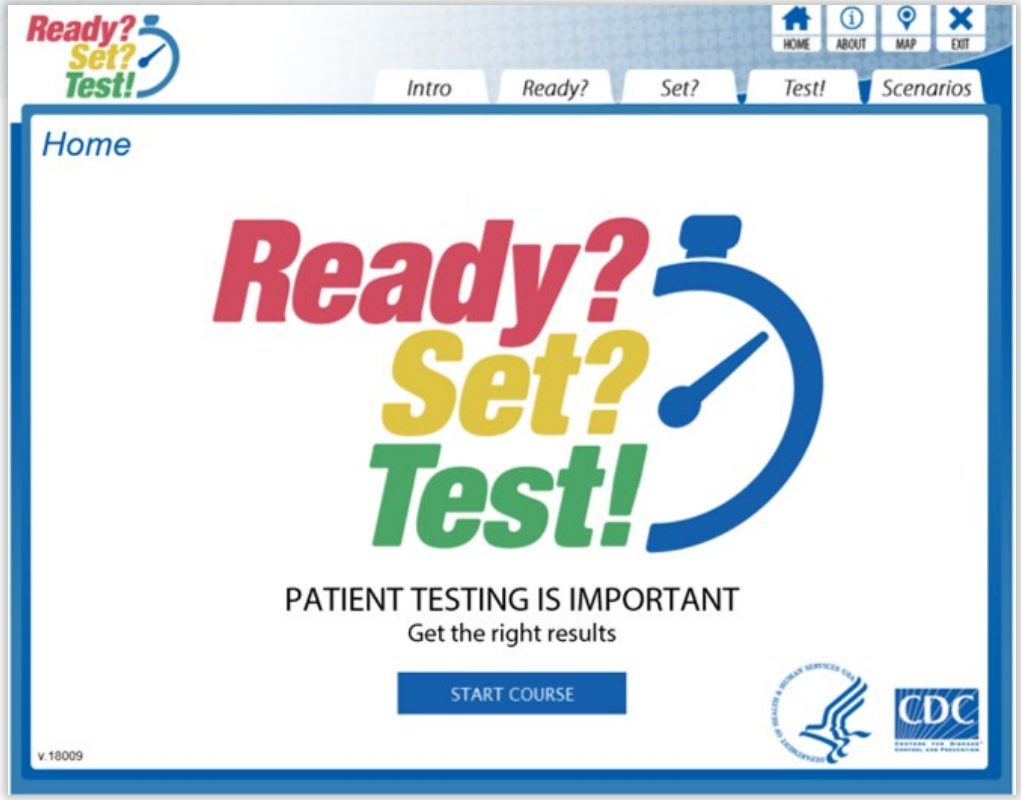
www.cdc.gov/waivedtesting

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



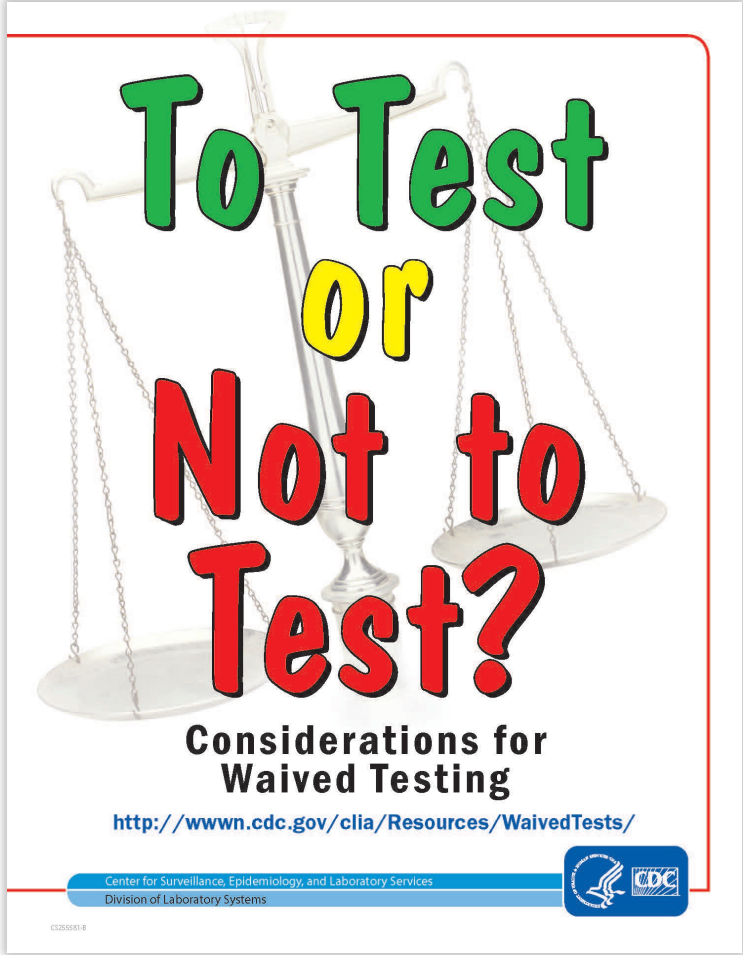
Ready? Set? Test! Online Course: New Update Available



