Clinical Laboratory COVID-19 Response Call

Monday, October 18, 2021, at 3:00 PM EDT

- **Welcome**
  - Jasmine Chaitram, CDC Division of Laboratory Systems (DLS)
- **Say Yes! COVID Test**
  - Rachael Fleurence & Matthew McMahon, National Institutes of Health (NIH)
- **COVID-19 Testing and Policy in Utah K–12 Schools**
  - William Lanier, Utah Department of Health
- **CMS Update**
  - Felicidad (Faye) Valcarcel, Centers for Medicare and Medicaid Services (CMS)
- **SARS-CoV-2 Variants Update**
  - John Barnes, CDC Laboratory and Testing Task Force for the COVID-19 Response

Division of Laboratory Systems (DLS)

Vision

Exemplary laboratory science and practice advance clinical care, public health, and health equity.

Mission

Improve public health, patient outcomes, and health equity by advancing clinical and public health laboratory quality and safety, data and biorepository science, and workforce competency.

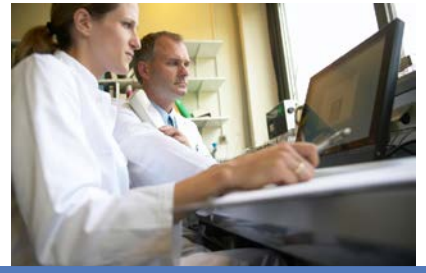
Four Goal Areas

Quality Laboratory Science

- Improve the quality and value of laboratory medicine and biorepository science for better health outcomes and public health surveillance

Highly Competent Laboratory Workforce

- Strengthen the laboratory workforce to support clinical and public health laboratory practice



Safe and Prepared Laboratories

- Enhance the safety and response capabilities of clinical and public health laboratories

Accessible and Usable Laboratory Data

- Increase access and use of laboratory data to support response, surveillance, and patient care

Next Generation Sequencing Quality Initiative: New Tools!

- Find new quality management system tools and resources online, such as
  - Sequencer pre-installation checklists
  - Updated guides related to waste disposal
  - Information management throughout the NGS workflow
- All documents are available to download for free
- Find previously published guidance on managing laboratory processes and quality throughout the testing lifecycle

www.cdc.gov/labquality/qms-tools-and-resources.html

CLIAC 2021 Fall Meeting

November 3-4, Virtual Meeting

- Register for the meeting and save the date on CDC's CLIAC website
- Contribute during the public comment period, closing Monday November 1
- Hear updates from CDC, FDA, and CMS including an overview of the FDA's Center for Biologics Evaluation and Research and a CDC laboratory safety update from DLS
- Topics include
  - Next Generation Sequencing (NGS) in Clinical and Public Health Laboratories
  - Laboratory Data Exchange and Harmonization

www.cdc.gov/cliac/upcoming-meeting.html

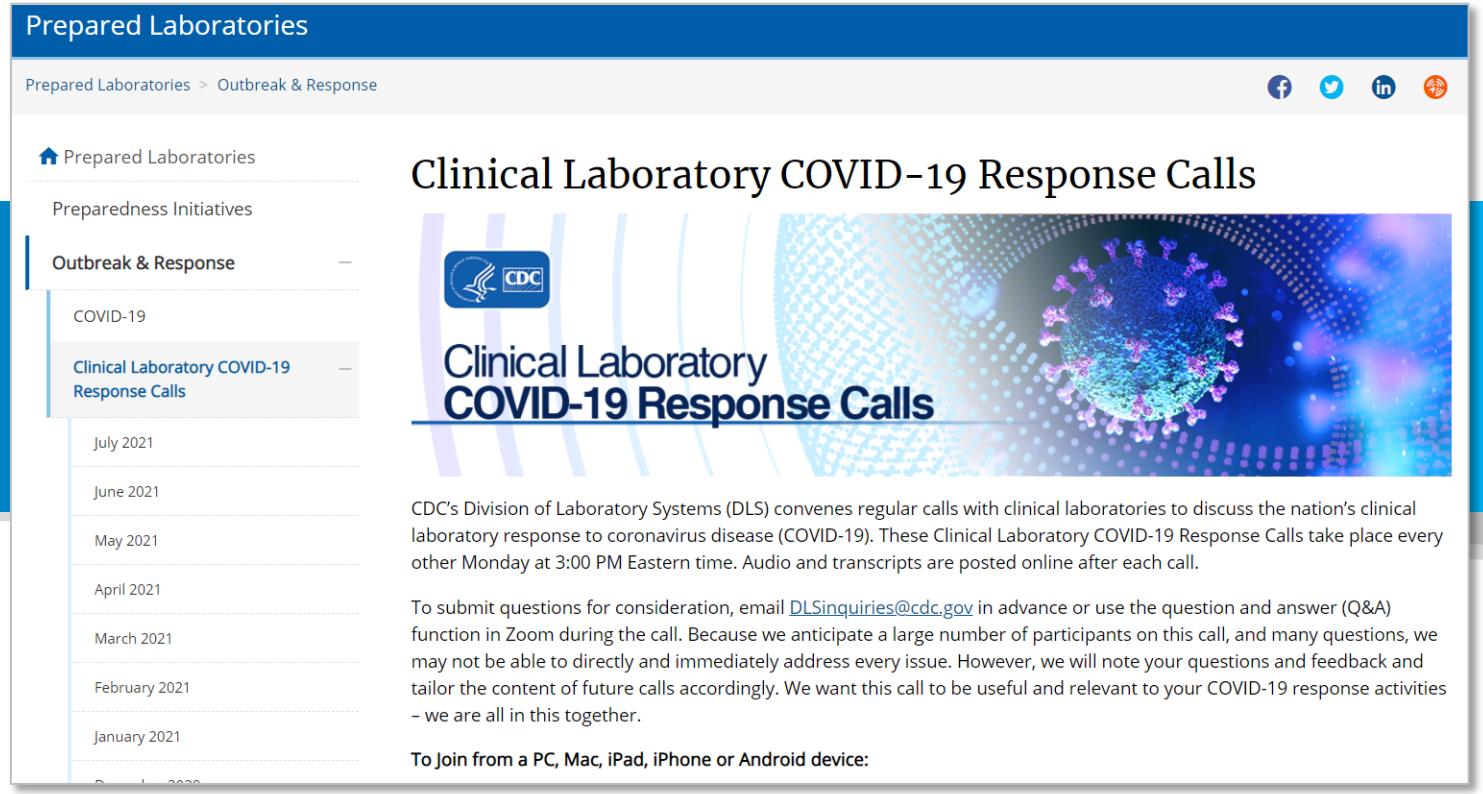
New eLearning Course: Introduction to Laboratory Risk Management

- **CDC Laboratory Training**
  - https://www.cdc.gov/labtraining/training-courses/Introduction-to-Laboratory-Risk-Management.html
- **CDC TRAIN**
  - https://www.train.org/cdctrain/course/1090331/

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 CDC Preparedness Portal



Next CLCR Call

The next call will be on **Monday, November 1**

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

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

Slide decks may contain presentation material from panelists who are not affiliated with CDC. Presentation content from external panelists may not necessarily reflect CDC's official position on the topic(s) covered.

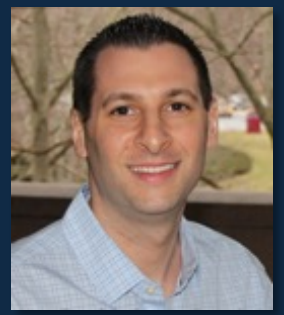
“Say Yes! COVID Test ”

Deployment of rapid testing programs in multiple communities across the United-States

October 18, 2021

Presenters

Q& A
SYCT Team



Rachael Fleurence, Ph.D.
Senior Advisor, Immediate Office of the Director
Special Assistant to the NIH Director for COVID-19 Diagnostics

Matt McMahon, Ph.D.
Director SEED, Office of the Director

Q&A
Liz Di Nenno, Ph.D.
Office of the Director, Division of HIV Prevention
Centers for Disease Control and Prevention

Acknowledgements
Dr Andrew Weitz, PhD, Program Director NIBIB
Dr Krishna Juluru, MD, Presidential Innovation Fellow, NIBIB

Program Overview

"Say Yes! COVID Test" is a partnership between NIH, CDC, and local public health departments which offers residents a chance to reduce the spread of COVID-19 through frequent, rapid testing from the privacy of their own home.

