Clinical Laboratory COVID-19 Response Call

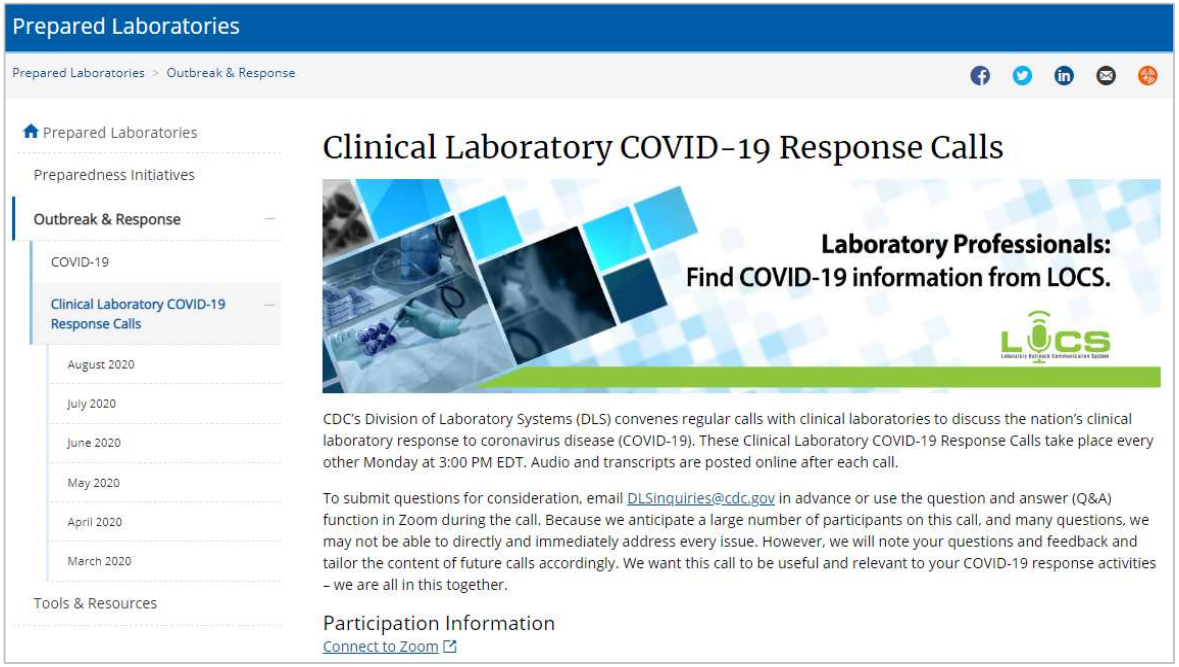
Monday, November 30th, 2020 at 3:00 PM ET

- **Welcome**
  - Jasmine Chaitram, CDC Division of Laboratory Systems (DLS)
- **CMS Reimbursement Update**
  - Sarah Harding and Sarah Shirey-Losso, Centers for Medicare and Medicaid Services (CMS)
- **Individualized Quality Control Plan (IQCP) Q&A**
  - Amy Zale, Centers for Medicare and Medicaid Services (CMS)
- **Antigen Tests - Lessons Learned**
  - Reynolds (Ren) Salerno, CDC Division of Laboratory Systems (DLS)
- **FDA Update**
  - Tim Stenzel, U.S. Food and Drug Administration (FDA)

CDC Preparedness Portal

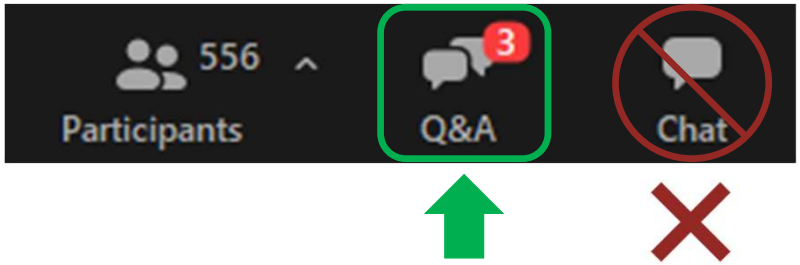
https://www.cdc.gov/csels/dls/preparedlabs/covid-19-clinical-calls.html