- 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

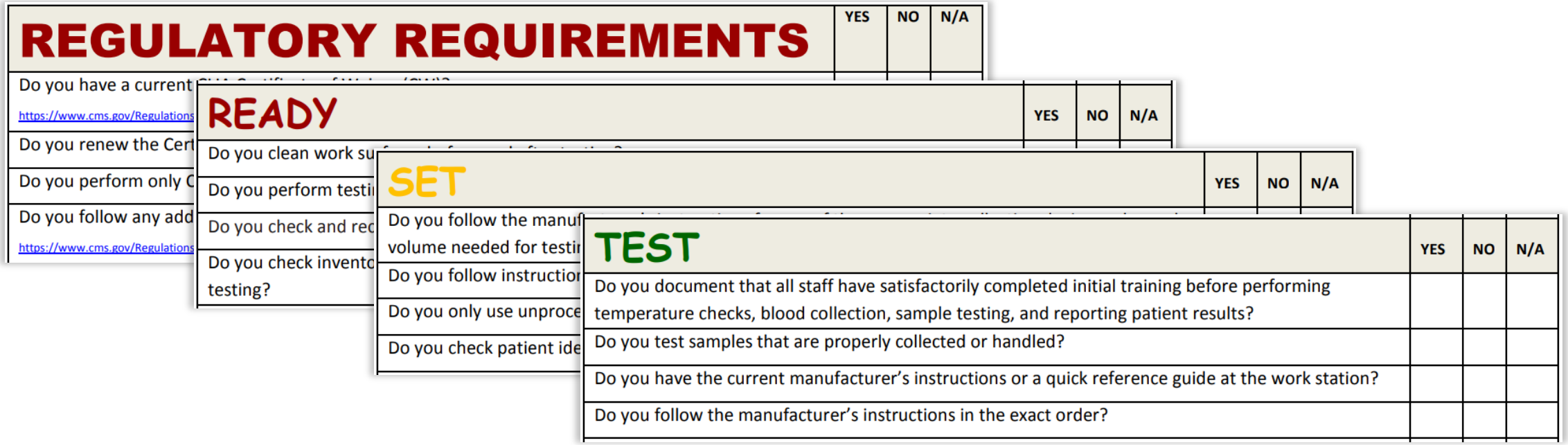
To Test or Not to Test?

- 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



REGULATORY REQUIREMENTS

	YES	NO	N/A
Do you have a current [illegible] https://www.cms.gov/Regulations			
Do you renew the Cert			
Do you perform only C			
Do you follow any add https://www.cms.gov/Regulations			

READY

	YES	NO	N/A
Do you clean work su			
Do you perform testi			
Do you check and rec			
Do you check invento testing?			

SET

	YES	NO	N/A
Do you follow the manuf volume needed for testi			
Do you follow instructio			
Do you only use unproce			
Do you check patient ide			

TEST

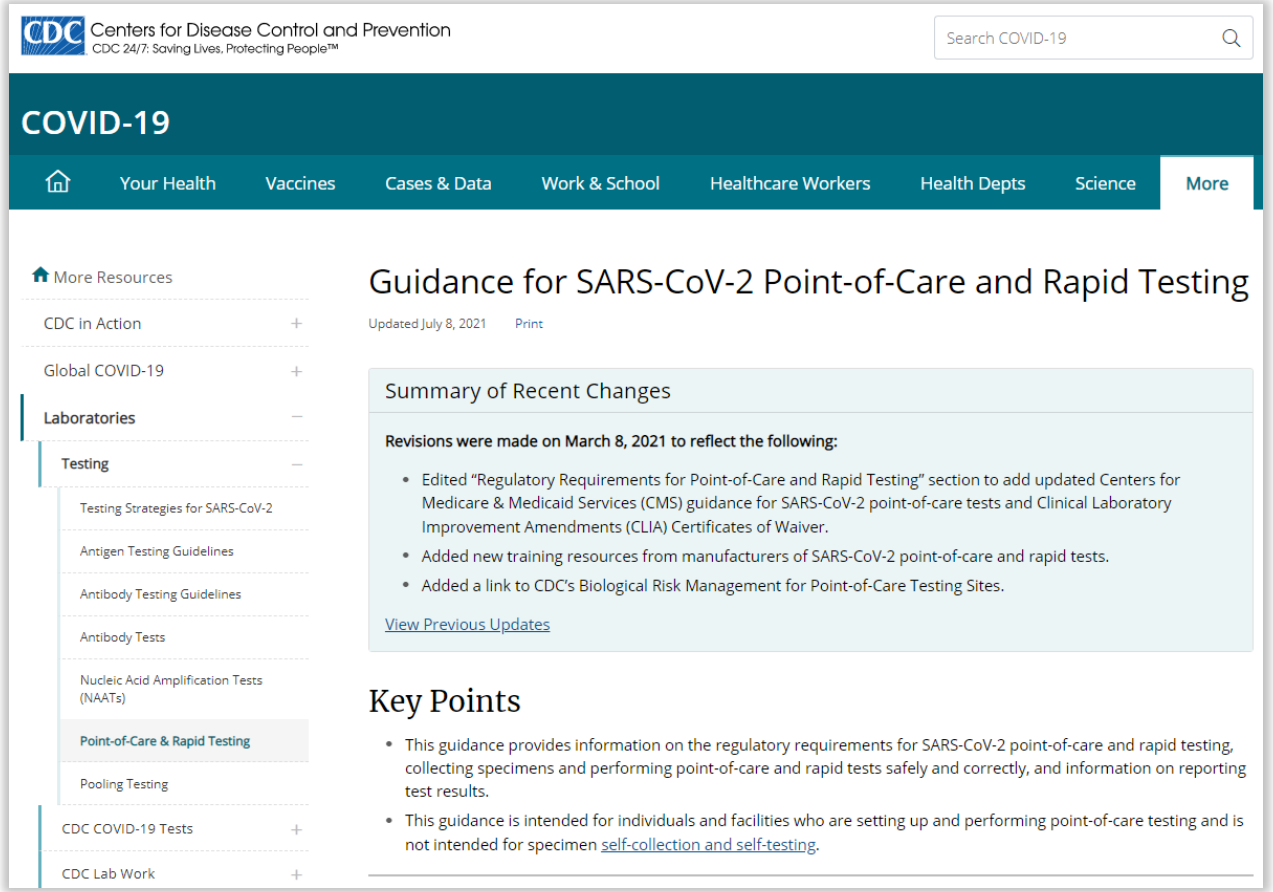
	YES	NO	N/A
Do you document that all staff have satisfactorily completed initial training before performing temperature checks, blood collection, sample testing, and reporting patient results?			
Do you test samples that are properly collected or handled?			
Do you have the current manufacturer's instructions 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