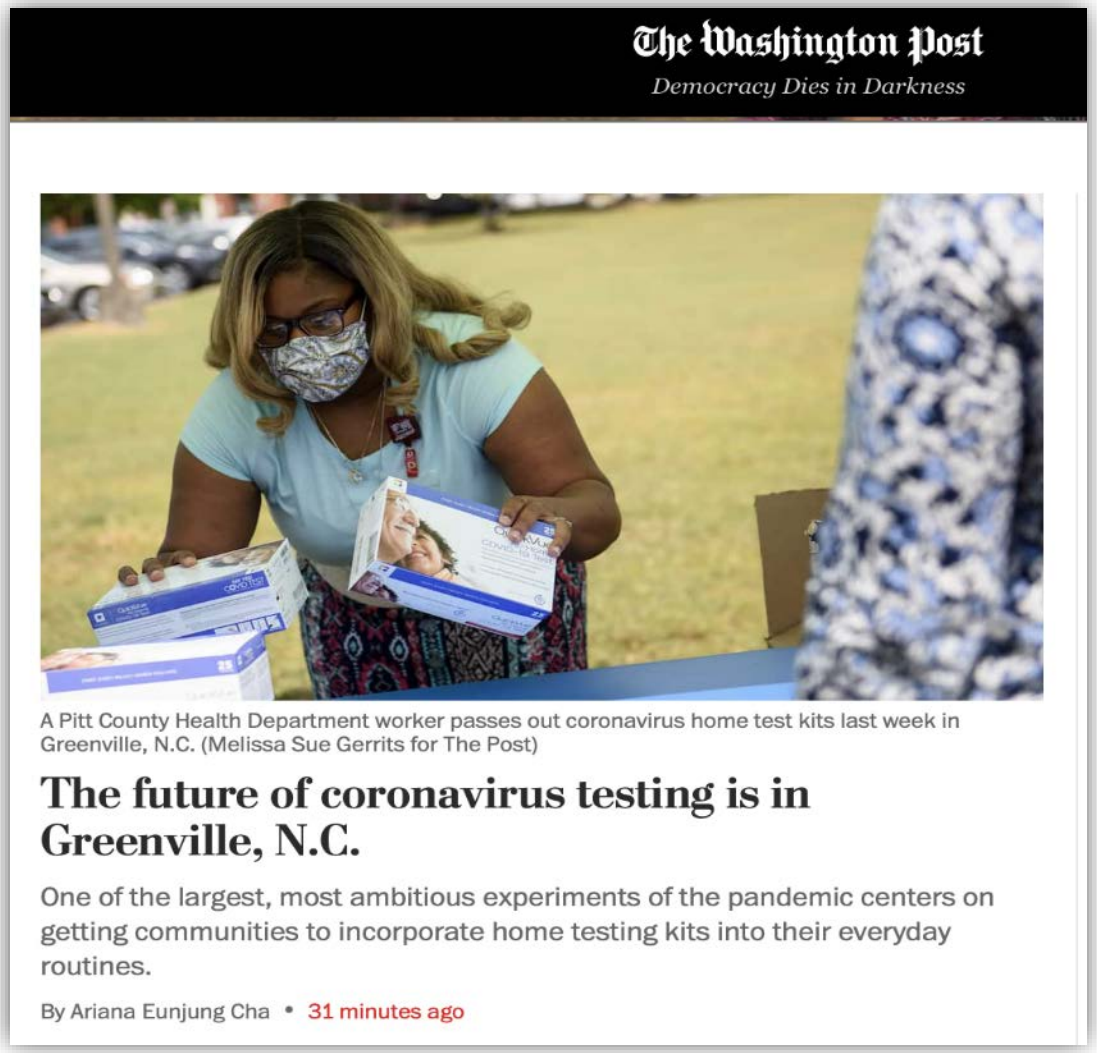
Participants can order free, at-home rapid antigen tests through one of the following ways:

1. On-line ordering with Amazon fulfilment, or

2. Picking up at a local site through community events

Key Program Questions

- Will residents order/pick-up tests?
- What are ways to ensure undeserved/vulnerable populations have access to the free tests ?
- Will residents use tests for screening (2-3 times a week) ?
- Will they voluntarily report test results ?
- Does providing tests to a large portion of a community break community transmission?
- Is the program scalable ?



The Washington Post
Democracy Dies in Darkness

A Pitt County Health Department worker passes out coronavirus home test kits last week in Greenville, N.C. (Melissa Sue Gerrits for The Post)

The future of coronavirus testing is in Greenville, N.C.

One of the largest, most ambitious experiments of the pandemic centers on getting communities to incorporate home testing kits into their everyday routines.

