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
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

Updated Guidance for Waste Management


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](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.

Division of Laboratory Systems

Excellent Laboratories, Outstanding Health
Number of Certificate of Waiver Laboratories: 2018-2021

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

Total: 260,047
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.
- 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/ncidod/dls/waivedtests](http://www.cdc.gov/ncidod/dls/waivedtests)

**READY? SET? TEST!**

- Get the right results.

http://www.cdc.gov/ncidod/dls/waivedtests

**To Test or Not to Test?**

Considerations for Waived Testing

[http://www.cdc.gov/ncidod/dls/waivedtests](http://www.cdc.gov/ncidod/dls/waivedtests)

**¿Preparado? ¿Listo? ¡Ya!**

Obtenga los resultados correctos.

- ¿Está seguro de que el paciente ha sido preparado para la prueba?
- Revisar el medio ambiente de trabajo y la calidad del sistema de la prueba.
- Mida el rendimiento de todos los procedimientos de laboratorio para la prueba.
- Siga las instrucciones para la evaluación de los materiales de la prueba.
- Informe al laboratorio de todos los resultados de las pruebas.

[http://www.cdc.gov/ncidod/dls/waivedtests](http://www.cdc.gov/ncidod/dls/waivedtests)

**¿Realizar pruebas o no realizar pruebas?**

Consideraciones para la realización de pruebas exentas

[http://www.cdc.gov/ncidod/dls/waivedtests](http://www.cdc.gov/ncidod/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
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
• 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

**Waived Testing Self-Assessment Checklist**
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

• COVID-19 Point-of-Care Batch Testing Tips

• Nasal Mid-Turbinate (NMT) Specimen Collection Steps

• Nasopharyngeal (NP) Specimen Collection Steps
Purpose

To support effective use of antigen tests for different testing situations

Tips for Rapid Antigen Tests

Laboratory Biosafety Guidelines for Handling and Processing Specimens

Purpose

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

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
Purpose

To provide guidance on the reporting requirements for laboratories

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

- CDC Information for Laboratories about COVID-19
- FDA COVID-19 and Medical Devices
- CMS Clinical Laboratory Improvement Amendments (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

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.

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.
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

COVID-19 Frequently Asked Questions

COVID-19 Updates

FDA Townhall Meetings

Independent Evaluations of COVID-19 Serological Tests
https://open.fda.gov/apis/device/covid19serology/
- **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**
SARS-CoV-2 Variants Update

John Barnes

CDC Laboratory and Testing Task Force for the COVID-19 Response
Thank You For Your Time!

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

This box being opened by an American Hero
#lovethelab
#labprofessionalsrock