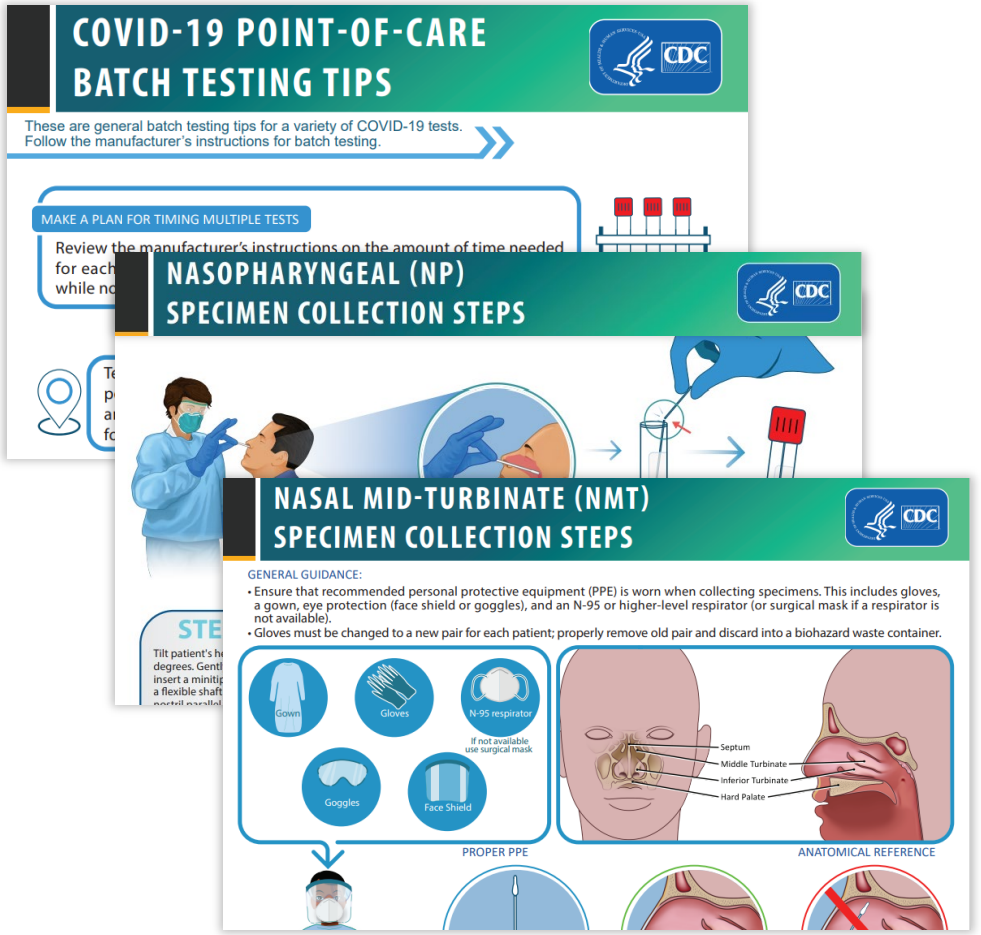
To provide guidance on the regulatory requirements for SARS-CoV-2 point-of-care (POC) testing, using POC tests safely, and information on reporting POC test results

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



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
- Nasopharyngeal (NP) Specimen Collection Steps
  - https://www.cdc.gov/coronavirus/2019-ncov/downloads/lab/NP_Specimen_Collection_Infographic_FINAL_508.pdf