By Ariana Eunjung Cha • 31 minutes ago

Program Components

Public health department leads local initiative

1 Million rapid antigen tests

Website and digital app

Focus on underserved and vulnerable populations

Test result reporting to public health

Survey

Incentive program

Program evaluation

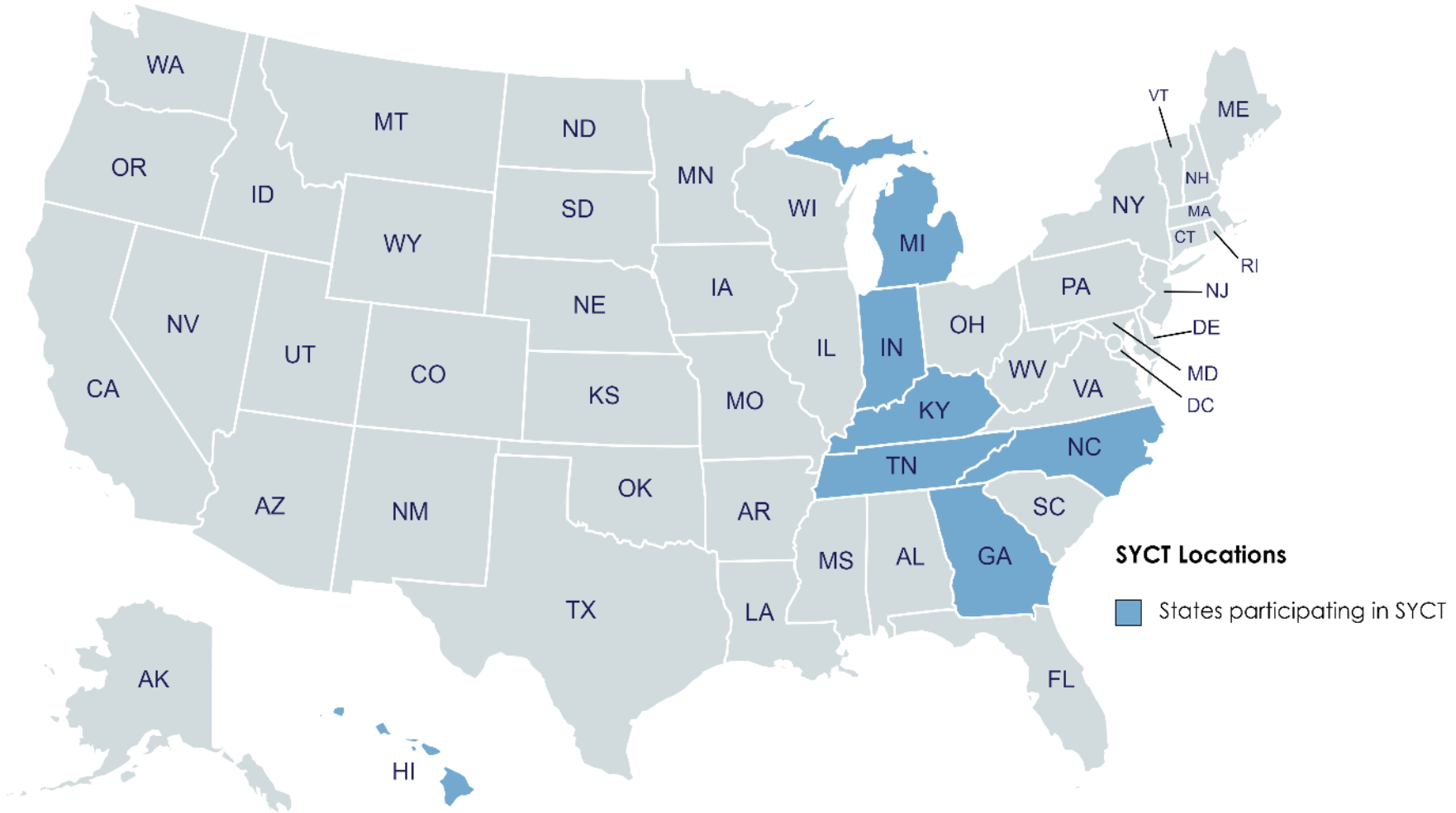
2021 Program Locations and Timeline

March-June:
- Pitt County, NC
- Hamilton County, TN

July-August:
- Ann Arbor, MI
- Ypsilanti, MI

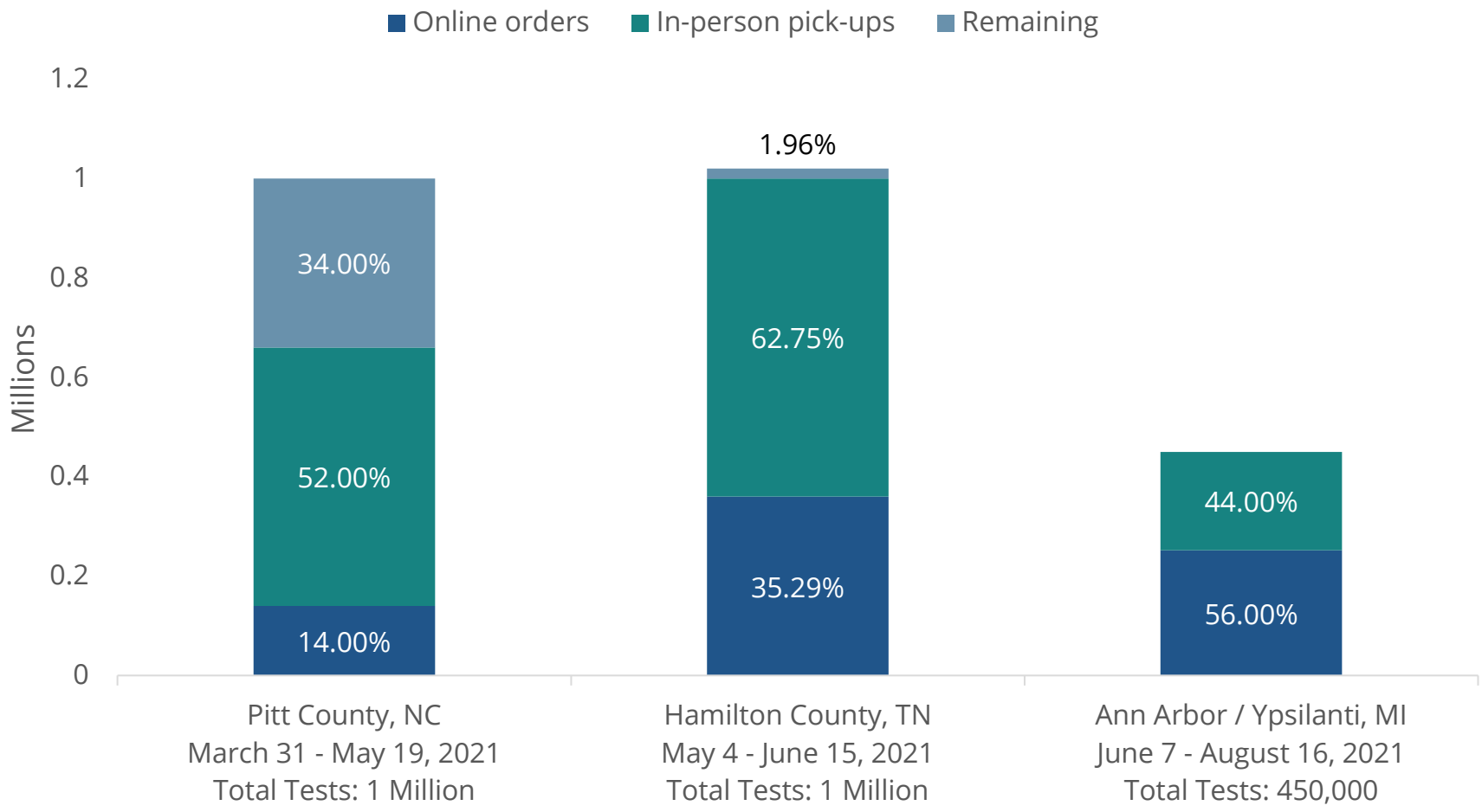
September-November:
- Fulton County, GA
- Honolulu County, HI

October-December:
- Louisville Metro, KY
- Marion County, IN



PHASE I/II: INITIAL FINDINGS IN NC, TN, MI

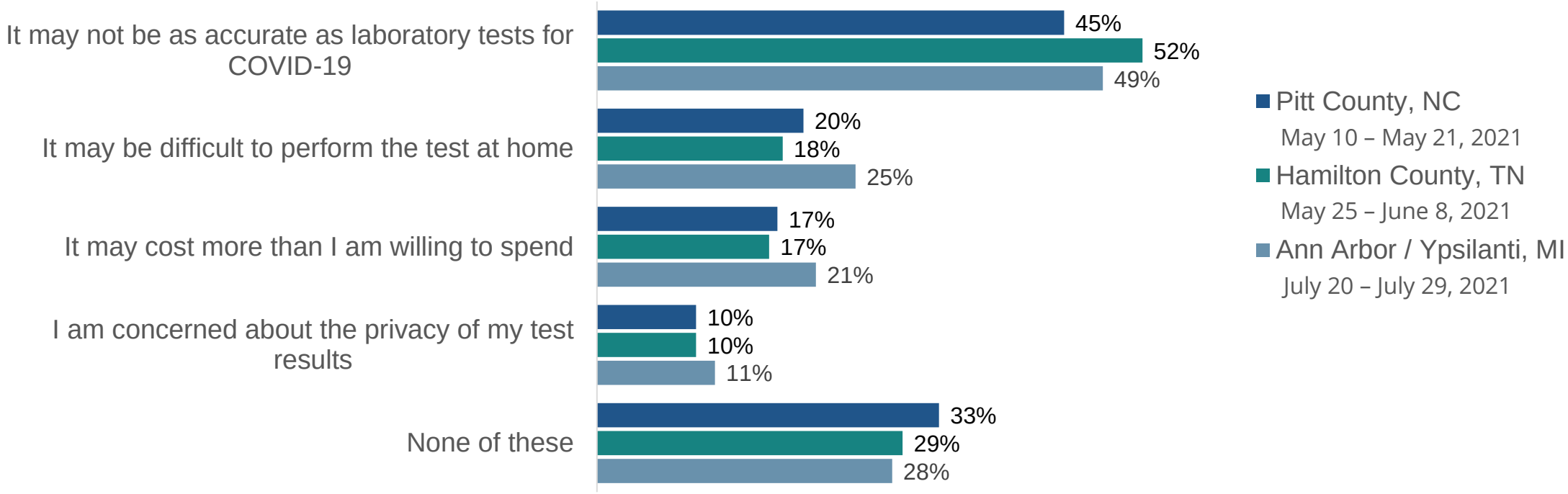
Phase I: Online Orders vs. In-Person Pick Up in NC, TN and MI



Note: All the remaining tests from North Carolina and Tennessee sites were redistributed elsewhere.

