

# Clinical Laboratory COVID-19 Response Call

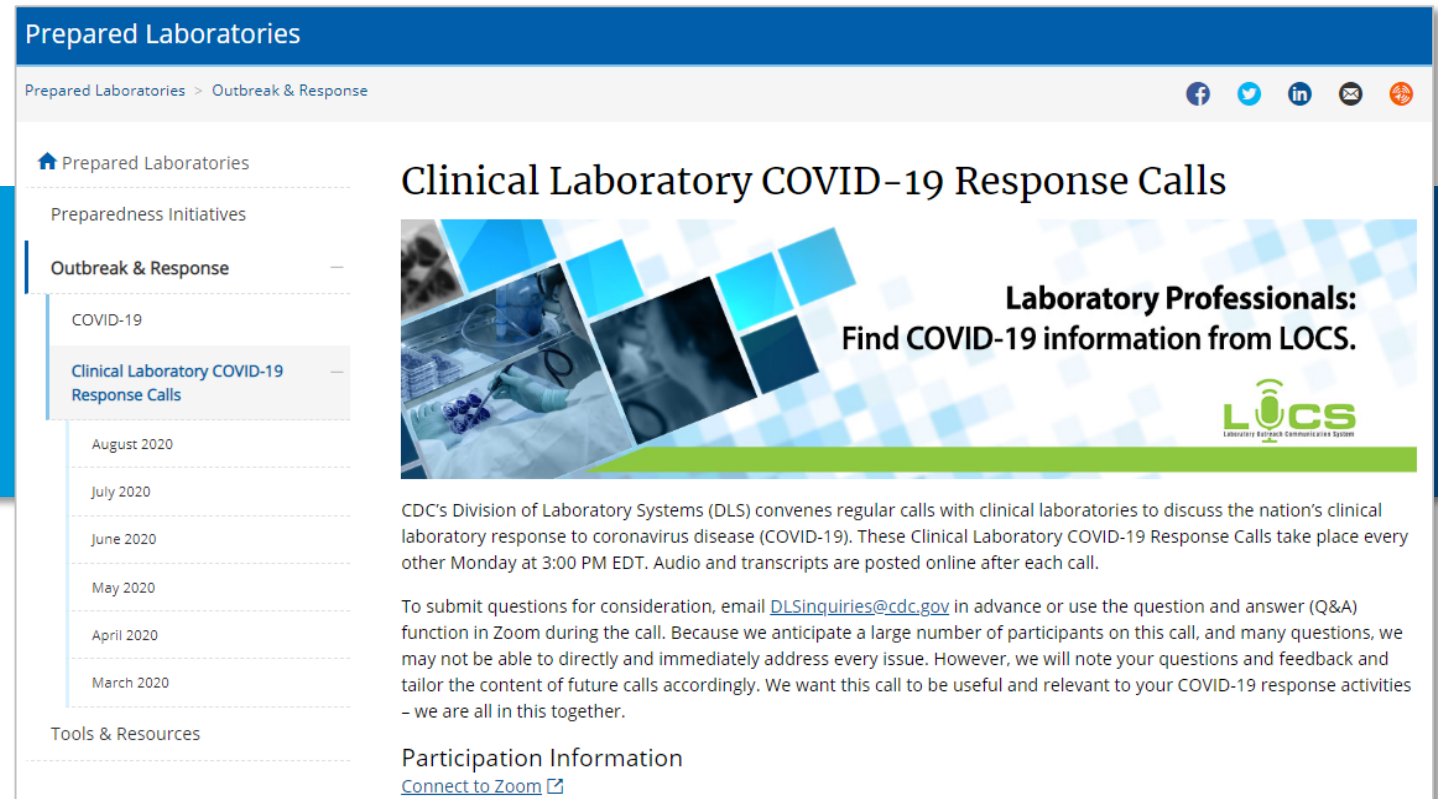
Monday, December 14<sup>th</sup>, 2020 at 3:00 PM ET

- **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



The screenshot shows the 'Prepared Laboratories' section of the CDC website. The left sidebar contains a navigation menu with 'Prepared Laboratories' selected, followed by 'Preparedness Initiatives', 'Outbreak & Response' (which is expanded to show 'COVID-19', 'Clinical Laboratory COVID-19 Response Calls', and a list of months from August 2020 to March 2020), and 'Tools & Resources'. The main content area is titled 'Clinical Laboratory COVID-19 Response Calls' and features a banner with the text 'Laboratory Professionals: Find COVID-19 information from LOCS.' and the LOCS logo. Below the banner, a paragraph explains that CDC's Division of Laboratory Systems (DLS) convenes 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 Zoom. At the bottom, there is a 'Participation Information' section with a link to 'Connect to Zoom'.