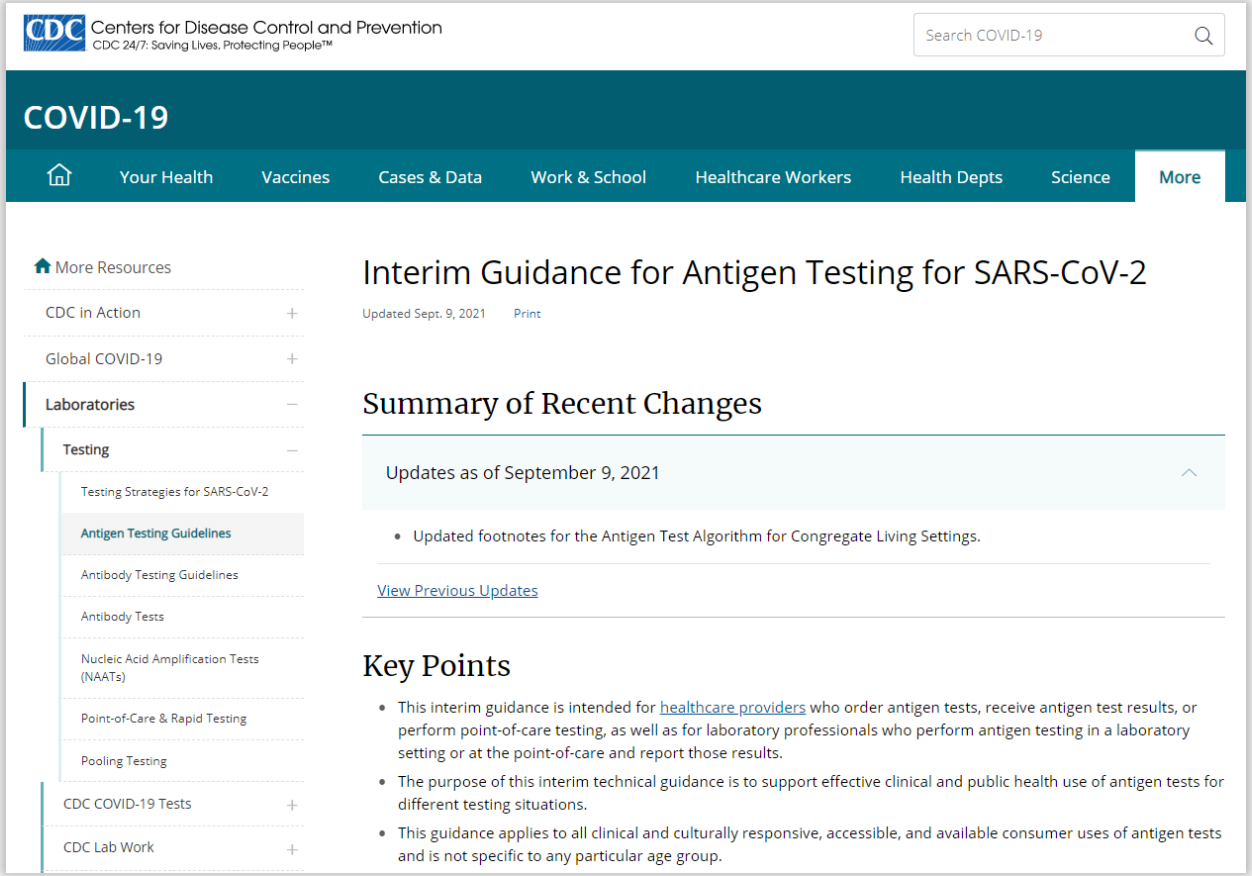


Guidance for Antigen Testing

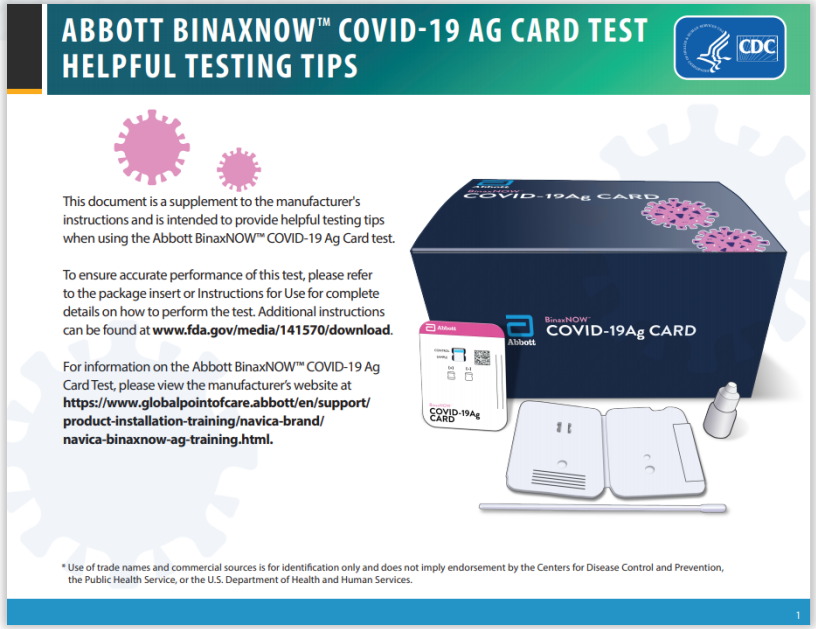
Purpose

To support effective use of antigen tests for different testing situations

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



Tips for Rapid Antigen Tests



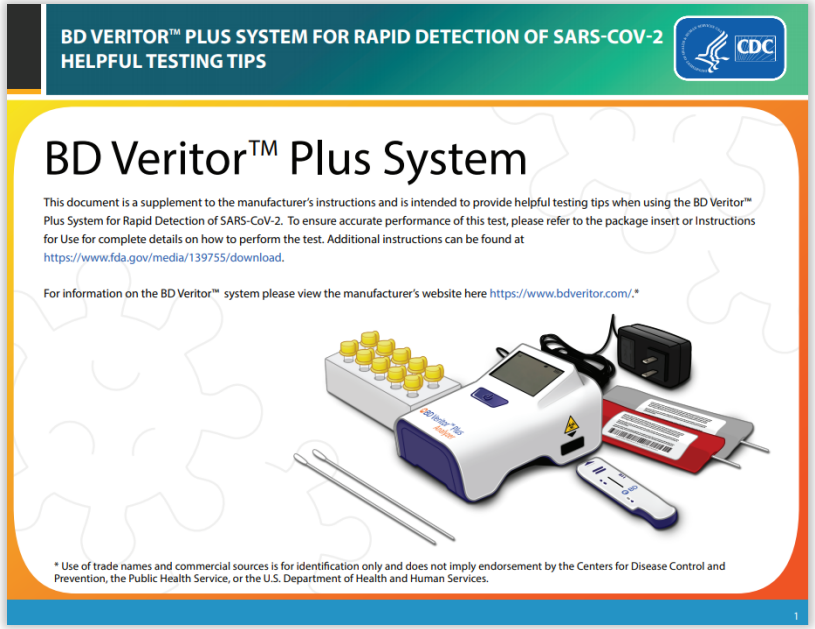
ABBOTT BINAXNOW™ COVID-19 AG CARD TEST
HELPFUL TESTING TIPS

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**.

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/.*