Program Learnings From Phase I: Testing Concerns

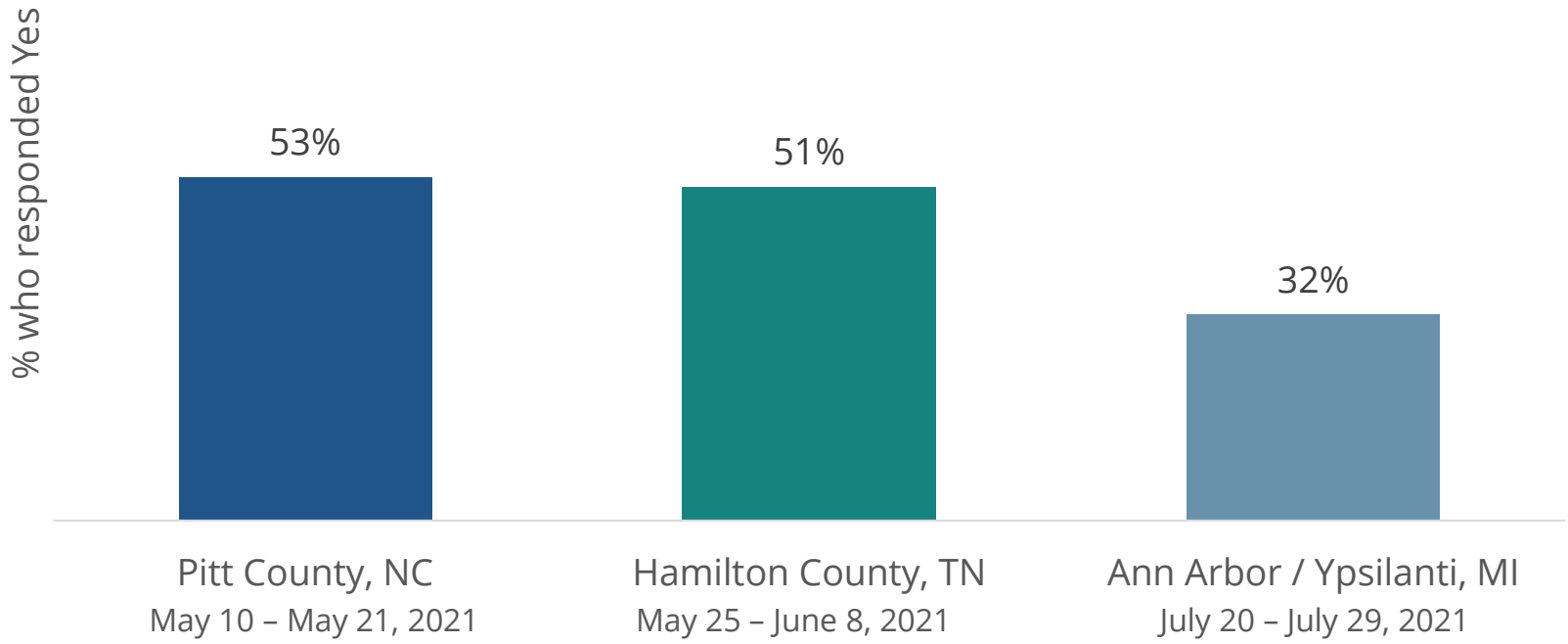
Q: Which of the following would concern you about using at-home COVID-19 tests? [Select All That Apply] Total (n=400 per location)



Presented with a list of possible concerns about at-home COVID tests, **accuracy was the most frequent concern** across locations.

Program Learnings From Phase I: Program Awareness

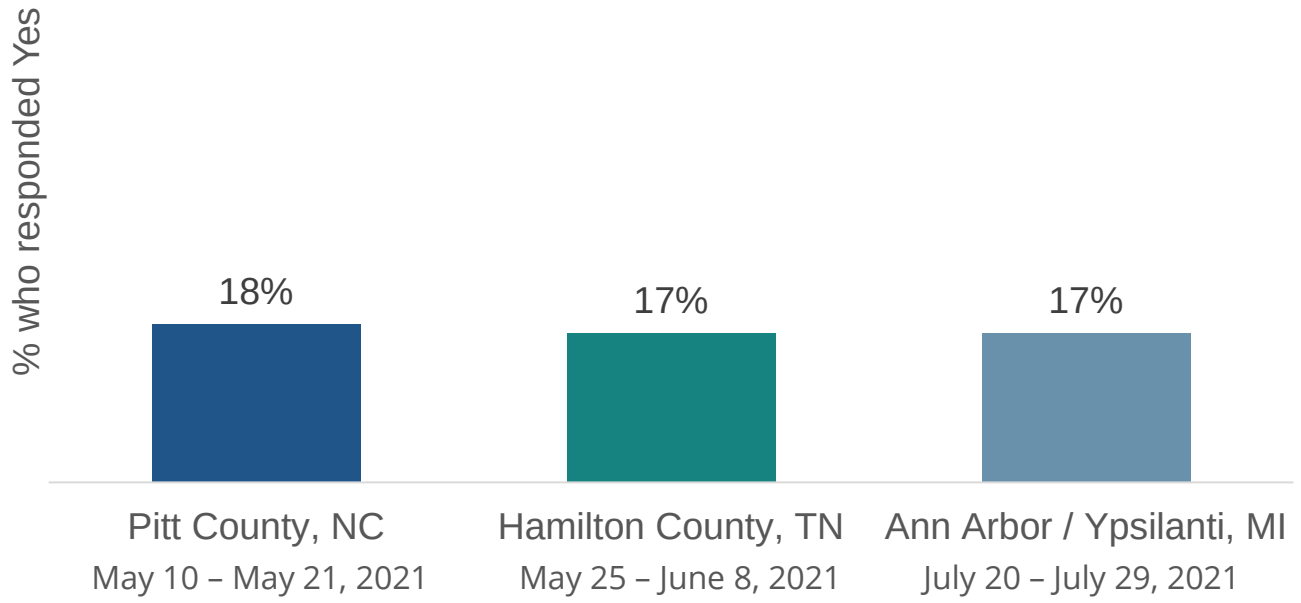
Q: Are you aware that the Health Department is providing at-home test kits to households for free? Total (n=400 per location).



Awareness of the Say Yes! Program was **lower in Ann Arbor / Ypsilanti, MI**.

Program Learnings From Phase I: Resident Acquisition

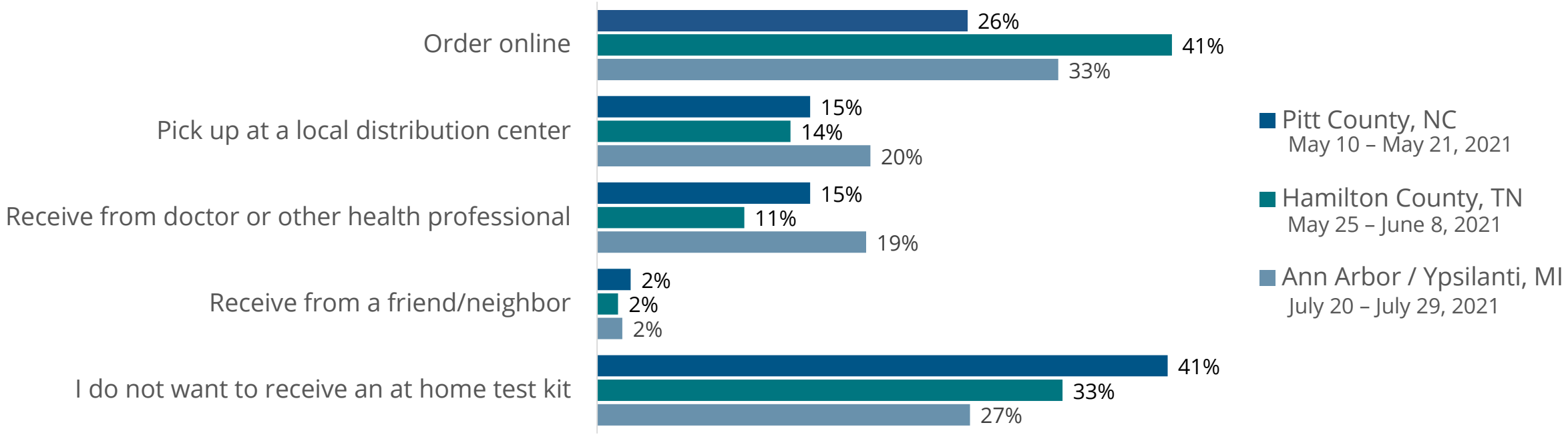
Q: Have you received the free at-home tests provided to the residents in your location? Total (n=400 per location)



Despite differences in program awareness, the **incidence of actual resident acquisition of the at-home tests was similar** across locations.