Prepared Laboratories

Prepared Laboratories > Outbreak & Response

Prepared Laboratories

Preparedness Initiatives

Outbreak & Response

COVID-19

Clinical Laboratory COVID-19 Response Calls

August 2020

July 2020

June 2020

May 2020

April 2020

March 2020

Tools & Resources

## Clinical Laboratory COVID-19 Response Calls

**Laboratory Professionals:**  
Find COVID-19 information from LOCS.

LOCS  
Laboratory Outreach Communications System

CDC's Division of Laboratory Systems (DLS) convenes regular calls with clinical laboratories to discuss the nation's clinical laboratory response to coronavirus disease (COVID-19). These Clinical Laboratory COVID-19 Response Calls take place every other Monday at 3:00 PM EDT. Audio and transcripts are posted online after each call.

To submit questions for consideration, email [DLInquiries@cdc.gov](mailto:DLInquiries@cdc.gov) in advance or use the question and answer (Q&A) function in Zoom during the call. Because we anticipate a large number of participants on this call, and many questions, we may not be able to directly and immediately address every issue. However, we will note your questions and feedback and tailor the content of future calls accordingly. We want this call to be useful and relevant to your COVID-19 response activities – we are all in this together.

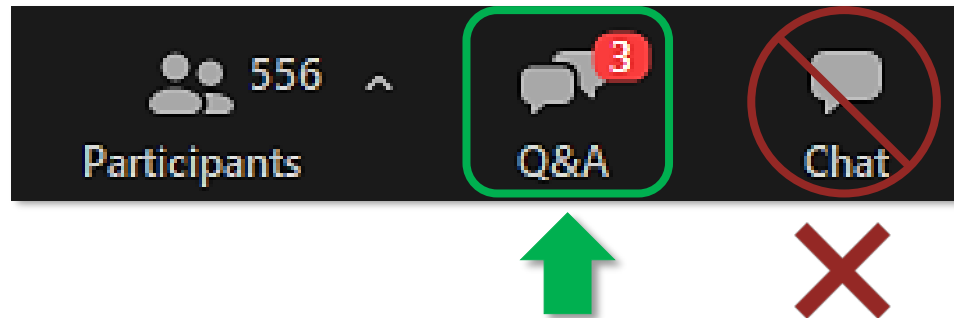
Participation Information

[Connect to Zoom](#)

# 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

# Schedule for Clinical Laboratory COVID-19 Response Calls

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The next call will be on **Monday, December 28<sup>th</sup>**  
from **3:00 PM to 4:00 PM ET**

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# 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)

CASES ARE RISING  
ACT NOW!

  
WEAR A MASK   STAY 6 FEET APART   AVOID CROWDS

## 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](#) that contains tips, reminders, and resources along with forms and examples for use in your testing site (also available in [Spanish](#) ).
- A [Self-Assessment Checklist](#) you can use to help assure good testing practices and provide reliable, high-quality test results.
- For general batch testing tips, view the [COVID-19 Point-of-Care Batch Testing Tips Infographic](#) [2 MB, 2 Pages].