* 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.

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

Sofia® & Sofia®2

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.

For information on the Quidel® Sofia® POC tests, please view the manufacturer's website at www.quidel.com.*

* 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.

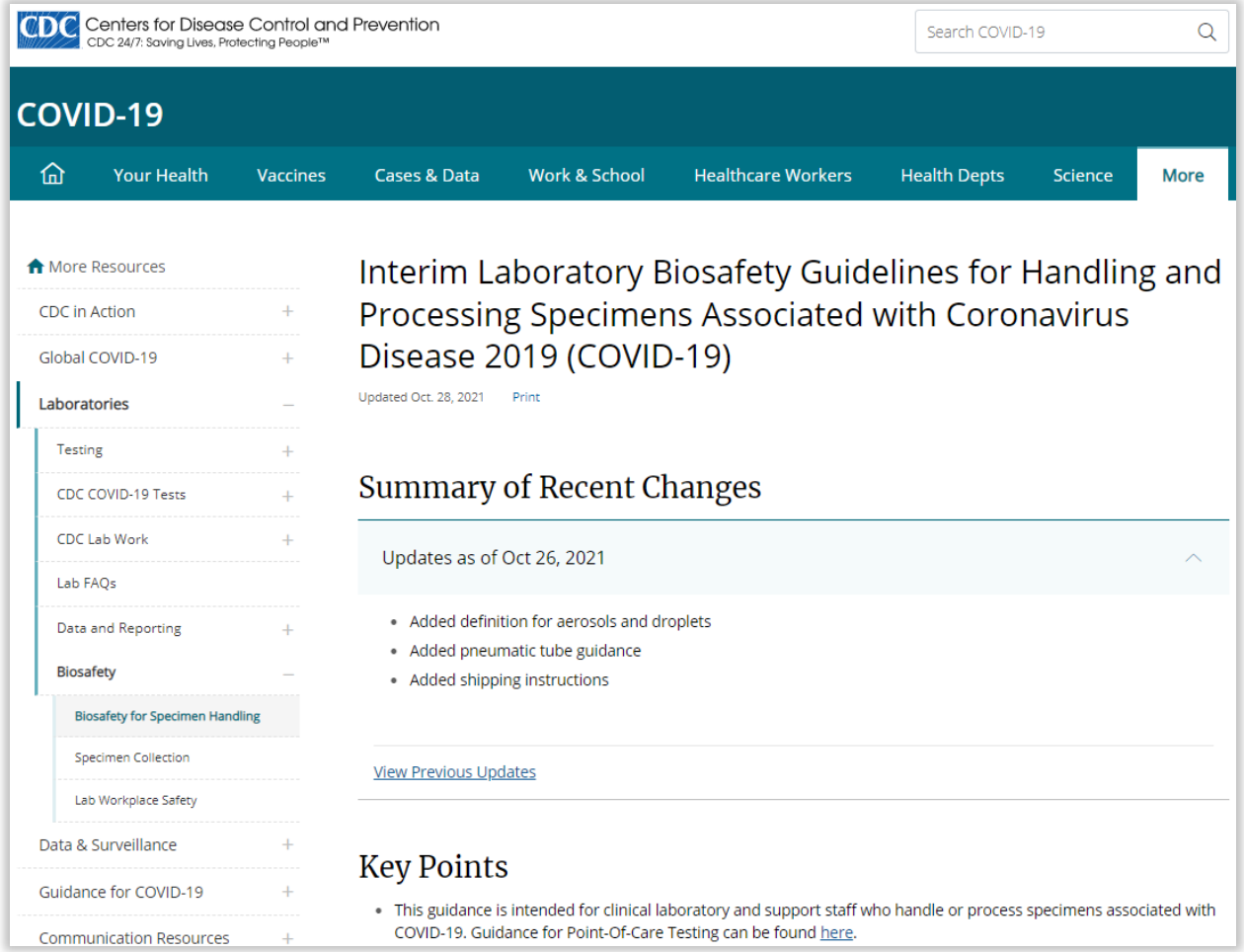
https://www.cdc.gov/coronavirus/2019-ncov/lab/point-of-care-testing.html

