Clinical Laboratory COVID-19 Response Call Monday, December 14th, 2020 at 3:00 PM ET

Welcome

- Jasmine Chaitram, CDC Division of Laboratory Systems (DLS)
- Expanded Screening Testing
 - Peggy Honein, State, Tribal, Local, and Territorial Support, CDC COVID-19 Emergency Response
- BinaxNOW™ COVID-19 Rapid Antigen Test Utilization Rapid Query
 - Marcus Plescia, Association of State and Territorial Health Officials (ASTHO)
- COVID-19 Diagnostic Data Project
 - Kristen Honey, CDC Office of the Assistant Secretary of Health (OASH)
 - Nick Ipiotis, CDC Office of the Chief Information Officer (OCIO)
 - John Wiley, Data Robot
- Managing Laboratory Supply Shortage Issues
 - RADM Michael Iademarco, Joint Coordination Cell (JCC) Testing and Diagnostics Workgroup
- CMS Update Enforcement Discretion Guidance
 - Amy Zale, Centers for Medicare and Medicaid Services (CMS)

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



New Point-of-Care Testing Guidance

The new Help with Performing Point-of-Care Tests section features:

- CDC educational materials
- Training resources from test manufacturers
- "Lessons Learned" documents designed to support healthcare personnel who perform point-of-care (POC) testing for SARS-CoV-2

LOCS message:

CDC Offers Help with Performing Point-of-Care Tests for SARS-CoV-2

COVID-19 (Coronavirus Disease)







Help with Performing Point-of-Care Tests

CDC has free training and tools to help you learn the basics about performing POC testing. The companies that make the tests and testing systems also have free training resources designed to help you use the machines. Find links in this section to resources and training that will help you get ready to test.

CDC Educational Materials for Point of Care Testing

CDC has resources to help you understand "waived tests," a category of tests that many COVID-19 POC tests fall into. Some of our free educational and training resources include:

- Ready? Set? Test!, an online training course that explains the waived testing process.
- A Ready? Set? Test! booklet Declarations-left that contains tips, reminders, and resources along with forms and examples for use in your testing site (also available in Spanish 12).
- A Self-Assessment Checklist Note of the power of the powe
- For general batch testing tips, view the COVID-19 Point-of-Care Batch Testing Tips Infographic [2] (2 MB, 2 Pages).

Visit CDC's Waived Tests page for more information and resources.

Training Resources from Test Manufacturers for COVID-19 POC Testing

Below are links to trainings developed by manufacturers of COVID-19 testing devices. Linking to these resources does not constitute an endorsement by the Department of Health and Human Services (HHS) or any of its employees of the sponsors or the information and products presented on the site.

This list of tests and associated resources will be updated as more manufacturer-specific training links become available.

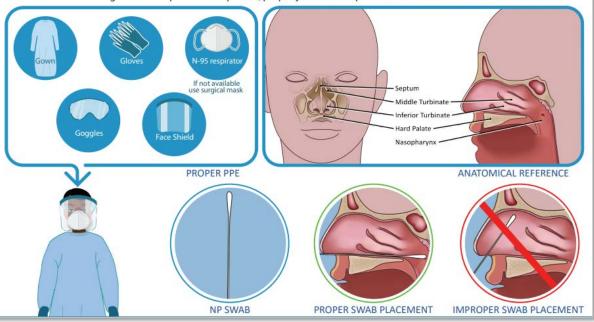
New Infographics

NASOPHARYNGEAL (NP) SPECIMEN COLLECTION STEPS



GENERAL GUIDANCE:

- Ensure that recommended personal protective equipment (PPE) is worn when collecting specimens. This includes gloves, a gown, eye protection (face shield or goggles), and an N-95 or higher-level respirator (or surgical mask if a respirator is not available).
- Gloves must be changed to a new pair for each patient; properly remove old pair and discard into a biohazard waste container.