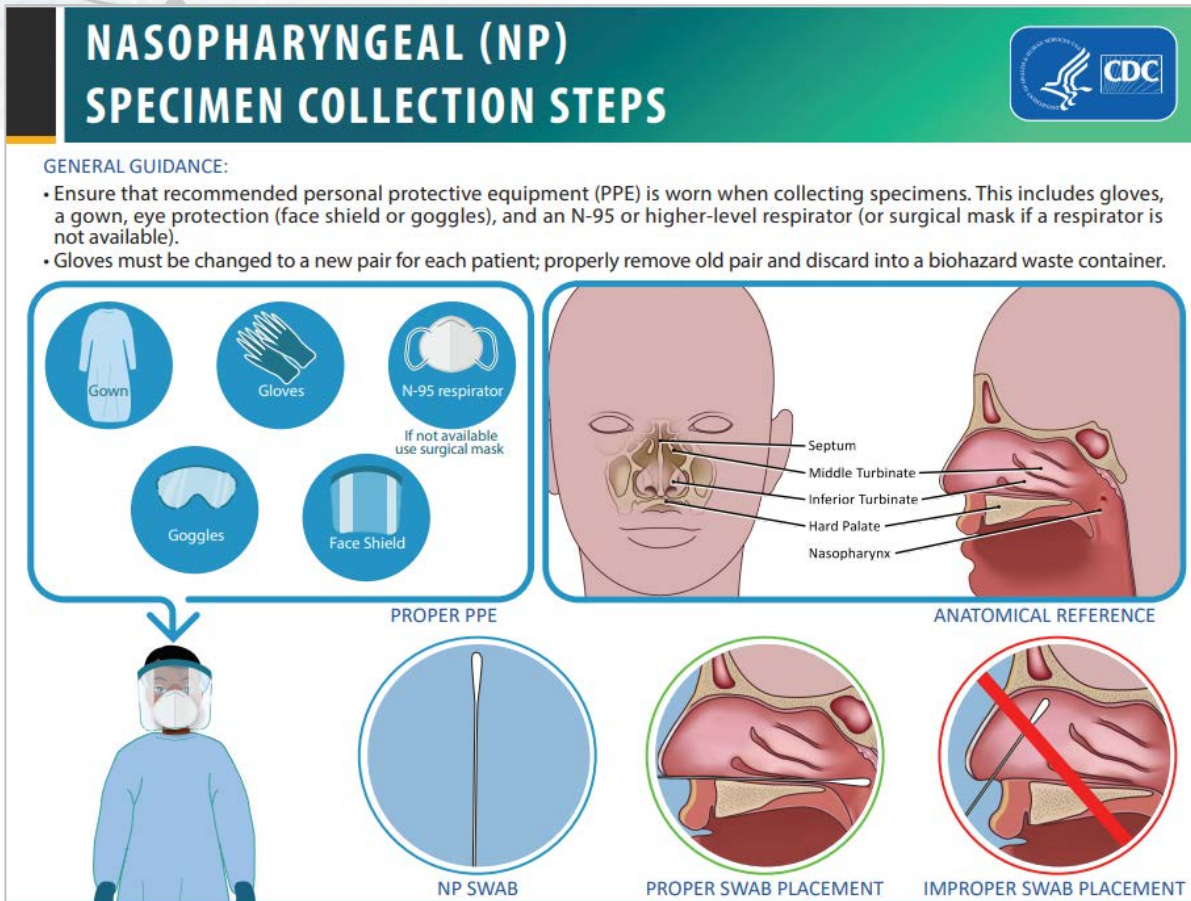
Visit CDC’s [Waived Tests](#) page for more information and resources.

### 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 Specimen Collection Steps:**  
[https://www.cdc.gov/coronavirus/2019-ncov/downloads/lab/NP\\_Specimen\\_Collection\\_Infographic\\_FINAL\\_508.pdf](https://www.cdc.gov/coronavirus/2019-ncov/downloads/lab/NP_Specimen_Collection_Infographic_FINAL_508.pdf)
- **Nasal Mid-Turbinate Specimen Collection Steps:**  
[https://www.cdc.gov/coronavirus/2019-ncov/downloads/lab/NMT\\_Specimen\\_Collection\\_Infographic\\_FINAL\\_508.pdf](https://www.cdc.gov/coronavirus/2019-ncov/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>

## Laboratory Job Aids



This page includes links to free job aids intended to assist clinical and public health laboratory professionals with diagnostic testing, preparedness, core science, informatics, quality, safety, and packing and shipping.

The job aids on this page were developed to accompany eLearning courses on the [CDC Laboratory Training](#) webpage. Each job aid includes a link to the course that it is associated with.

Job aids are available as PDFs and editable Word documents for laboratories to tailor to fit their needs.