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

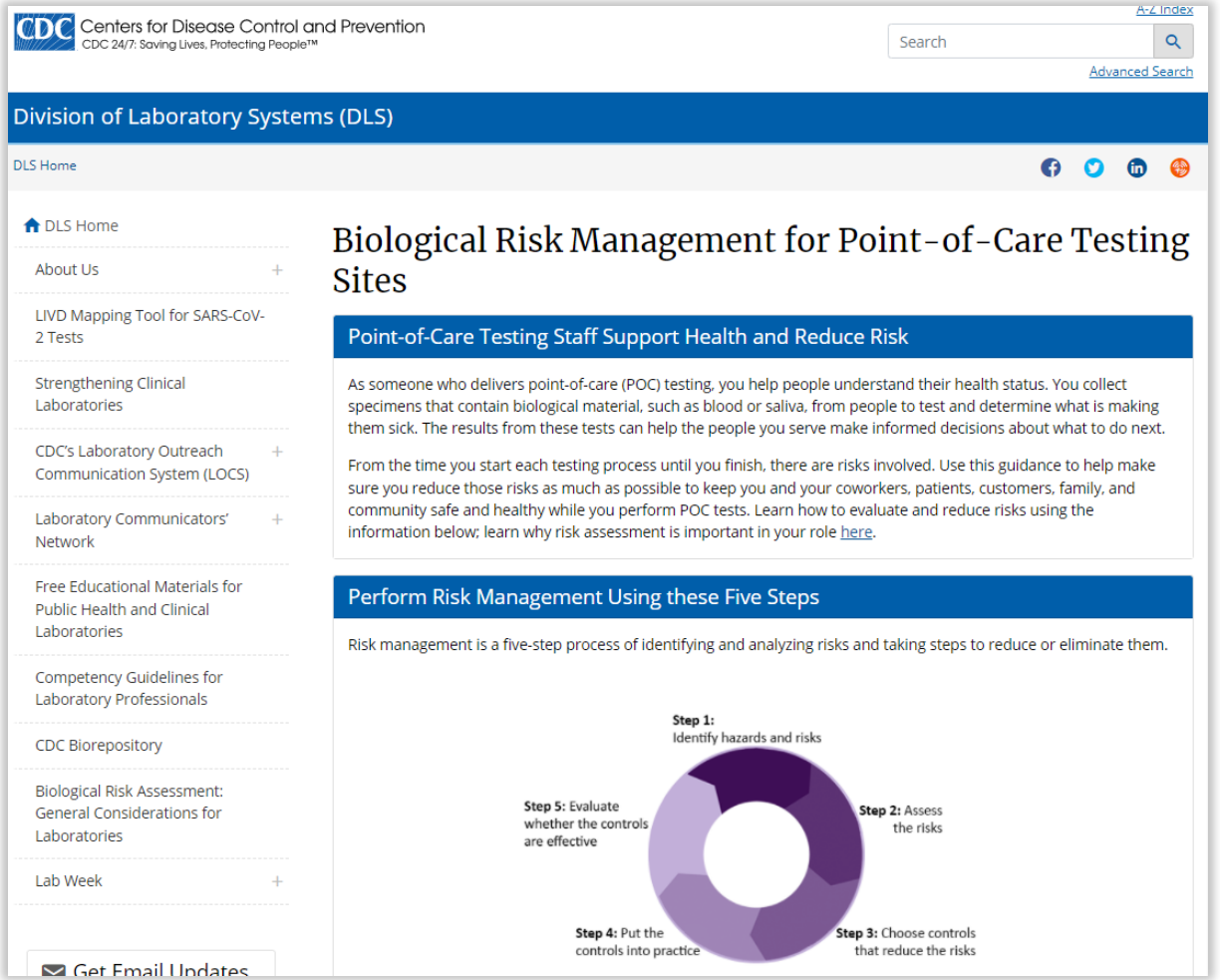


Biological Risk Management for Point-of-Care Testing Sites

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