Program Learnings From Phase I: Preferred Method To Order

Q: How would you prefer to receive a free home test kit?
Those who had not received test kit - Pitt County NC (n=329),
Hamilton County TN (n=334), Ann Arbor / Ypsilanti MI (n=334)



Online ordering was most preferred; the incidence of those not wanting at-home test kits was lower in Hamilton County, TN and Ann Arbor / Ypsilanti, MI than in Pitt County, NC.

Forthcoming Activities

Program Evaluation will use aggregated data to assess program impact on community transmission

- UNC / Duke University and University of Massachusetts to conduct **ecological study**, including matched controls

- Planned **outcome measures**:
  - Cases of SARS-CoV-2
  - Measures of SARS-CoV-2, including variants, in wastewater
  - Mobility outcomes
  - Hospitalizations attributable to SARS-CoV-2
  - SARS-CoV-2 ICU admissions

- Results expected **Fall 2021 / Winter 2022**

PHASE III: UNDERWAY IN GA, HI, KY, IN

Status Of Phase III Communities – September 22, 2021

Fulton County, GA

- Launched Sept. 20

October 15: 33% of stock ordered or distributed

Honolulu County, HI

- Launched Sept. 20

October 15: 100% of stock ordered or distributed

Louisville Metro, KY

- Launched October 11

October 15: 13% of stock ordered or distributed

Marion County, IN

- Launched October 18

Acknowledgements: Say Yes! COVID Test Partners

The National Institutes of Health

- Office of the Director
- National Institute of Biomedical Imaging and Bioengineering (NIBIB)
- National Institute of Minority Health and Health Disparities (NIMHD)

Centers for Disease Control and Prevention

Local public health departments

- Pitt County, NC; Hamilton County, TN; Washtenaw County, MI; Fulton County, GA; Honolulu County, HI; Louisville Metro, KY; and Marion County, IN

Local residents and community leaders

Operational and logistical partners:

- CareEvolution
- Amazon
- Quidel
- DataRobot
- Research America!

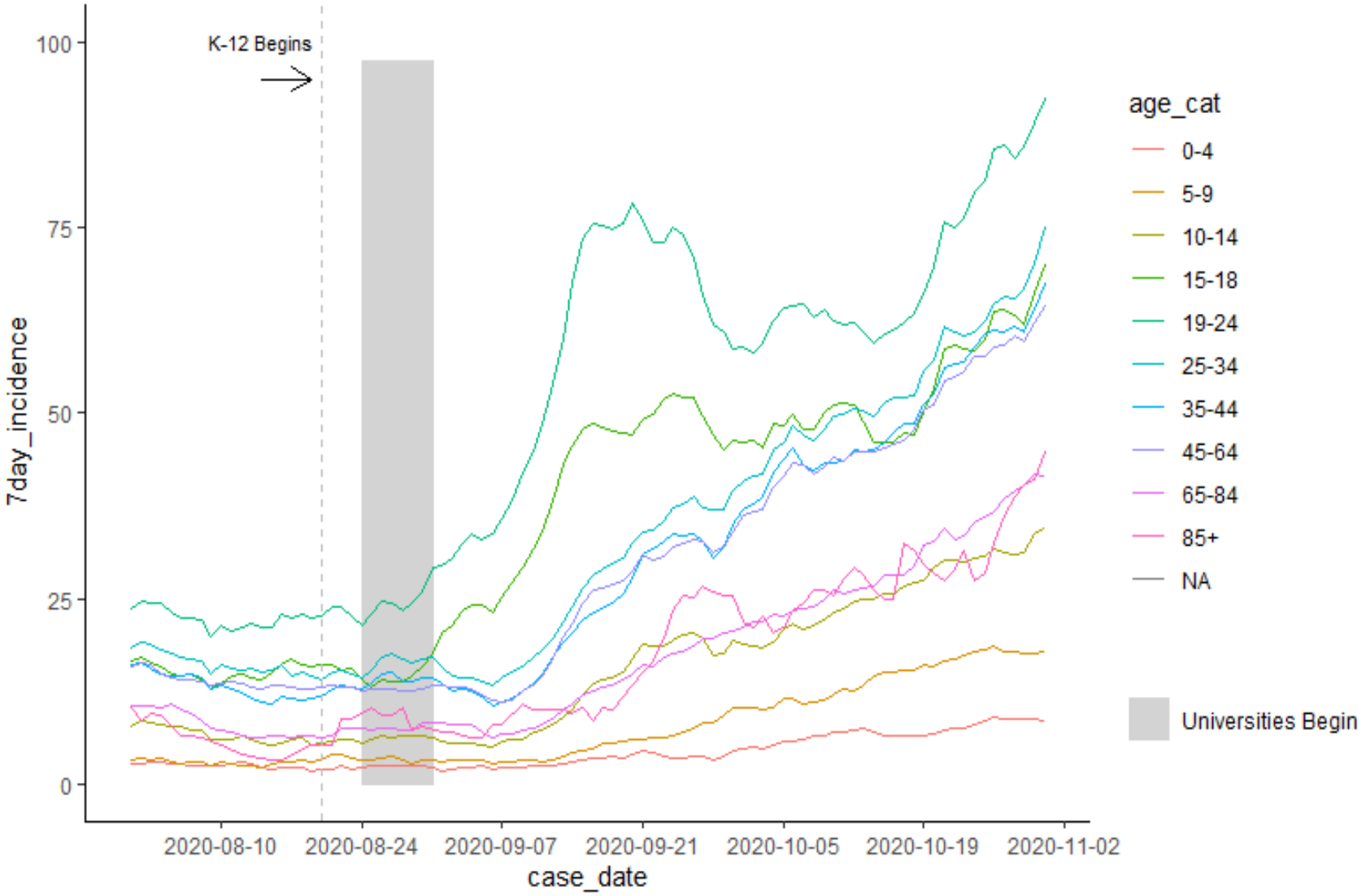
Research and community engagement partners

- University of Massachusetts
- University of North Carolina – Chapel Hill
- Duke University
- Duke Clinical Research Institute
- Community-Campus Partnerships for Health

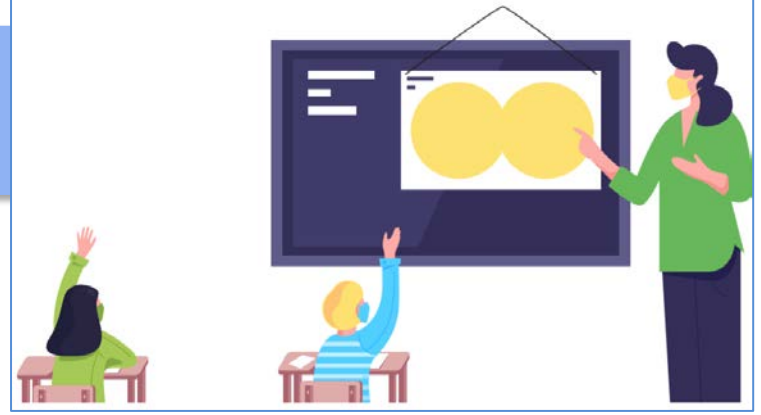
COVID-19 Testing and Policy in Utah K–12 Schools

