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)
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](mailto:media@cdc.gov)
- If you are a patient, please direct any questions to your healthcare provider
The next call will be on Monday, December 28th from 3:00 PM to 4:00 PM ET
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
New Infographics


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**

- **Frequently Asked Questions about COVID-19 for Laboratories**

- **Interim Guidance for Collecting, Handling, and Testing Clinical Specimens**

- **Diagnostic Tools and Virus**

- **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/
Training and Workforce Development

Questions about education and training?
Contact LabTrainingNeeds@cdc.gov
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)

- In development, 60%
- Completed, 33.30%
- Not yet begun, 3.30%
- Do not intend to make a plan, 3.30%
Use of rapid antigen tests (n=30)

- Surveillance testing: 13.3%
- Screening asymptomatic individuals: 46.7%
- Outbreak investigation and response: 46.7%
- Diagnosis of symptomatic individuals: 46.7% (Symptomatic individuals and others), 26.7% (Symptomatic individuals only)
- Unsure: 20.0%
<table>
<thead>
<tr>
<th>Facility/population</th>
<th>Average ranking</th>
</tr>
</thead>
<tbody>
<tr>
<td>K-12 Schools</td>
<td>2.39</td>
</tr>
<tr>
<td>Long-term care facilities</td>
<td>2.53</td>
</tr>
<tr>
<td>Colleges and Universities</td>
<td>3.00</td>
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<tr>
<td>FQHCs/CHCs</td>
<td>3.36</td>
</tr>
<tr>
<td>Congregate work settings</td>
<td>4.33</td>
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<tr>
<td>Any facility outbreak response</td>
<td>4.50</td>
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<tr>
<td>Critical access hospitals</td>
<td>4.83</td>
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<tr>
<td>Tribal clinics</td>
<td>5.20</td>
</tr>
<tr>
<td>Essential personnel</td>
<td>5.38</td>
</tr>
</tbody>
</table>
Reporting requirements (n=28)

- Positive and negative results: 85.7%
- Positive test results only: 3.6%
- Other periodic reports: 17.9%
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

DELIBERATIVE AND PRE-DECISIONAL COMMUNICATION
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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*
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.
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
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**
  

- **FAQs Only**
  
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