

Clinical Laboratory COVID-19 Response Call

Monday, September 28th, 2020 at 3:00 PM EDT

- **Welcome**

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

- **CLSI Resources for COVID-19 Testing**

- James Nichols, Clinical Laboratory Standards Institute (CLSI)

- **CMS Update – Testing and Reporting Questions**

- Regina Van Brakle and Amy Zale, Centers for Medicare & Medicaid Services (CMS)

- **CDC COVID-19 Laboratory Task Force Update**

- Leslie Dauphin, CDC COVID-19 Response Laboratory Task Force

- **FDA Update**

- Tim Stenzel, U.S. Food and Drug Administration (FDA)

Schedule for Clinical Laboratory COVID-19 Response Calls

Due to the upcoming Columbus Day holiday, we will hold the next call on **Monday, October 19th** from **3:00 PM to 4:00 PM EDT.**



We Want to Hear From You!

Training and Workforce Development

Questions about education and training?

Contact LabTrainingNeeds@cdc.gov



COVID-19 Resources for Laboratories

- **Interim Guidance for Collecting, Handling, and Testing Clinical Specimens**
<https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html>
- **Diagnostic Tools and Virus**
<https://www.cdc.gov/coronavirus/2019-ncov/lab/tool-virus-requests.html>
- **Emergency Preparedness for Laboratory Personnel**
<https://emergency.cdc.gov/labissues/index.asp>
- **CDC's Laboratory Outreach Communication System (LOCS)**
<https://www.cdc.gov/csels/dls/locs/>
- **IVD Industry Connectivity Consortium**
<https://ivdconnectivity.org/livd/>
- **LOINC In-Vitro Diagnostic (LIVD) Test Code Mapping for SARS-CoV-2 Tests**
<https://www.cdc.gov/csels/dls/sars-cov-2-livd-codes.html>

More COVID-19 Resources for Laboratories

- **Frequently Asked Questions on Laboratory Data Reporting Guidance for COVID-19 Testing:**
<https://www.cdc.gov/coronavirus/2019-ncov/lab/reporting-lab-data.html#faqs>
- **Definitions for Diagnostic, Screening, and Surveillance Testing** (See "Testing Strategies for SARS-CoV-2" section):
<https://www.cdc.gov/coronavirus/2019-ncov/lab/faqs.html>
- **Additions to the [Frequently Asked Questions \(FAQs\) about COVID-19 for Laboratories](#)**
 - **False Negatives and False Positives from COVID-19 Testing**
<https://www.cdc.gov/coronavirus/2019-ncov/lab/faqs.html#Interpreting-Results-of-Diagnostic-Tests>
 - **Surveillance, Screening, and Diagnostic Testing for COVID-19**
<https://www.cdc.gov/coronavirus/2019-ncov/lab/faqs.html#Testing-Strategies-for-SARS-CoV-2>
- **Antigen Testing Guidelines**
<https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html>

New Codes for SARS-CoV-2 Antigen Testing

- **94558-4 (qualitative) – Tests for SARS-CoV-2 Antigen**
 - [Abbott BinaxNOW COVID-19 Antigen Card](#)
 - [BD Veritor System for Rapid Detection of SARS-CoV-2](#)
- **95209-3 (qualitative) – Tests for SARS-CoV and SARS-CoV-2 Antigens**
 - [LumiraDx SARS-CoV-2 Antigen Test](#)
 - [Sofia SARS Antigen FIA](#)

For more information, view the LOCS message sent on September 23, 2020:
https://www.cdc.gov/csels/dls/locs/2020/livd_codes_for_sars-cov-2_antigen_tests.html

New Preparedness Portal

<https://www.cdc.gov/csels/dls/preparedlabs>

CDC DIVISION OF LABORATORY SYSTEMS

FREE ONLINE COURSE

Packing and Shipping Dangerous Goods: What the Laboratory Staff Must Know

Initiatives and Partnerships
Find out about initiatives and partnerships to support laboratories in a response.

Outbreak & Response
Learn how CDC supports laboratories responding to disease outbreaks and pandemics such as COVID-19.

Tools & Resources
Get products, tools, and resources to prepare laboratory staff and systems.