CDR Willy Lanier
US Public Health Service
Utah State Public Health Veterinarian
CDC Career Epidemiology Field Officer, UDOH
wlanier@utah.gov

Concerning Rates in Ages 15–24



Guiding Principles



Goals:

1. Decrease COVID transmission in school populations
2. Allow students to participate in in-person learning safely
3. Allow students to participate in extracurricular activities safely

Routine, serial testing in a population reduces the risk of transmission by:

1. Identifying positive cases for isolation; and
2. Incentivizing preventive behaviors

Football Testing

- Governor's order effective 11/9/20 paused school extracurricular activities
- Exception: High school football tournament play
- Required neg. COVID test within 72 hours before game (students and adults)
- Week 1: 16 teams (>1800 people; ~4% positive)
- Week 2: 6 teams (>800 people; ~2% positive)
- Tested by UDOH/contractors, local health, school nurses, hospital staff
- Became the pilot project for "Test to Play"

"Test to Play"

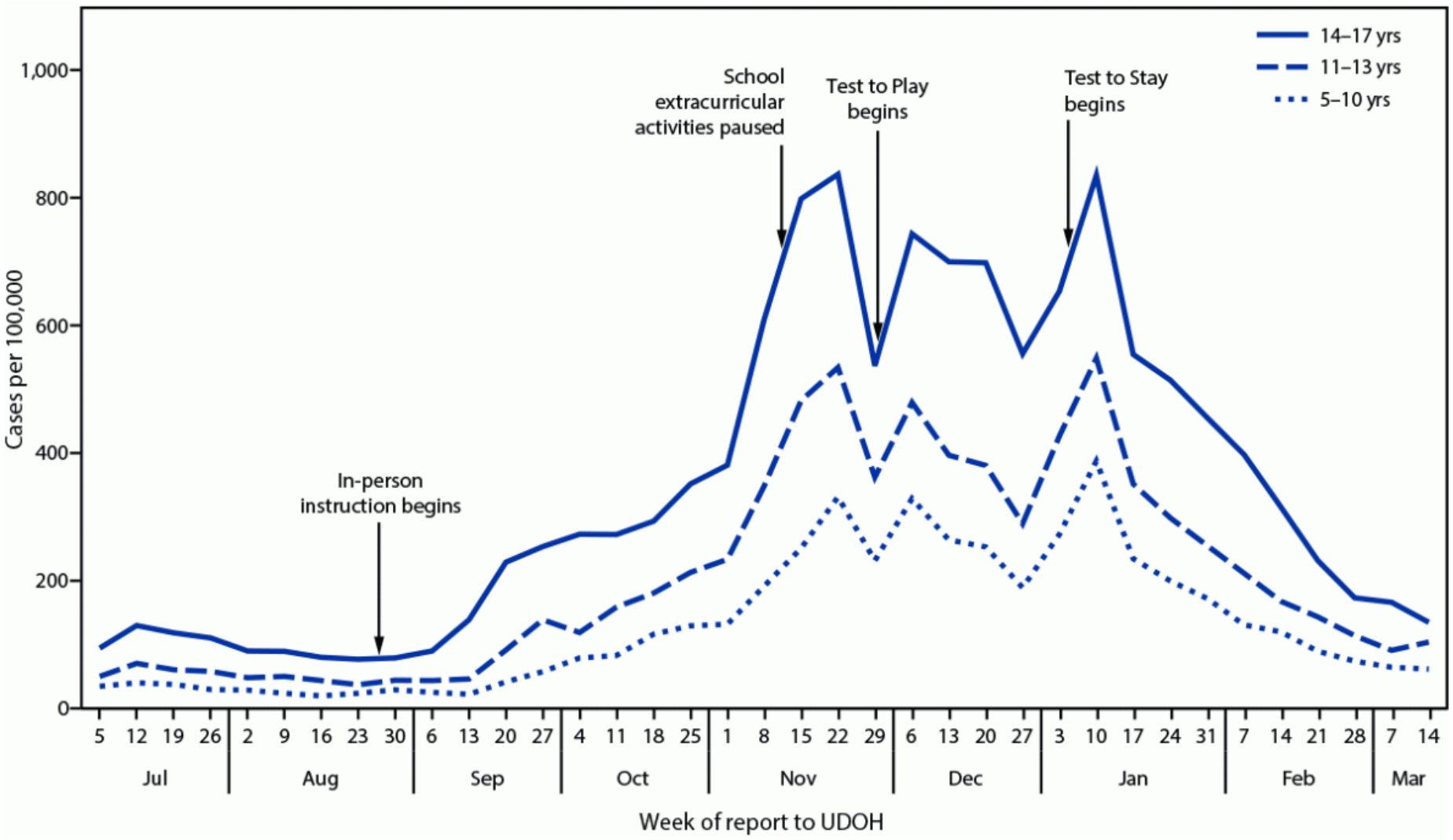
- Utah Public Health Order 2020-25 (effective 11/30/20)
- High school athletic & extracurricular activity participants (students/adults)
  - Required to be tested for COVID at least every other week
  - No symptoms, not in isolation or quarantine
- State provided schools rapid tests, PPE, training, resources, & reporting system
- School staff did/managed the testing under school district CLIA waiver (independent testing clinics)
- School staff could also be tested by schools

"Test to Stay"

- In 2020, schools were recommended to transition to virtual learning once they met established case threshold
- Test to Stay option: Offer testing to everyone in school
  - Negative: stay in in-person learning
  - Positive: isolate at home
  - Opt out: virtual learning
- Test to Stay successfully piloted at two high schools in Dec 2020
- In 2021, a school at threshold could either:
  - Transition to virtual learning; or
  - Test to Stay

Test to Stay Pilot at Kearns HS 12/7/20. | Granite School District. https://www.deseret.com/utah/2020/12/8/22164433/1000-plus-kearns-high-students-staff-test-to-stay-in-school-in-covid-19-test-pilot-syracuse

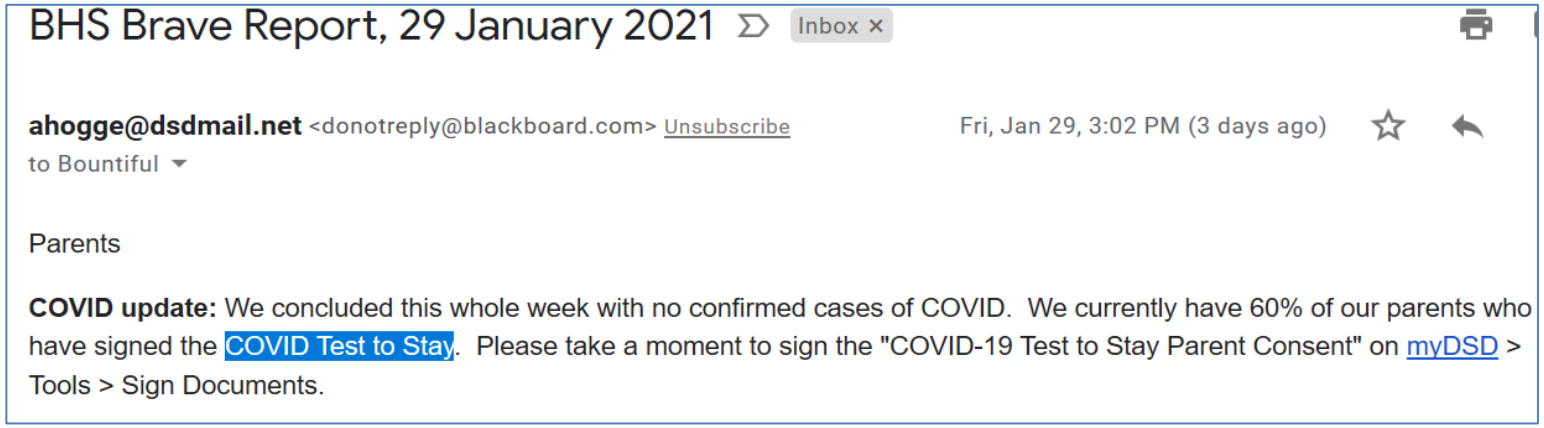
Utah COVID trends among ages 5–17



MMWR May 28, 2021: COVID-19 Testing to Sustain In-Person Instruction and Extracurricular Activities in High Schools — Utah, November 2020–March 2021