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



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

Schedule for Clinical Laboratory COVID-19 Response Calls

The next call will be on **Monday, December 14th**

from **3:00 PM to 4:00 PM ET**

2021 Proficiency Testing (PT) for SARS-CoV-2

Program	Website	Contact Information
Accutest	www.oneworldaccuracy.com	• support@1wa.org • (800) 665-2575
ACP Medical Laboratory Evaluation	www.acponline.org/mle	• mle@acponline.org • (800) 338-2746, ext. 4510
American Academy of Family Physicians	www.aafp.org/pt	• pt@aafp.org • (800) 274-7911
American Association of Bioanalysts Proficiency	www.aab-pts.org	• customerservice@aab-pts.org • (800) 234-5315
American Proficiency Institute	www.api-pt.com	• (800) 333-0958
College of American Pathologists	www.cap.org	• (800) 323-4040, option 1
Puerto Rico Proficiency Testing Service	*No website available*	• (787) 274-6827
Wisconsin State Laboratory of Hygiene	www.wslhpt.org	• ptservice@slh.wisc.edu • (800) 462-5261

COVID-19 Resources for Laboratories

- **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
- **IVD Industry Connectivity Consortium**
  https://ivdconnectivity.org/livd/
- **Antigen Testing Guidance**
  https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html
- **Frequently Asked Questions about COVID-19 for Laboratories**
  https://www.cdc.gov/coronavirus/2019-ncov/lab/faqs.html
- **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 Laboratory Outreach Communication System (LOCS)**
  https://www.cdc.gov/csels/dls/locs/

We Want to Hear From You!

Training and Workforce Development

Questions about education and training?

Contact LabTrainingNeeds@cdc.gov

Waste Management Guidance for SARS-CoV-2 Point-of-Care Testing

https://www.cdc.gov/csels/dls/locs/2020/waste_management_guidance_for_sars-cov-2_point-of-care_testing.html

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

LOCS
Laboratory Outreach Communication System

Audience: Clinical Laboratory Professionals

Level: Laboratory Advisory

When disposing of waste generated from SARS-CoV-2 point-of-care testing, laboratories and testing sites should treat all waste from suspected or confirmed COVID-19 patient specimens and kit components as biohazardous waste. Since waste regulations vary from state to state, disposal must comply with all applicable local, regional, national, and international regulations. Personnel should follow guidance according to federal, state, local, tribal, and territorial regulatory requirements.

Facilities should also perform a site-specific and activity-specific risk assessment to identify and mitigate risks. Risk assessments and mitigation measures depend on several factors:

- The procedures performed
- Identification of the hazards involved in the process and/or procedures
- The competency level of the personnel who perform the procedures
- The laboratory equipment and facility
- The resources available

Follow Standard Precautions when handling clinical specimens, all of which may contain potentially infectious materials. Follow routine laboratory practices and procedures for decontamination of work surfaces and management of laboratory waste.

CMS Reimbursement Update

Sarah Harding and **Sarah Shirey-Losso**
Centers for Medicare and Medicaid Services (CMS)

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

Centers for Medicare and Medicaid Services (CMS)

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

  https://www.cms.gov/medicareprovider-enrollment-and-certificationsurveycertificationgeninfopolicy-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

Individualized Quality Control Plan (IQCP) Q&A

Amy Zale
Centers for Medicare and Medicaid Services (CMS)