Resources

- Learn about CDC's [Laboratory Outreach Communication System \(LOCS\)](#) and find recent messages
- Get participant info and more for CDC's regular [Clinical Laboratory COVID-19 Response](#) calls
- Find CDC's [Information for Laboratories about Coronavirus \(COVID-19\)](#)
- Stay informed with CDC's [Coronavirus \(COVID-19\)](#) website

Contact Us

Please email DLInquiries@cdc.gov and use "Laboratory Preparedness and Response" in the subject line.

LABORATORIES

Information for Laboratories about Coronavirus (COVID-19)

Updated Aug. 16, 2020 [Print](#)

[Using Antigen Tests](#)
Interim guidance for SARS-CoV-2 rapid antigen testing for clinicians and laboratory professionals. [Learn More](#)

Resources for Laboratories

Diagnostic Tests

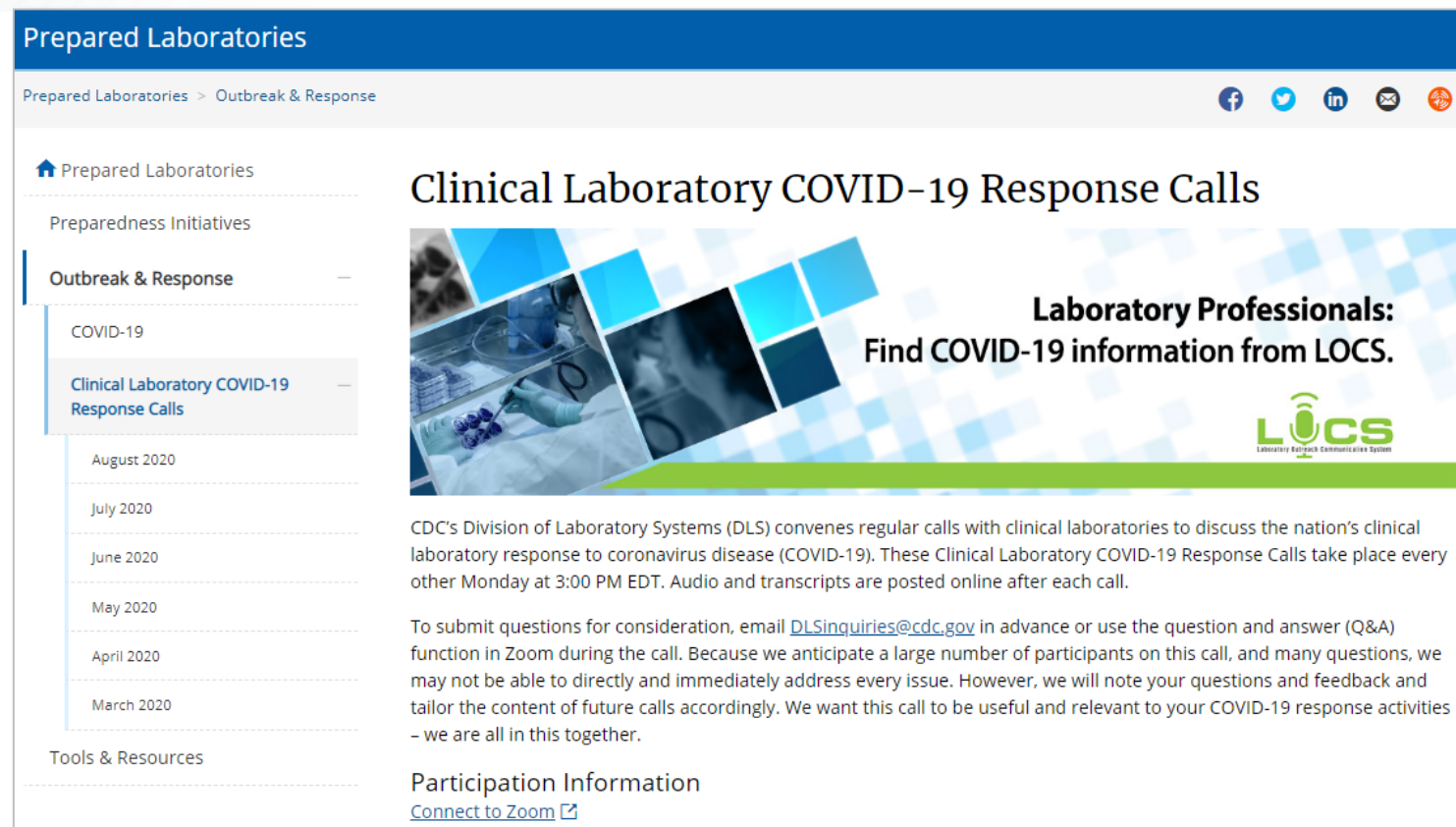
- [Multiplex Assay for Flu and COVID-19, Supplies, and Fact Sheets](#)
- [Diagnostic Test for COVID-19 Only, Supplies, and Fact Sheets](#)