### Video Job Aids



# 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](mailto:LabTrainingNeeds@cdc.gov)



# Expanded Screening Testing Guidance

**Peggy Honein**

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



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



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

# BinaxNOW™ COVID-19 Rapid Antigen Test Utilization Rapid Query

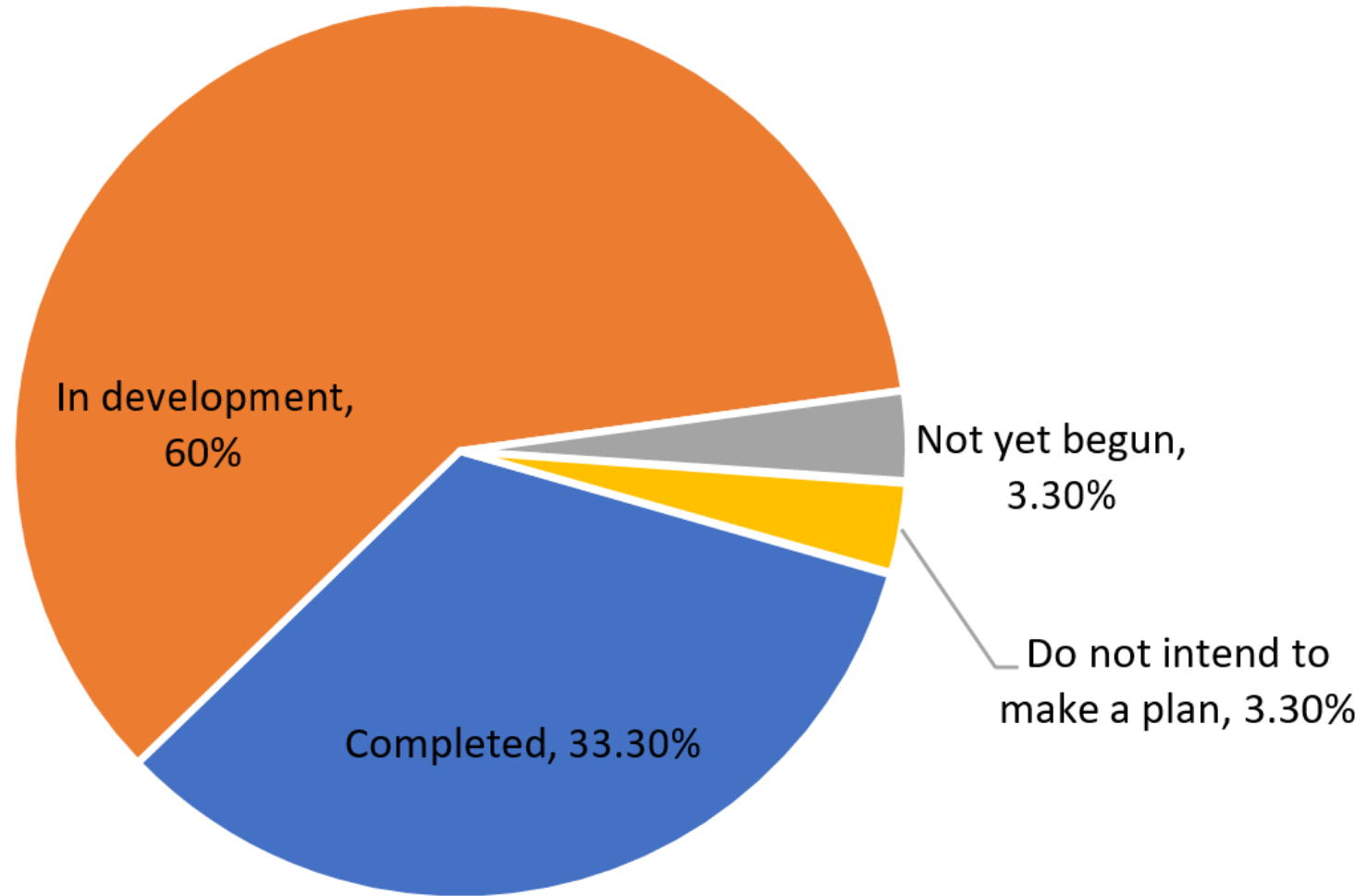
Marcus Plescia MD MPH

Chief Medical Officer

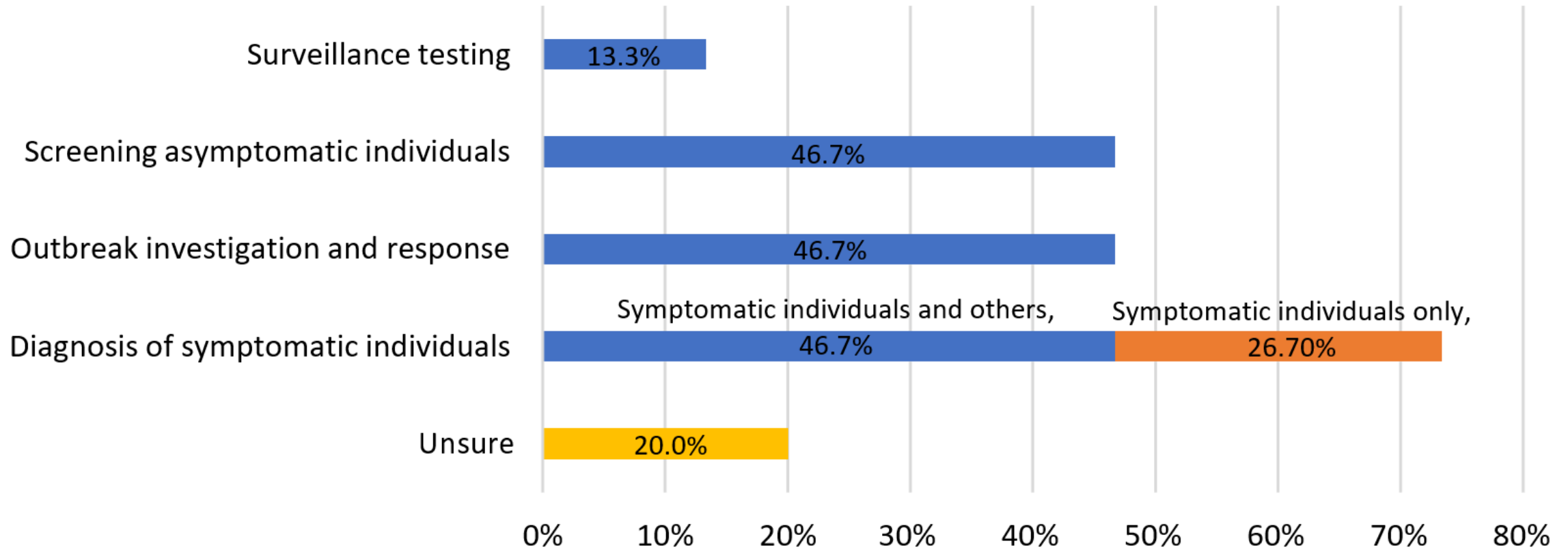
Association of State and Territorial Health Officials

12/14/2020

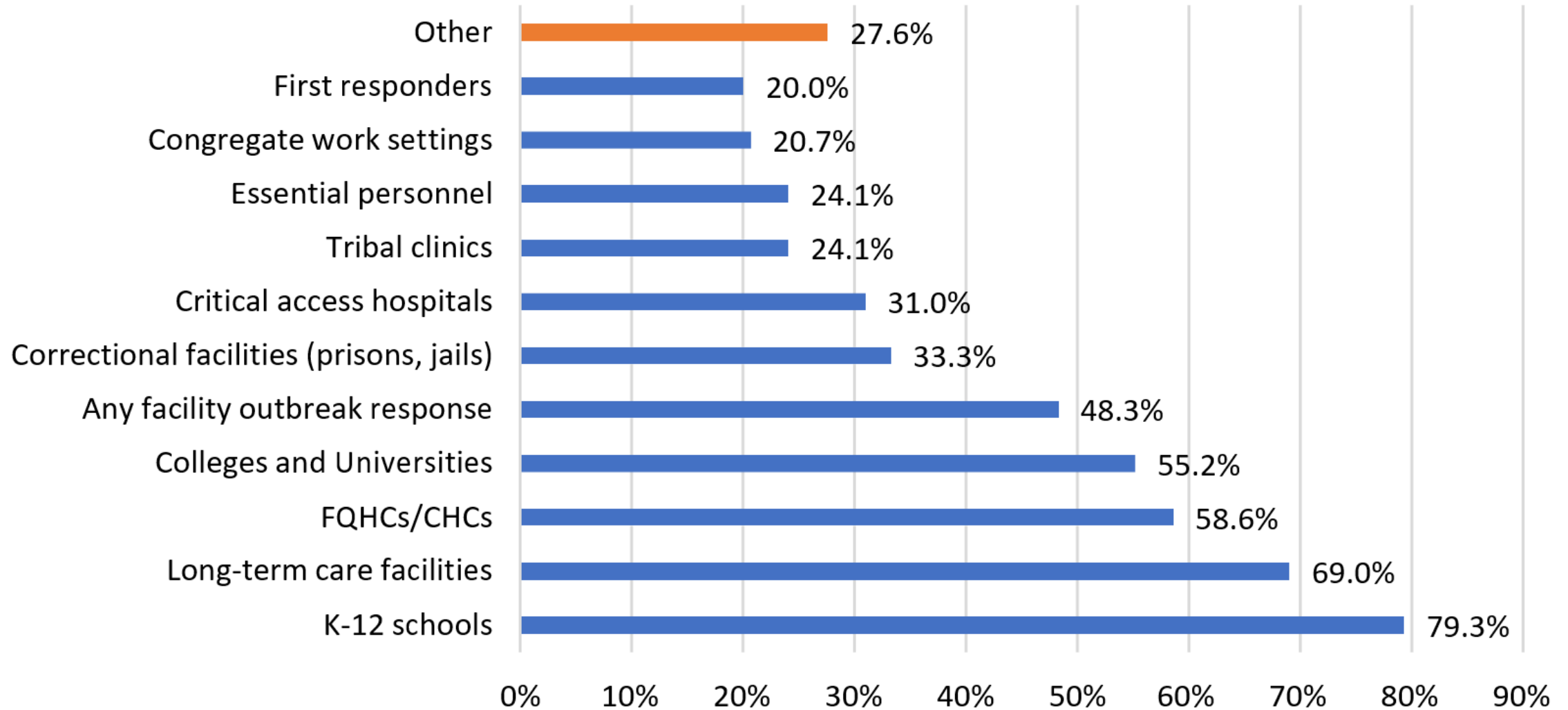
## Planning Phase (n=30)