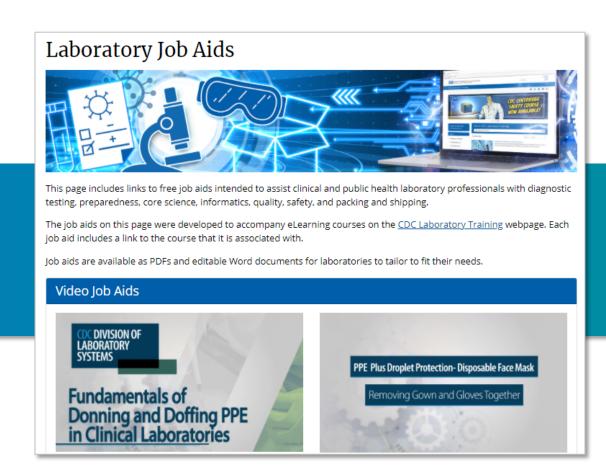
- Nasopharyngeal Specimen Collection Steps:
 - https://www.cdc.gov/coronavirus/2019ncov/downloads/lab/NP Specimen Collection I nfographic FINAL 508.pdf
- Nasal Mid-Turbinate Specimen Collection Steps:
 - https://www.cdc.gov/coronavirus/2019ncov/downloads/lab/NMT Specimen Collection Infographic FINAL 508.pdf
- Find these infographics on the Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens for COVID-19 Web page:
 - https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html

New PPE Videos

CDC recently released three new video job aids to provide clinical laboratory professionals with guidance regarding the proper use of personal protective equipment (PPE):

- Fundamentals of Donning and Doffing PPE
- PPE Plus Droplet Protection Disposable Face Mask
- PPE Plus Droplet Protection Disposable Face Mask (Removing Gown and Gloves Together)

Find these on the Laboratory Job Aids Web page: https://www.cdc.gov/labtraining/jobaids.html



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/2019nCoV/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 <u>LabTrainingNeeds@cdc.gov</u>



Center for Surveillance, Epidemiology, and Laboratory Services

Expanded Screening Testing Guidance

Peggy Honein

State, Tribal, Local, and Territorial Support, CDC COVID-19 Emergency Response

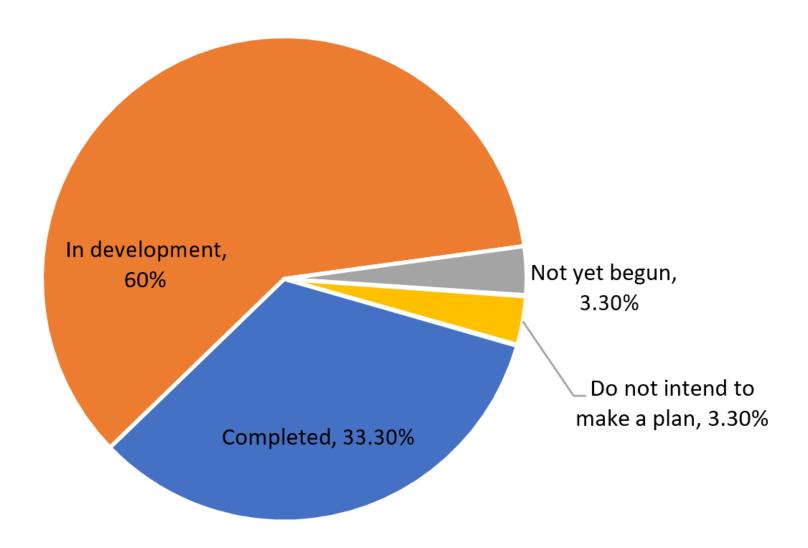


These slides were shared during the call, but are not available for public distribution.