Other Resources

- [Using Antigen Tests](#)
- [Pooling Procedures](#)

We've Moved!

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



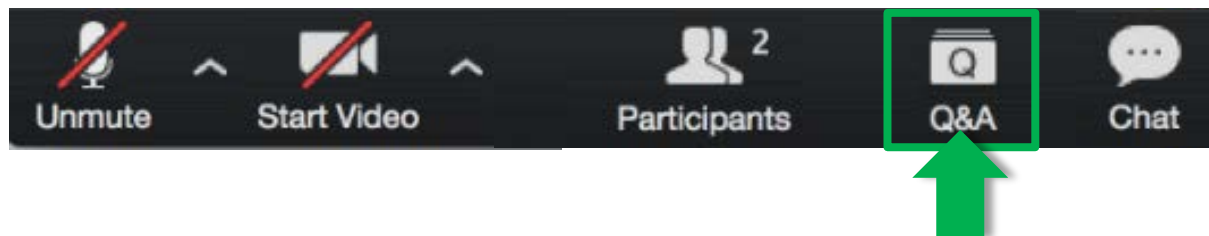
The screenshot shows the 'Prepared Laboratories' section of the CDC website. The main heading is 'Clinical Laboratory COVID-19 Response Calls'. Below the heading is a banner image with the text 'Laboratory Professionals: Find COVID-19 information from LOCS.' and the LOCS logo. The page content includes a paragraph about CDC's Division of Laboratory Systems (DLS) convening regular calls with clinical laboratories to discuss the nation's clinical laboratory response to COVID-19. It also provides instructions on how to submit questions for consideration via email or a Zoom function. A sidebar on the left lists navigation options: Prepared Laboratories, Preparedness Initiatives, Outbreak & Response (selected), COVID-19, Clinical Laboratory COVID-19 Response Calls (selected), and Tools & Resources. A list of dates from August 2020 to March 2020 is visible under the COVID-19 section. At the bottom, there is a link for 'Participation Information' and a 'Connect to Zoom' button.

CLCR call information, transcripts, & audio recordings now live on the new Preparedness Portal