## Use of rapid antigen tests (n=30)

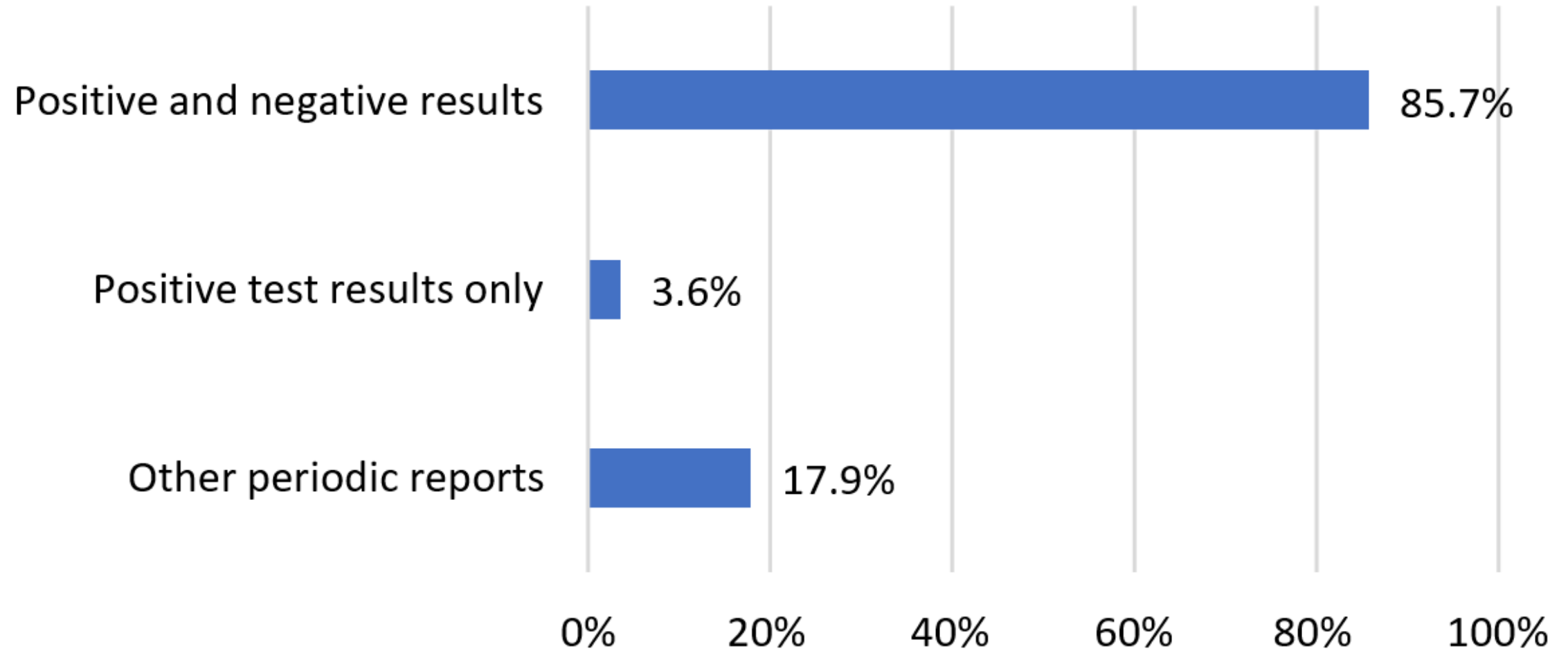


## Targeting populations (n=29)



<b>Facility/population</b>	<b>Average ranking</b>
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)





## OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

# Clinical Laboratory COVID-19 Response Call December 14, 2020

## COVID-19 Diagnostic Data Project

Leads:

- Kristen Honey, Office of the Assistant Secretary of Health
- Nick Ipiotis, Office of the CIO
- John Willey, DataRobot

Executive Sponsors: ADM Brett Giroir, HHS ASH; Perryn Ashmore HHS CIO (Acting)

Project Lead: Kristen Honey, Senior Advisor to the ASH, [Kristen.Honey@hhs.gov](mailto:Kristen.Honey@hhs.gov)

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## Hundreds of millions of point-of-care rapid tests being distributed across United States...