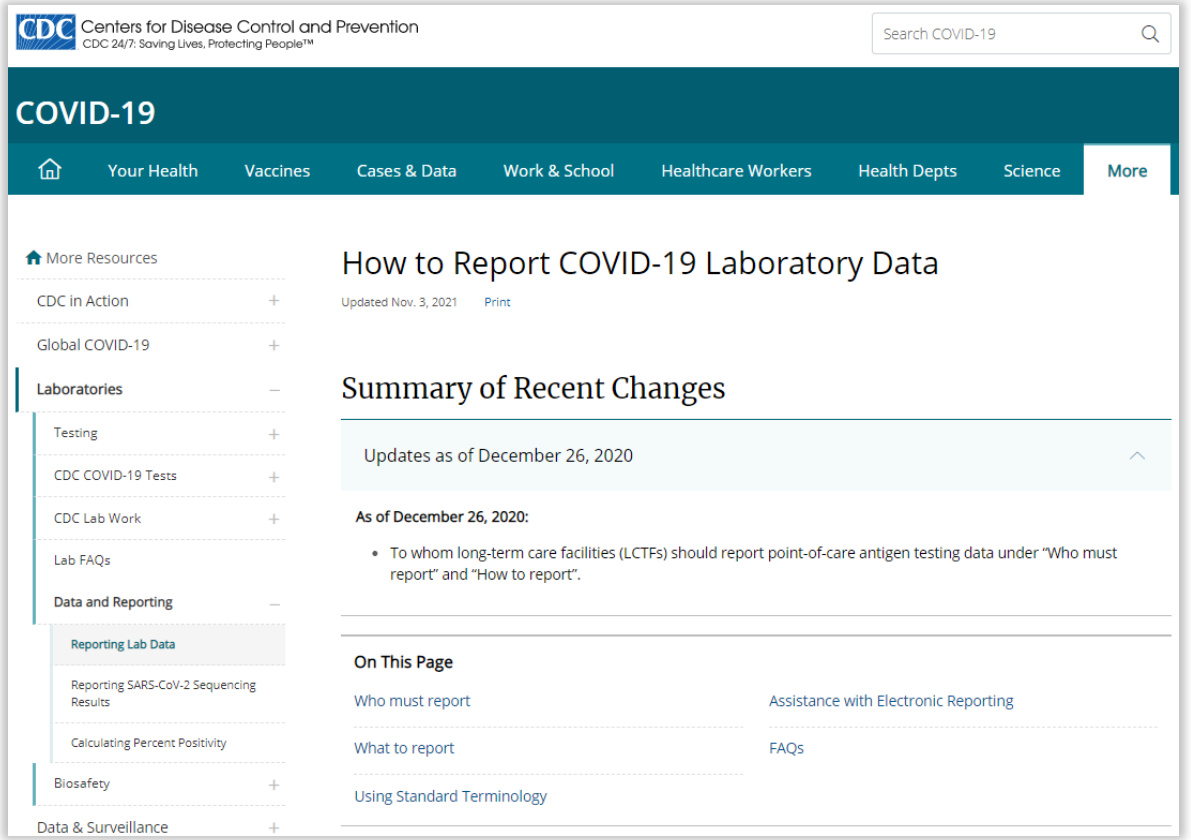


Reporting COVID-19 Laboratory Data

Purpose

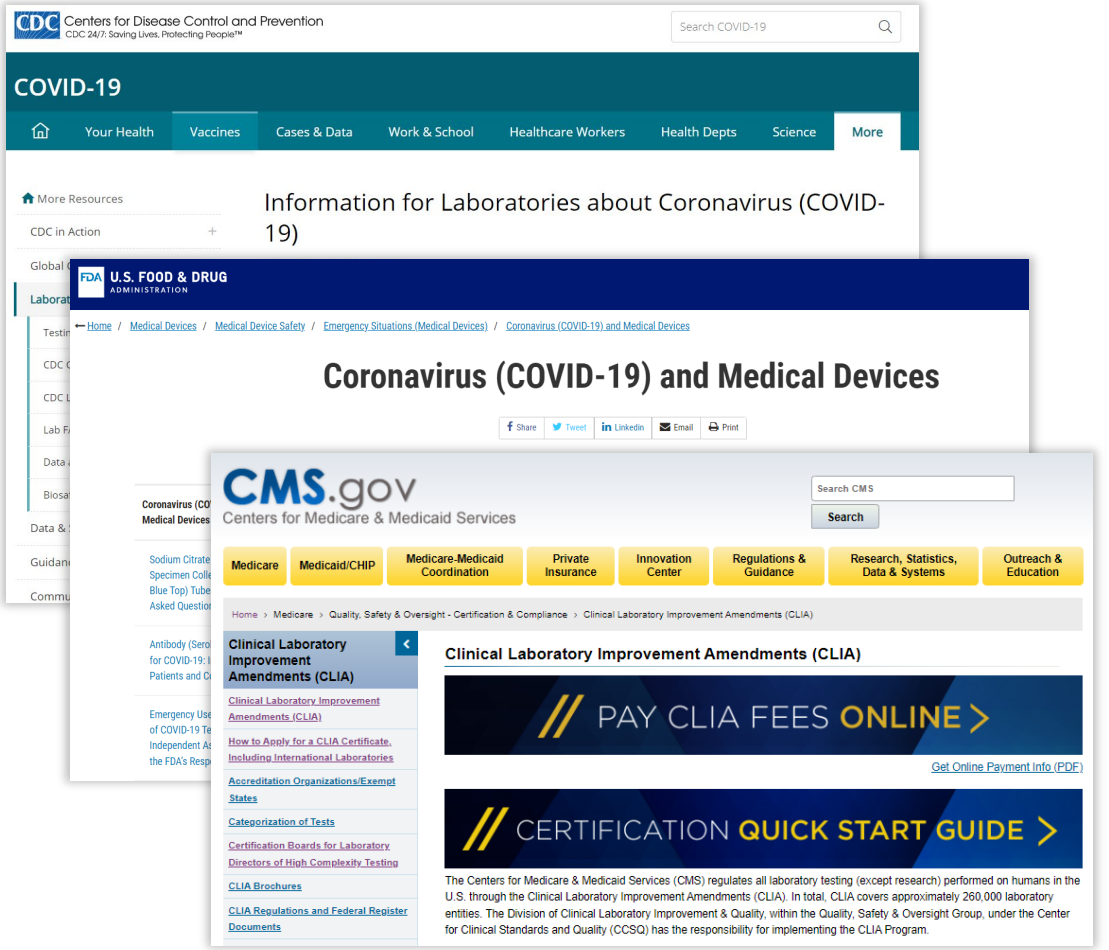
To provide guidance on the reporting requirements for laboratories