How to Ask a Question

- **Using the 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



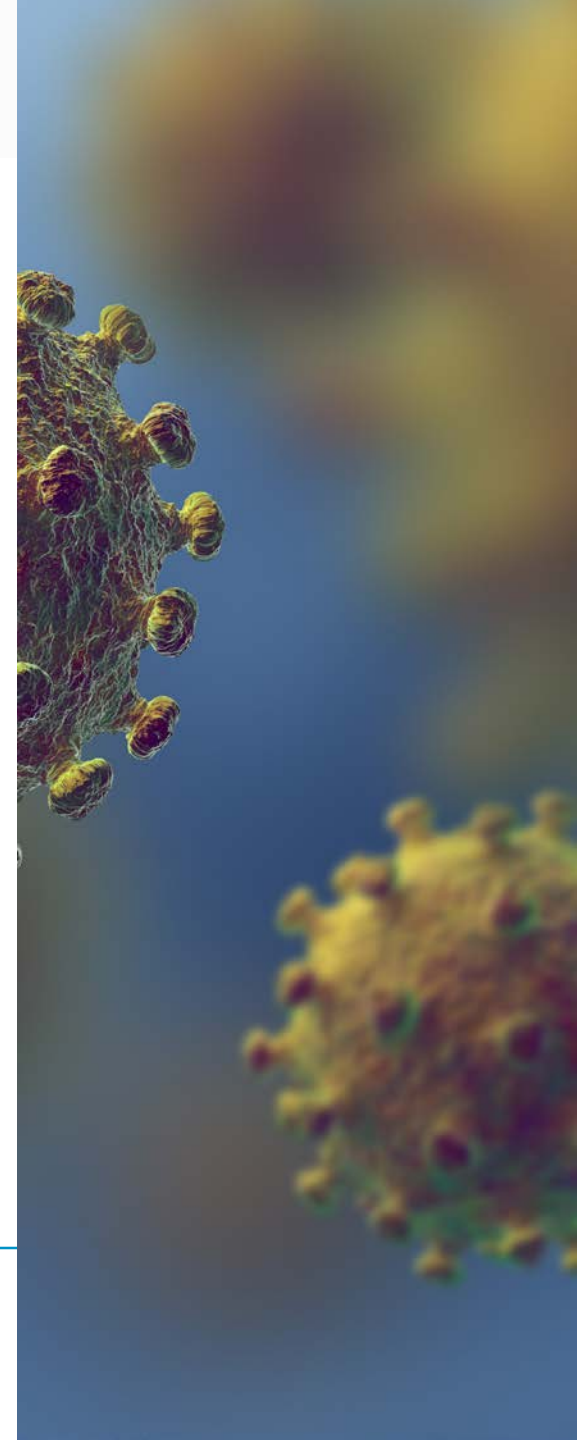
CLSI Resources for COVID-19 Testing

James H. Nichols, PhD, DABCC, FAACC
September 28, 2020

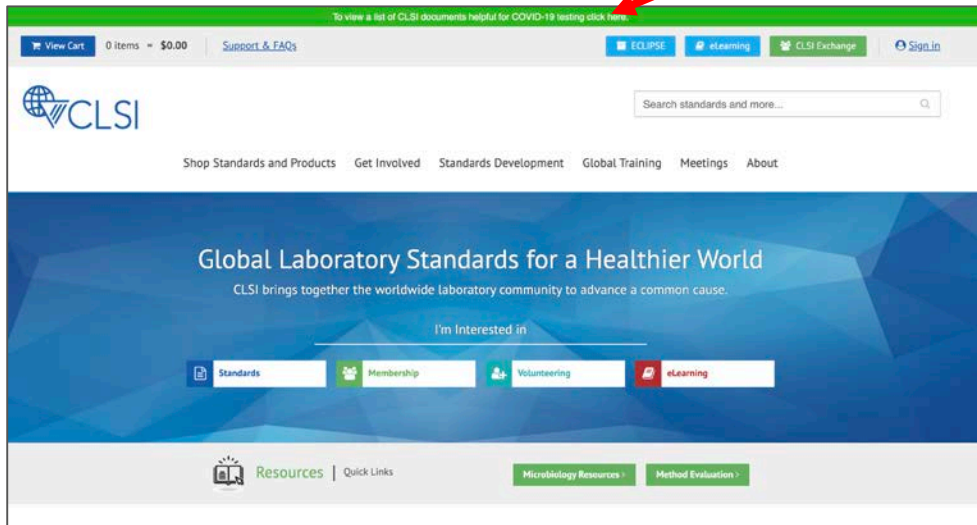
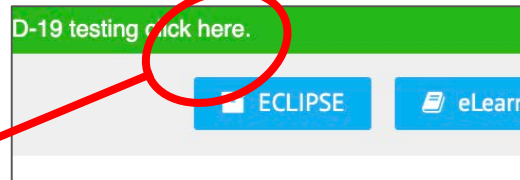