BinaxNOW™ COVID-19 Rapid Antigen Test Utilization Rapid Query

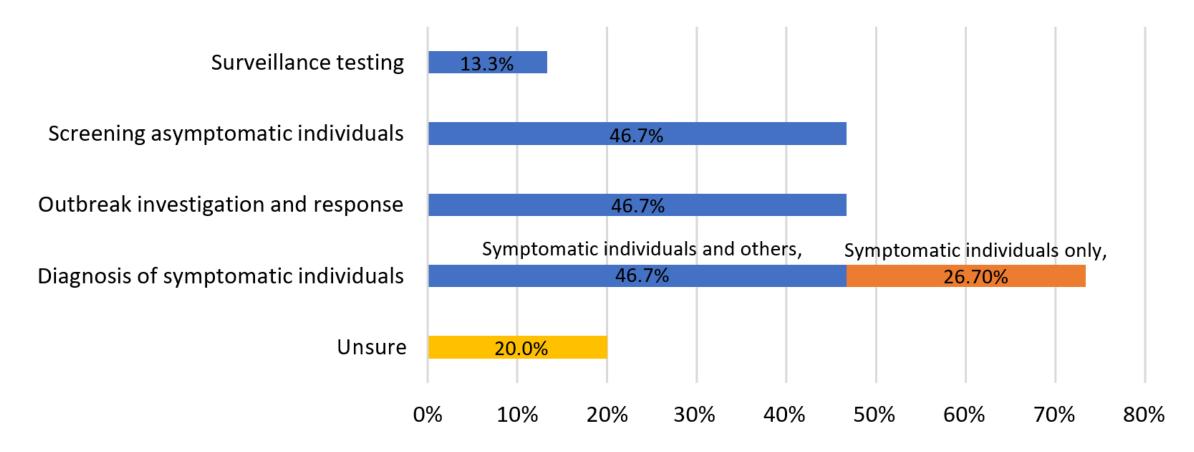
Marcus Plescia MD MPH
Chief Medical Officer
Association of State and Territorial Health Officials
12/14/2020

Planning Phase (n=30)



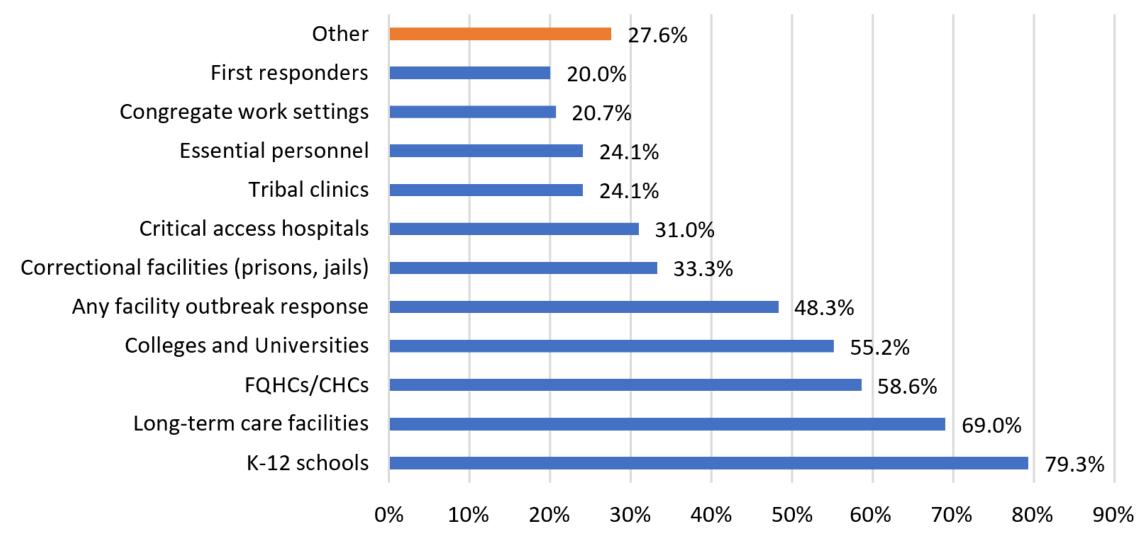


Use of rapid antigen tests (n=30)





Targeting populations (n=29)