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



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 | Web: www.cdc.gov

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/

FDA U.S. FOOD & DRUG ADMINISTRATION

U.S. Food and Drug Administration (FDA)

- **COVID-19 Diagnostic Development**
  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

U.S. FOOD & DRUG ADMINISTRATION

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

https://twitter.com/cdcgov

https://www.instagram.com/cdcgov

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

Thank You For Your Time!

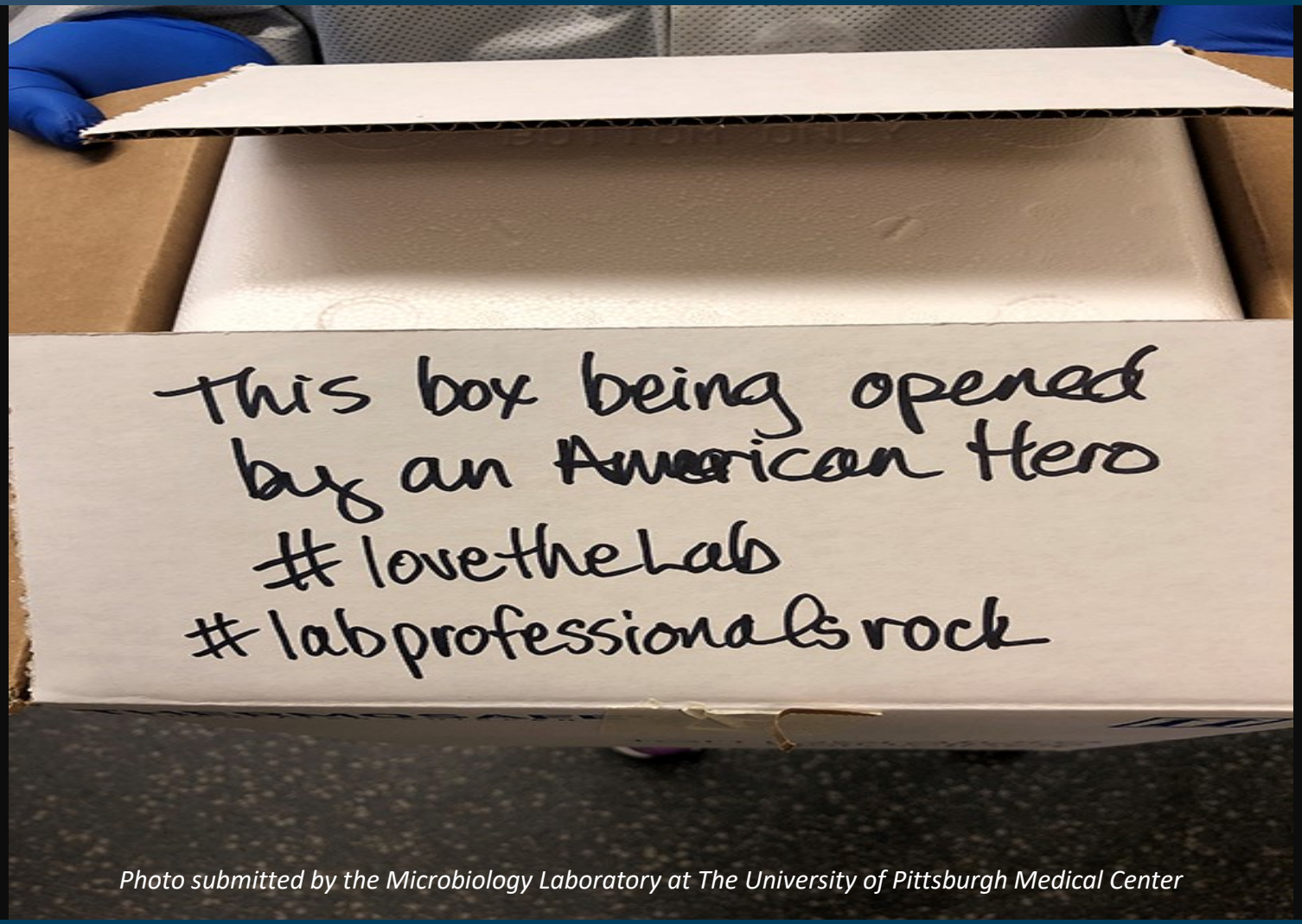


Photo submitted by the Microbiology Laboratory at The University of Pittsburgh Medical Center