CLSI Introduction

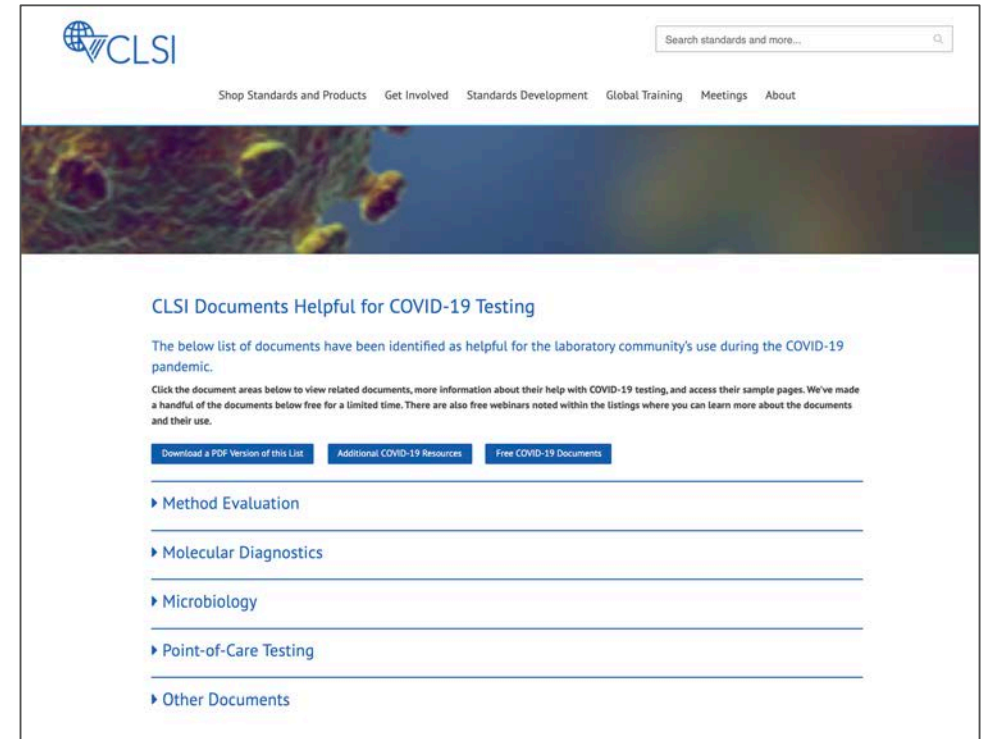
- Our focus is on the global medical laboratory community, including labs, manufacturers, and regulators.
- We develop, promote, and educate based on our consensus standards for laboratory testing.
- Our members include 1,400+ organizations and 400+ individuals from 75+ countries.
- Based on our motto “Fostering Excellence in Laboratory Medicine”, COVID-19 lab testing is right in our wheelhouse.



Access to Resources



www.clsi.org



CLSI eLearning Resources

- From CLSI's homepage, you can also click on "eLearning" to access free webinars for each of the COVID-19 related documents.
- These webinars present overviews of the contents of the documents, so that you can decide which are helpful for you.



Point-of-Care Testing Resources



POCT04—*Essential Tools for Implementation and Management of a Point-of-Care Testing Program*, helps laboratories ensure reliable results that are comparable to those obtained from medical laboratory instruments.

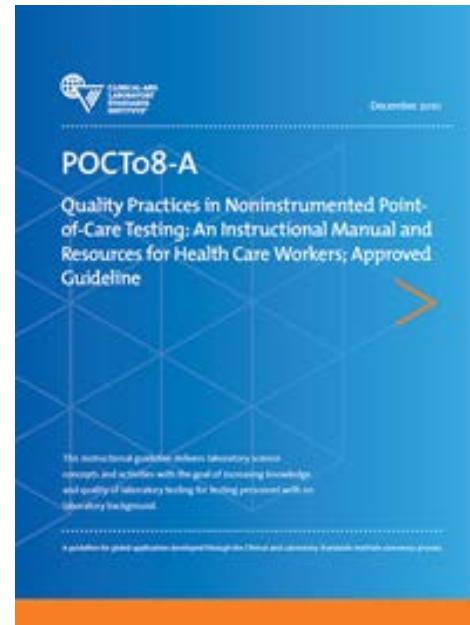


POCT07—*Quality Management Approaches to Reducing Errors at the Point-of-Care*, available for free, helps the laboratory implement a standardized error tracking system with the primary goals of reducing risk and increasing quality, while accumulating standardized data for benchmarking use.

Point-of-Care Testing Resources



POCT15—*Point-of-Care Testing for Infectious Diseases*, summarizes the current knowledge of rapid and point-of-care testing practices and methods for infectious diseases.



POCT08—*Quality Practices in Noninstrumented Point-of-Care Testing: An Instructional Manual and Resources for Health Care Workers*. This document includes laboratory science concepts and activities with the goal of increasing knowledge and quality of laboratory testing by personnel who do not have a laboratory background.

Thank you!