- 50mm+ antigen tests have been allocated by HHS to states, with 100M more to be distributed...
- And a variety of at-home tests will soon become available and dominate the testing landscape

## ...however a majority of the tests distributed do not have test results flowing to HHS

- Some states send no antigen results, others just send positive results
- Point of care test locations are finding that the burden of reporting is too high
- The lack of visibility on test results will become even more acute as at-home tests are more available

***Without robust reporting visibility into positive test rates across the country, HHS/CDC policy makers are unable to make fully informed decision in response to the pandemic***



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# Initial Objectives

## Objectives 1-3 lay the foundation...

1. **Document the testing ecosystem:** Identify the manufacturers, distributors, test administrators, test analysis labs/locations, and data reporters that are critical to helping improve testing data quality.
2. **Establish and implement a framework (“scoreboard”) for tracking data quality improvement:** Design and build data quality and completeness assessments and reporting compliance scoreboards.
3. **Launch the “COVID-19 At-Anywhere Diagnostics Design-a-thon”:** Engage 1,000+ external solvers; attract 10 teams from private industry and build momentum in all sectors.

## ...and enable us to accomplish items 4 & 5

4. **Increase the number of BinaxNOW test results accounted for by 100X:** Increase the number of BinaxNOW test results accounted for from 30,000 to more than 3,000,000. **Adapting goal to focus on all antigen tests rather than solely BinaxNOW tests.**
5. **Estimate of the rapid antigen test positivity rate** and guidelines for how to interpret overall test positivity rate given widespread surveillance testing.

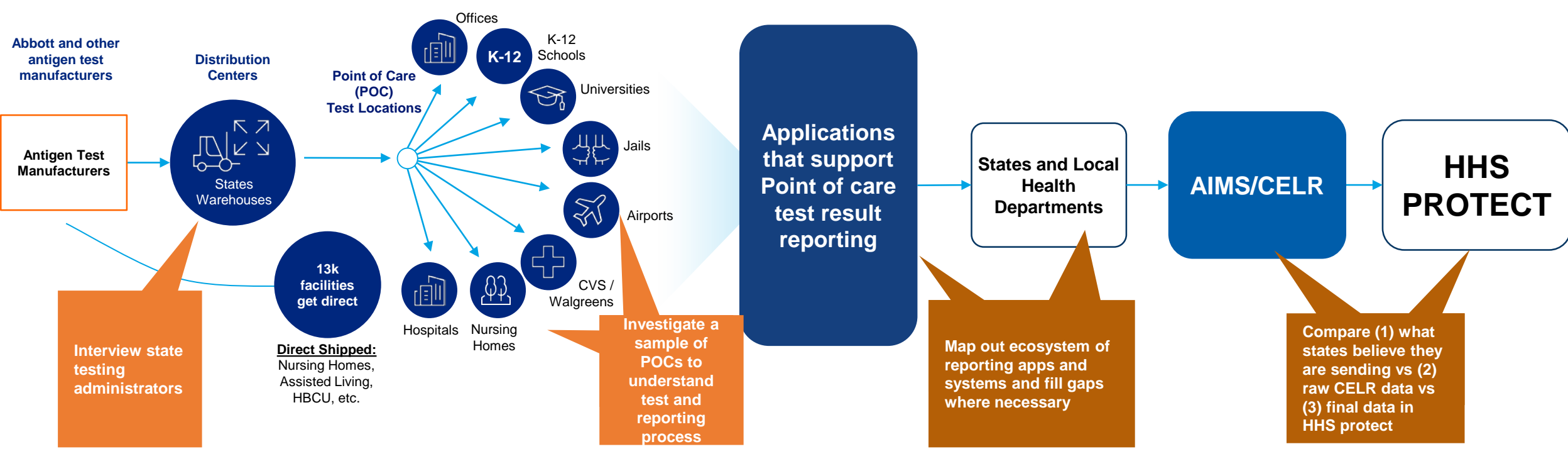


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# We are seeking to improve flow of test result data to states and back to HHS