PTI Results 11/30/20–3/20/21

- "Prioritized Testing Initiative" (PTI)
  - Acronym code to track results in Utah's surveillance database
  - Included Test to Play and Test to Stay results
  - Underreporting likely
- Overall: 1,886 (3.2%) positive among 59,552 students (165,078 tests)
- TTP: 1,771 (3.5%) positive among 50,400 students (148,262 tests)
- TTS: 90 (0.7%) positive among 13,809 students (14,531 tests)

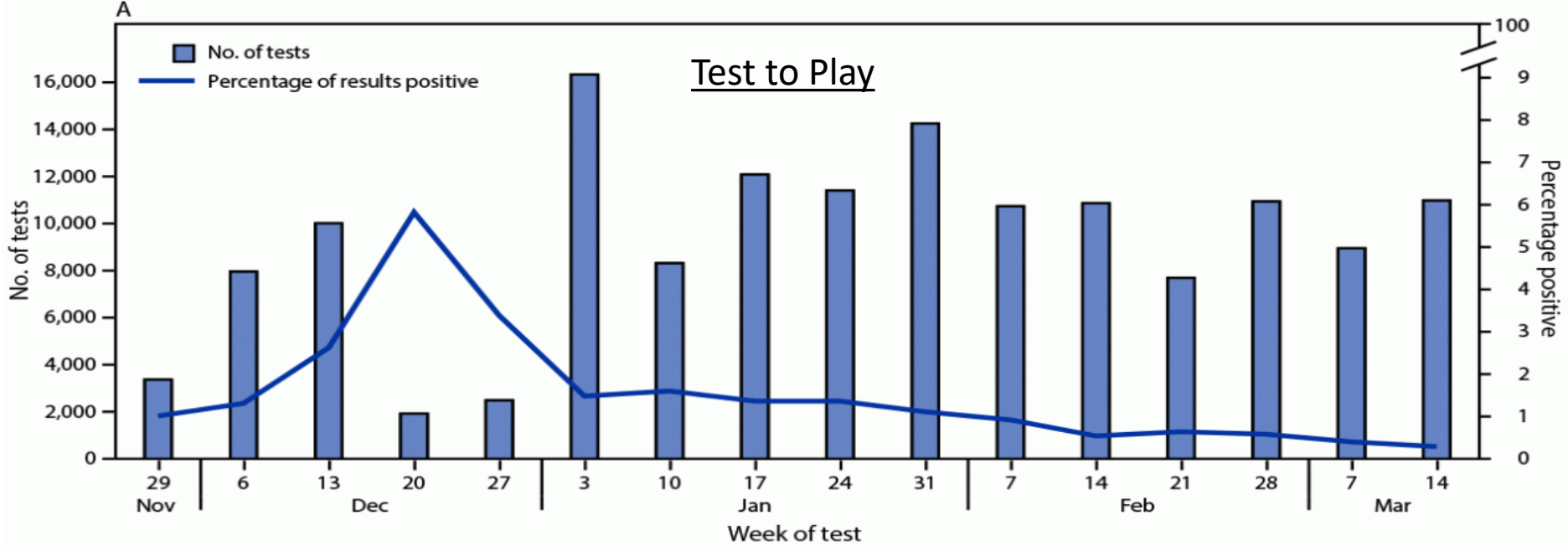

BHS Brave Report, 29 January 2021 Inbox ×

ahogge@dsdmail.net <donotreply@blackboard.com> Unsubscribe Fri, Jan 29, 3:02 PM (3 days ago)

to Bountiful

Parents

COVID update: We concluded this whole week with no confirmed cases of COVID. We currently have 60% of our parents who have signed the COVID Test to Stay. Please take a moment to sign the "COVID-19 Test to Stay Parent Consent" on myDSD > Tools > Sign Documents.


A
No. of tests
Percentage of results positive
Test to Play
No. of tests
Percentage positive
16,000
14,000
12,000
10,000
8,000
6,000
4,000
2,000
0
100
9
8
7
6
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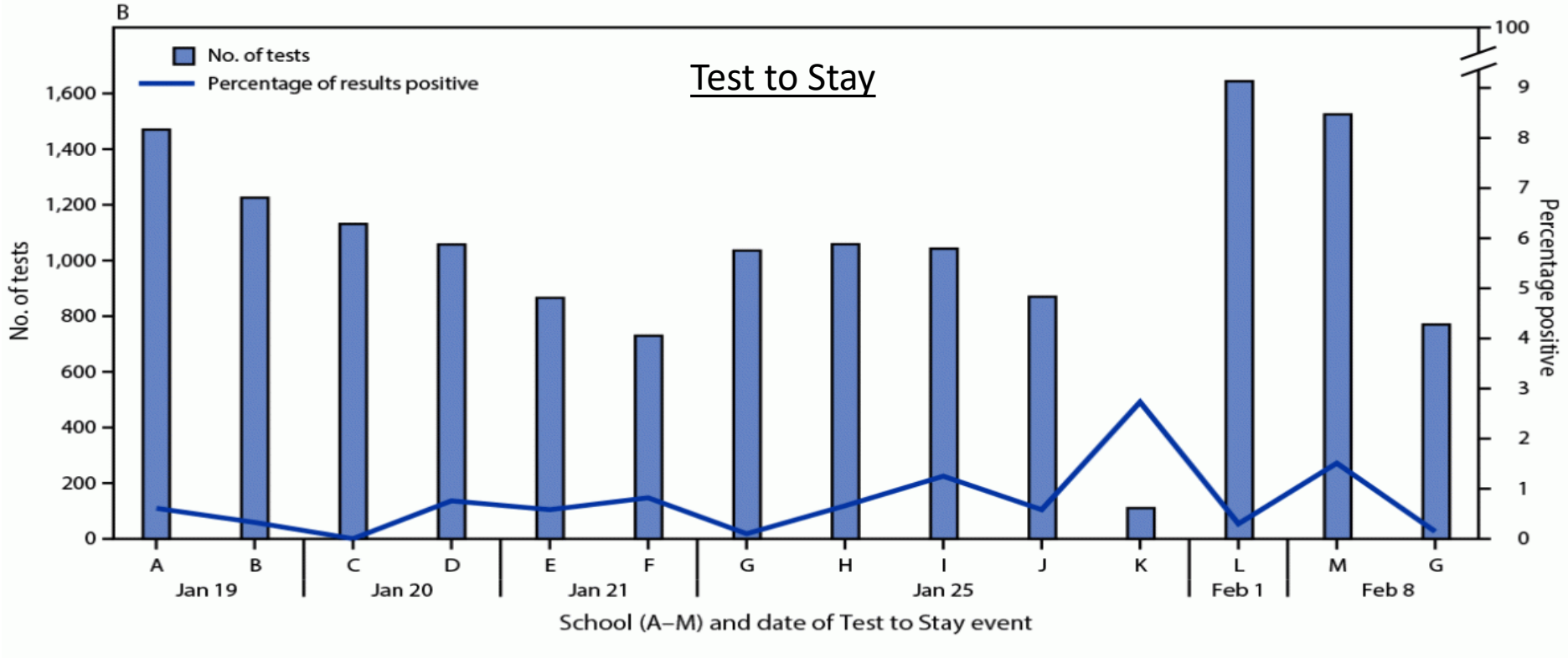
2
1
0
29 6 13 20 27 3 10 17 24 31 7 14 21 28 7 14
Nov Dec Jan Feb Mar
Week of test