James H. Nichols, PhD, DABCC, FAACC
james.h.nichols@vumc.org



CMS Update – Testing and Reporting Questions

Regina Van Brakle and Amy Zale
Centers for Medicare and Medicaid Services (CMS)



Centers for Medicare and Medicaid Services (CMS)

- **CLIA Laboratory Guidance During COVID-19 Memo and FAQs**

<https://www.cms.gov/medicareprovider-enrollment-and-certificationsurvey/certificationgeninfo/policy-and-memos-states-and/clinical-laboratory-improvement-amendments-clia-laboratory-guidance-during-covid-19-public-health>

- **FAQs Only**

<https://www.cms.gov/medicare/quality-safety-oversight-general-information/coronavirus>

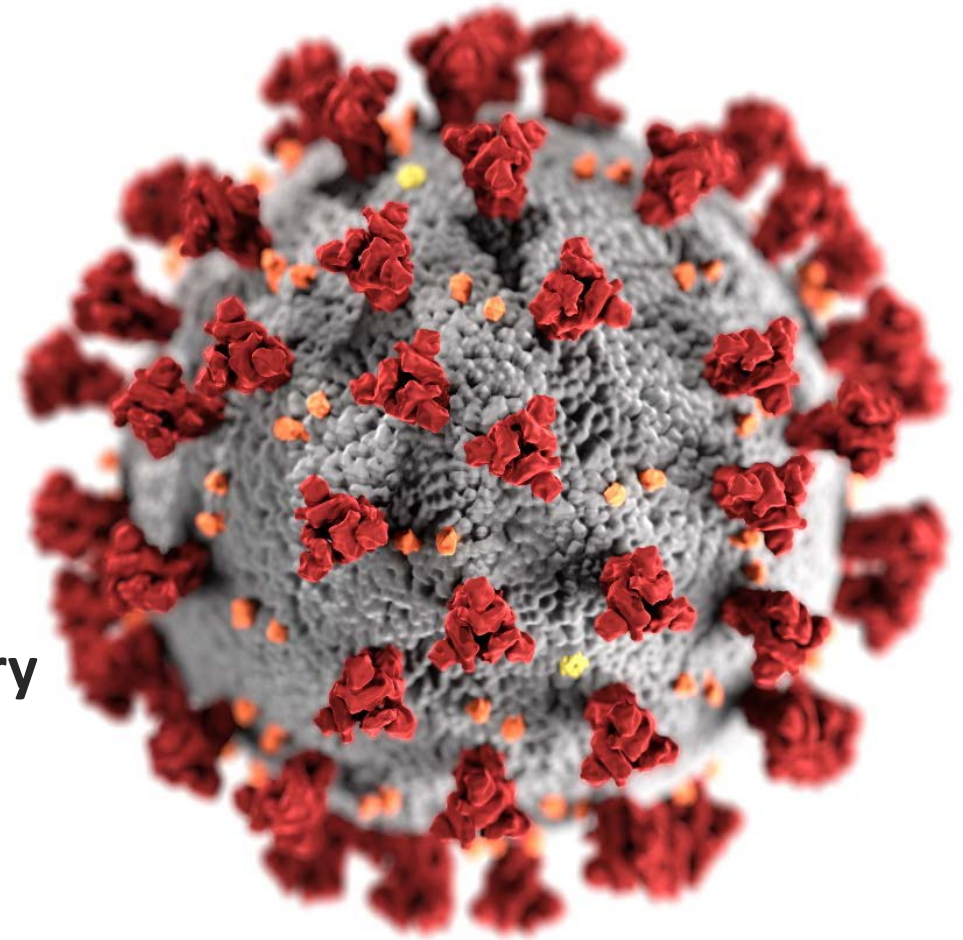


Priorities and Updates: Laboratory and Testing Task Force

Leslie Dauphin, PhD

Co-Lead, Laboratory and Testing Task Force

CDC COVID-19 Emergency Response



**CDC Division of Laboratory Systems Clinical Laboratory
COVID-19 Response Call**

September 28, 2020



cdc.gov/coronavirus

Overview

- Mission & Functions
- Priority Areas
- Updates and Ongoing Activities
- Plans and Next Steps



Laboratory and Testing Task Force

Mission:

- To increase laboratory testing capacity through work in CDC laboratories, support of clinical and public health laboratories (PHLs), and engagement with federal partners, commercial laboratories and laboratory organizations

Functions:

- Development of new laboratory tests and procedures
- Evaluation of laboratory reagents and instruments
- Development of guidance
- Support and technical assistance



Priority Areas

Laboratory Studies, Research and Development

- Assess rapid antigen test performance
- Evaluate different sample types with molecular diagnostic tests
- Validate new reagents and platforms

Laboratory Testing and Support

- Support labs with use of CDC-developed tests and reporting
- Manage and prioritize shipments of reagents from IRR
- Contribute to and assess performance of reference materials

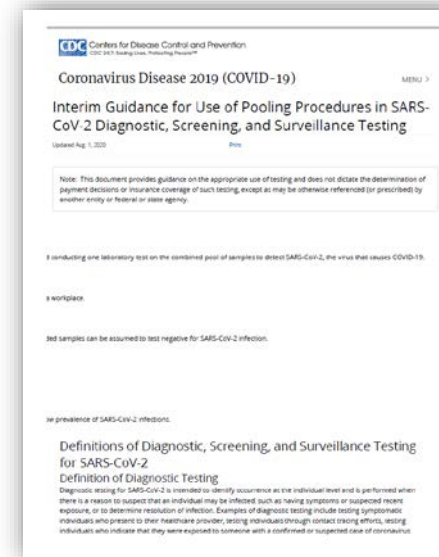
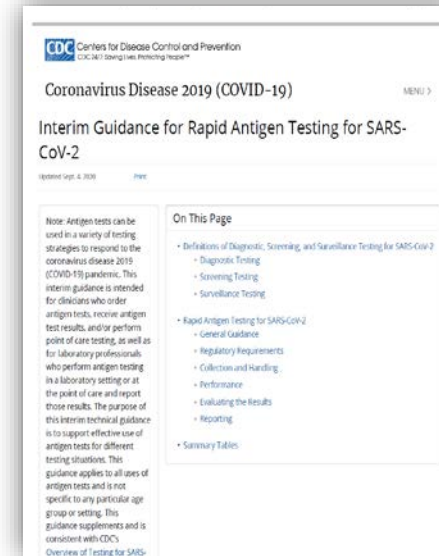
Guidance and Technical Support

- Provide technical assistance
- Develop guidance and frequently asked questions (FAQs) to support PHLs and clinical labs
- Support outbreak investigations and transmission studies



Updates and Ongoing Activities

- Evaluation of alternative procedures, instruments, platforms and reagents for diagnostic tests
- Development or updating of guidance and resources related to:
 - Laboratory testing
 - Biosafety
 - Point-of-care testing
- Ongoing testing, technical support and deployments to the field



Plans and Next Steps

- Collaborations and partnerships to learn about rapid antigen test performance in asymptomatic people
- Goal is to inform the best use of these tests in community settings



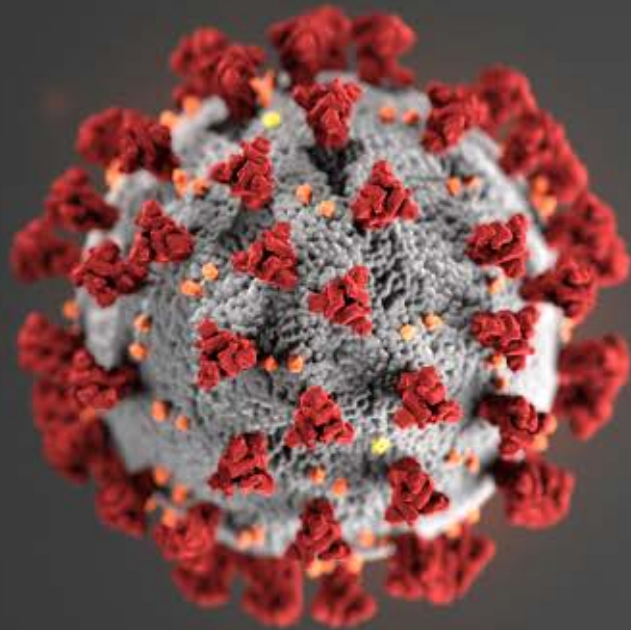
[Sofia 2 SARS Antigen FIA, Quidel; 5/8/20](#)



[BD Veritor System for Rapid Detection of SARS-CoV-2, BD; 7/2/20](#)



[BinaxNOW COVID-19 Ag CARD, Abbott; 8/26/20](#)



For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 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.