*Field teams interviewing state COVID administrators to inform what solutions can help minimize reporting breakages*

*Data and tech teams analyzing test data in fed systems to identify and fix reporting breakages*

# Managing Laboratory Supply Shortage Issues

**Dr. Michael Iademarco**

CDC COVID-19 Testing and Diagnostics Task Force



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

# CMS Update – Enforcement Discretion Guidance

**Amy Zale**

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-certificationsurvey/certification/geninfo/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>



# CDC Social Media



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

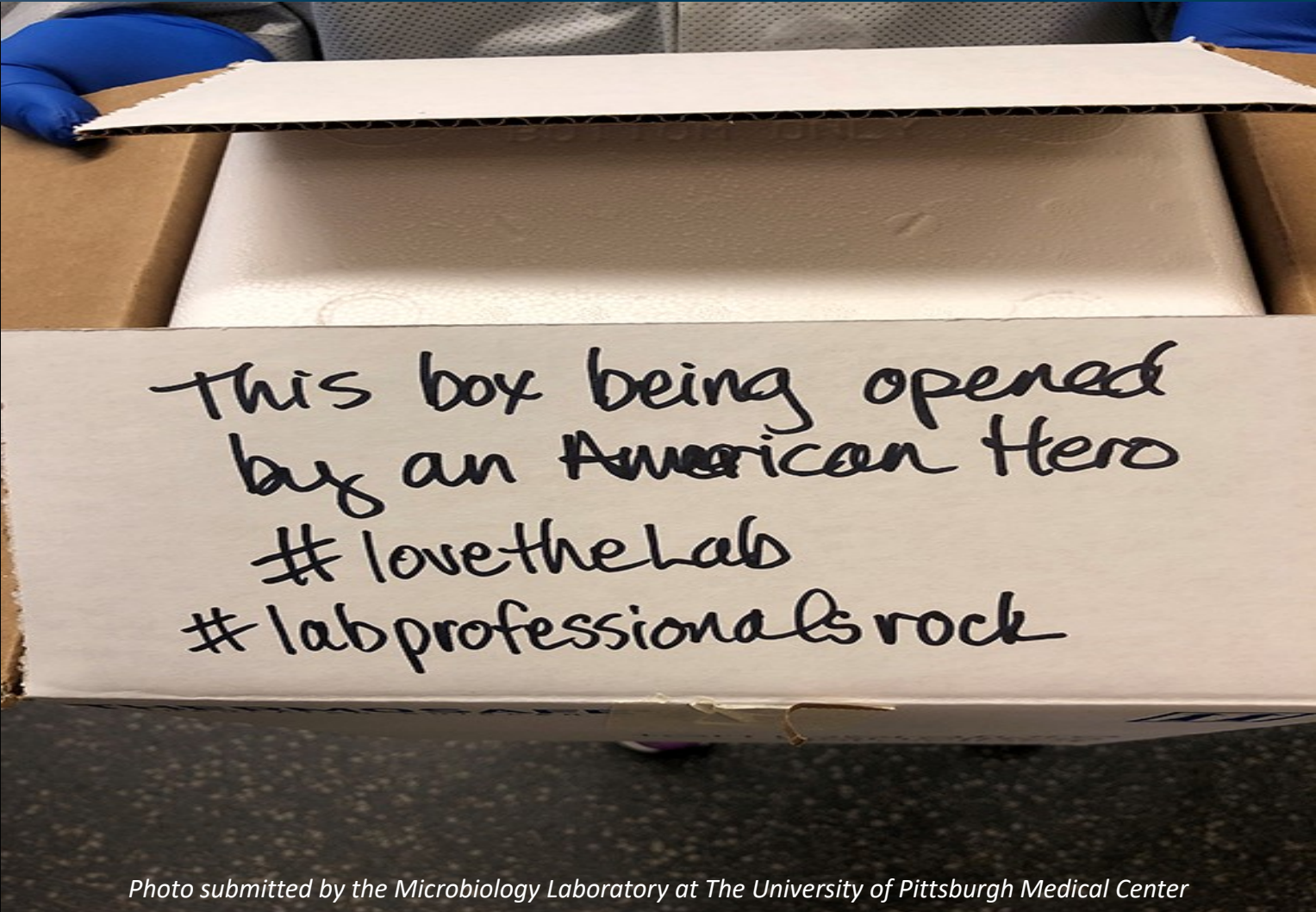


<https://twitter.com/cdcgov>



<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*