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

COVID-19 Antigen Tests – Lessons Learned

Reynolds (Ren) Salerno, PhD

Director, Division of Laboratory Systems

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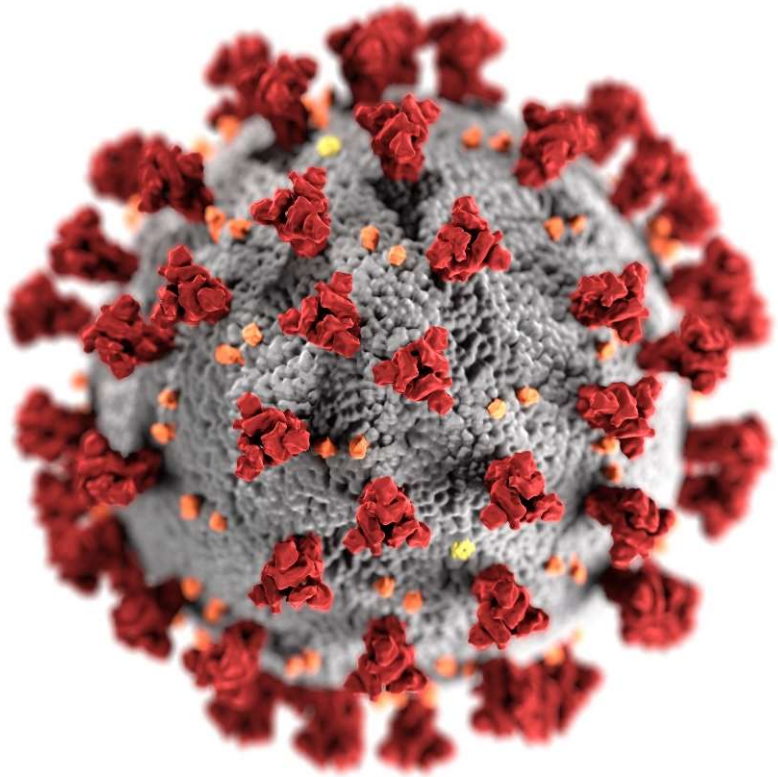
November 30, 2020



cdc.gov/coronavirus

Antigen Tests - Lessons Learned

Quidel Sofia 2 SARS Antigen FIA & Flu + SARS Antigen FIA

BD Veritor System for Rapid Detection of SARS-CoV-2

How to avoid process errors

- Change gloves between tests to avoid cross-contamination
- Don’t use viral transport media
- Don’t use expired reagents or damaged test cassettes/devices
- Keep track of and follow proper timing for reading the results when testing multiple specimens at the same time
- Use the test cassette/device within specified time after opening
- Keep the test device in a horizontal position when in use
- Results must be interpreted within specified timeframes

Antigen Tests - Lessons Learned

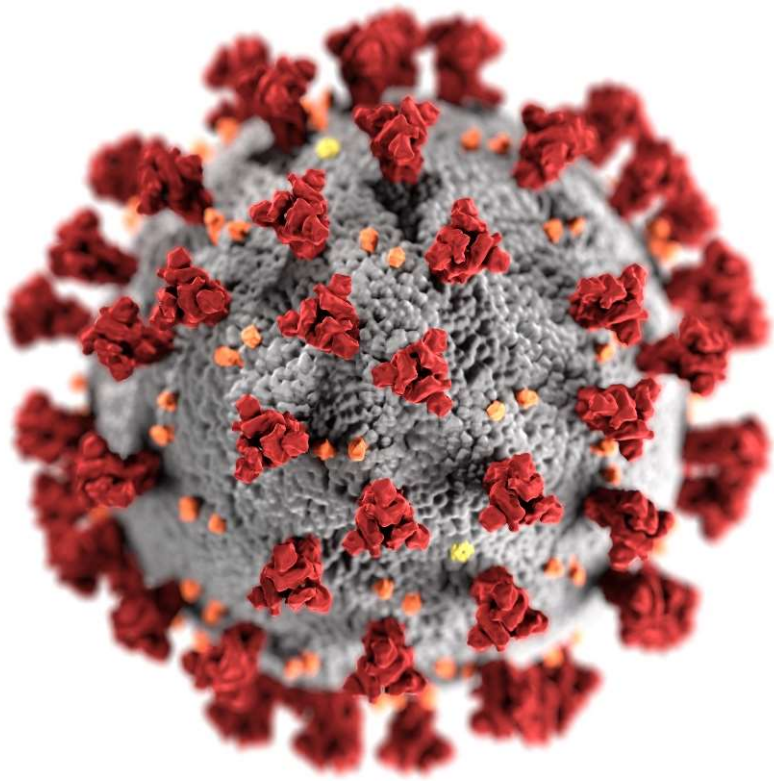
BinaxNOW COVID-19 Ag Card

How to avoid process errors

- Change gloves between tests to avoid cross-contamination
- Test specimens within 1 hour of collection
- Use only the correct volume of extraction reagent, no more, no less
- Use the test kit reagents/cards only when they are at room temperature
- Keep the card in a horizontal position when in use
- Read test results promptly at 15 minutes after the swab is inserted. Do not read results before 15 minutes or after 30 minutes

Next Steps

- Quidel Sofia, BD Veritor, and Abbott BinaxNOW lessons learned will be shared with
  - CDC task forces engaged in antigen test studies
  - External partners such as FDA and manufacturers
- Lessons learned are being converted to infographics
  - To be added on the Guidance for SARS-CoV-2 Point-of-Care Testing web page
- Additional communication about the infographics will be provided on partner calls and Laboratory Outreach Communication System (LOCS) messages



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/

FDA U.S. FOOD & DRUG ADMINISTRATION

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

CDC Social Media

https://www.facebook.com/CDC

https://twitter.com/cdcgov

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

Thank You For Your Time!