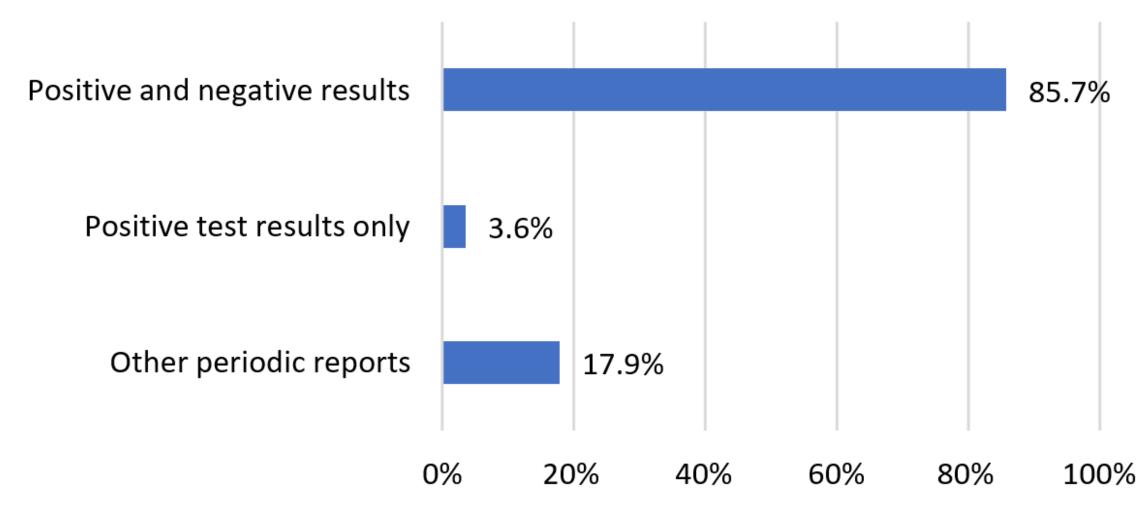




Facility/population	Average ranking
K-12 Schools	2.39
Long-term care facilities	2.53
Colleges and Universities	3.00
FQHCs/CHCs	3.36
Congregate work settings	4.33
Any facility outbreak response	4.50
Critical access hospitals	4.83
Tribal clinics	5.20
Essential personnel	5.38



Reporting requirements (n=28)





Center for Surveillance, Epidemiology, and Laboratory Services

COVID-19 Diagnostic Data Project

Kristen Honey, CDC Office of the Assistant Secretary of Health (OASH)

Nick Ipiotis, CDC Office of the CIO (OCIO)

John Wiley, Data Robot



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Center for Surveillance, Epidemiology, and Laboratory Services

Managing Laboratory Supply Shortage Issues

Dr. Michael lademarco
CDC COVID-19 Testing and Diagnostics Task Force



Center for Surveillance, Epidemiology, and Laboratory Services

CMS Update – Enforcement Discretion Guidance

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-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



CDC Social Media



https://www.facebook.com/CDC

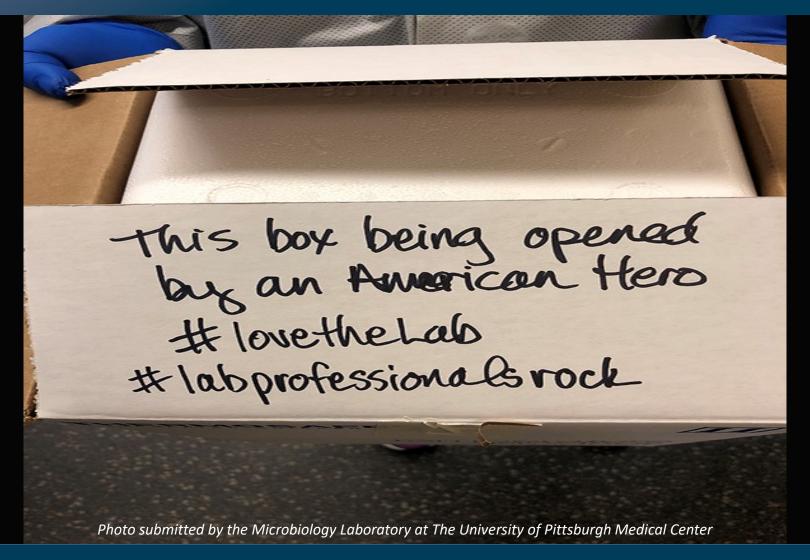


https://twitter.com/cdcgov



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

Thank You For Your Time!



Division of Laboratory Systems Excellent Laboratories, Outstanding Health

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