FDA Update

Tim Stenzel

U.S. Food and Drug Administration (FDA)



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

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/>

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 (*)

CDC Social Media



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

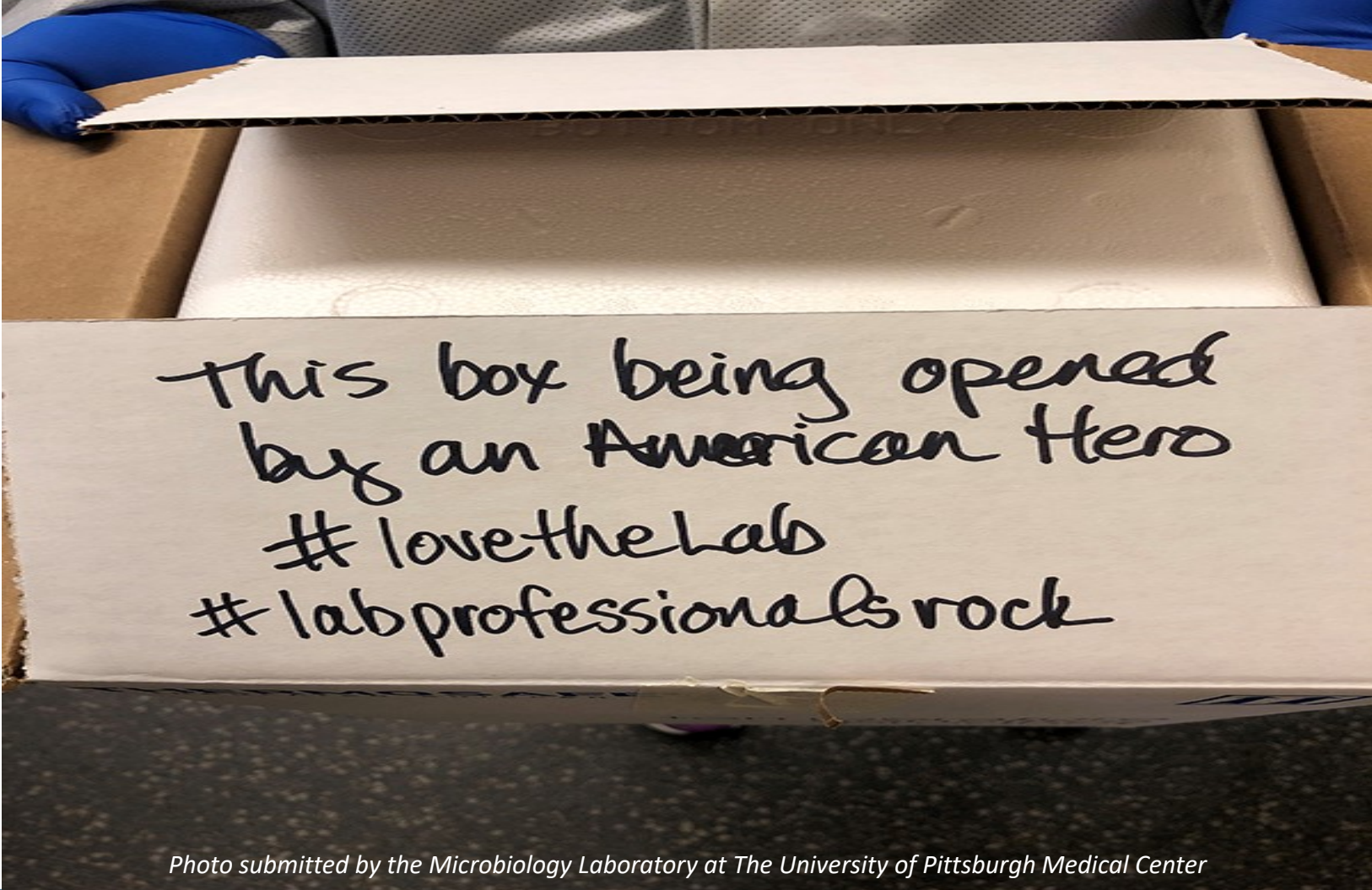


<https://twitter.com/cdcgov>



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

Thank You For Your Time!



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

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