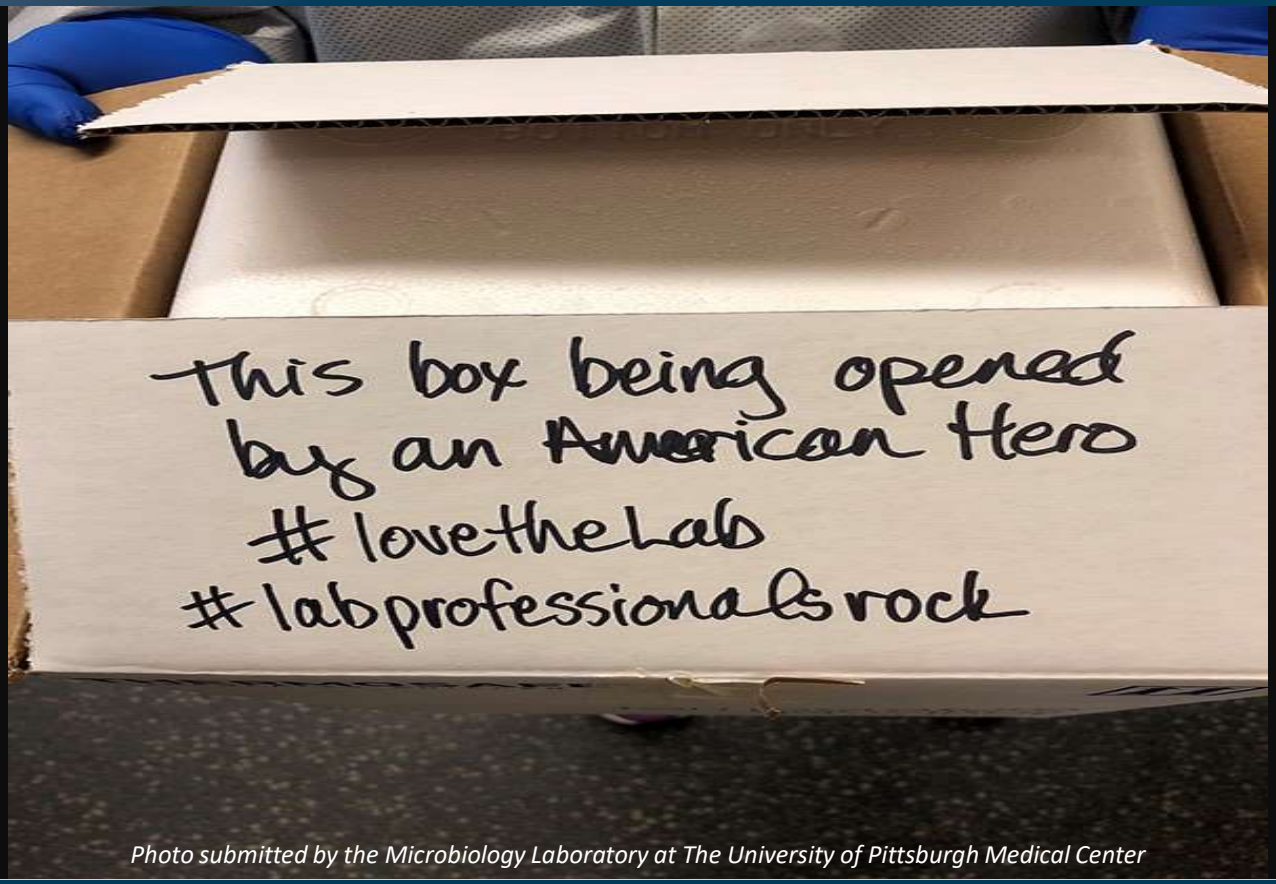


Photo submitted by the Microbiology Laboratory at The University of Pittsburgh Medical Center