B
No. of tests
Percentage of results positive
Test to Stay
No. of tests
Percentage positive
1,600
1,400
1,200
1,000
800
600
400
200
0
100
9
8
7
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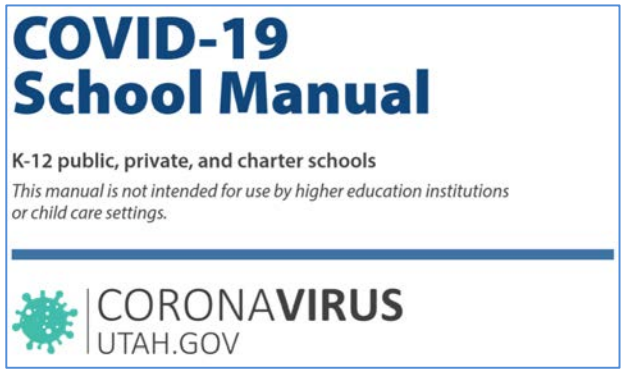
A B C D E F G H I J K L M G
Jan 19 Jan 20 Jan 21 Jan 25 Feb 1 Feb 8
School (A–M) and date of Test to Stay event

Dec 2020/Jan 2021 UT School Policy Updates

- Test to Play and Test to Stay in Utah COVID School Manual (12/17/20)
- Mask-on-mask = no quarantine
- Virtual learning period changed from 14 to 10 days (align with quarantine)
- School staff prioritized for vaccination



- Utah High School Activities Association Safe Participation Protocols:
  - *"To maximize mask wearing and physical distancing to promote safety, minimize the need for quarantining, and to avoid missing classroom time and extracurricular opportunities."*

2020/21–2021/22 UT School Policy & TTS

Utah Senate Bill 107 and Utah House Bill 1007 (Spring 2021)

2020–21	2021–22
Masks mandated	Mask mandates by schools no longer legal
Test to Play required	Test to Play not required
Test to Stay optional	Test to Stay mandated
Case threshold 15, then 15 or 1% if >1500 (students and staff)	Case threshold 30 or 2% if ≥1,500 (students)
20 TTS events (plus 2 pilot)	8 TTS events so far; 3.25% positivity (7,381 tests)

Take-aways

- Timing: risk perception and political will
- Motivation: participation in in-person instruction and extracurricular activities
- Power: partnerships and politics
- Kudos to school, LHD, and other partners

Thank you

Masked baseball game during 1918–19 flu pandemic.
https://sports.yahoo.com/coronavirus-heres-what-sports-looked-like-during-the-1918-spanish-flu-pandemic-184042838.html

CMS Update

Faye Valcarcel and
Sarah Bennett

Oct. 18, 2021

Centers for Medicare and Medicaid Services (CMS)

COVID-19 Test Kits Authorized for Over the Counter (OTC) Use

- COVID-19 OTC Tests, Self-Testing
- COVID-19 OTC Test Kits, Point-of-Care Test Site (POC), POC Personnel
- COVID-19 OTC Test Kits, Other Settings (e.g., schools, prisons, homeless shelters)
- COVID-19 Test Kits not authorized for OTC
- State requirements

Helpful Links:

State Agency Contacts:

- https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf

Accreditation Organization Contacts:

- https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/AOList.pdf

Helpful Link:

CLIA Interpretive Guidelines for Laboratories and Laboratory Services:

- https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107ap_c_lab.pdf

Helpful Link:

CLIA Regulations:

- https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493

Helpful Links:

- 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

Thank You

SARS-CoV-2 Variants Update

John Barnes
CDC Laboratory and Testing Task Force
for the COVID-19 Response

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

CDC Social Media

https://www.facebook.com/CDC

https://twitter.com/cdcgov

https://www.instagram.com/cdcgov

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

Thank You For Your Time!

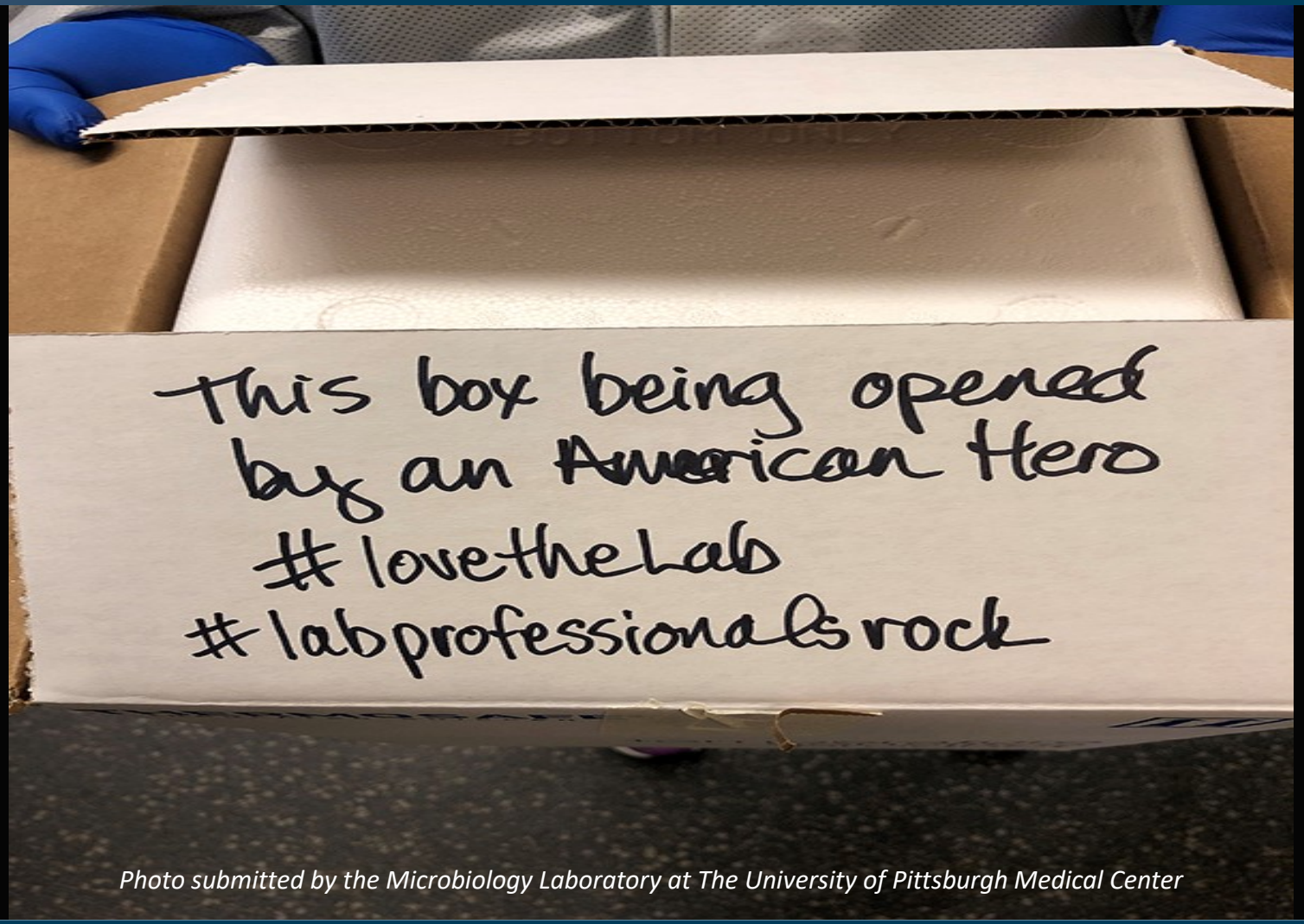


Photo submitted by the Microbiology Laboratory at The University of Pittsburgh Medical Center