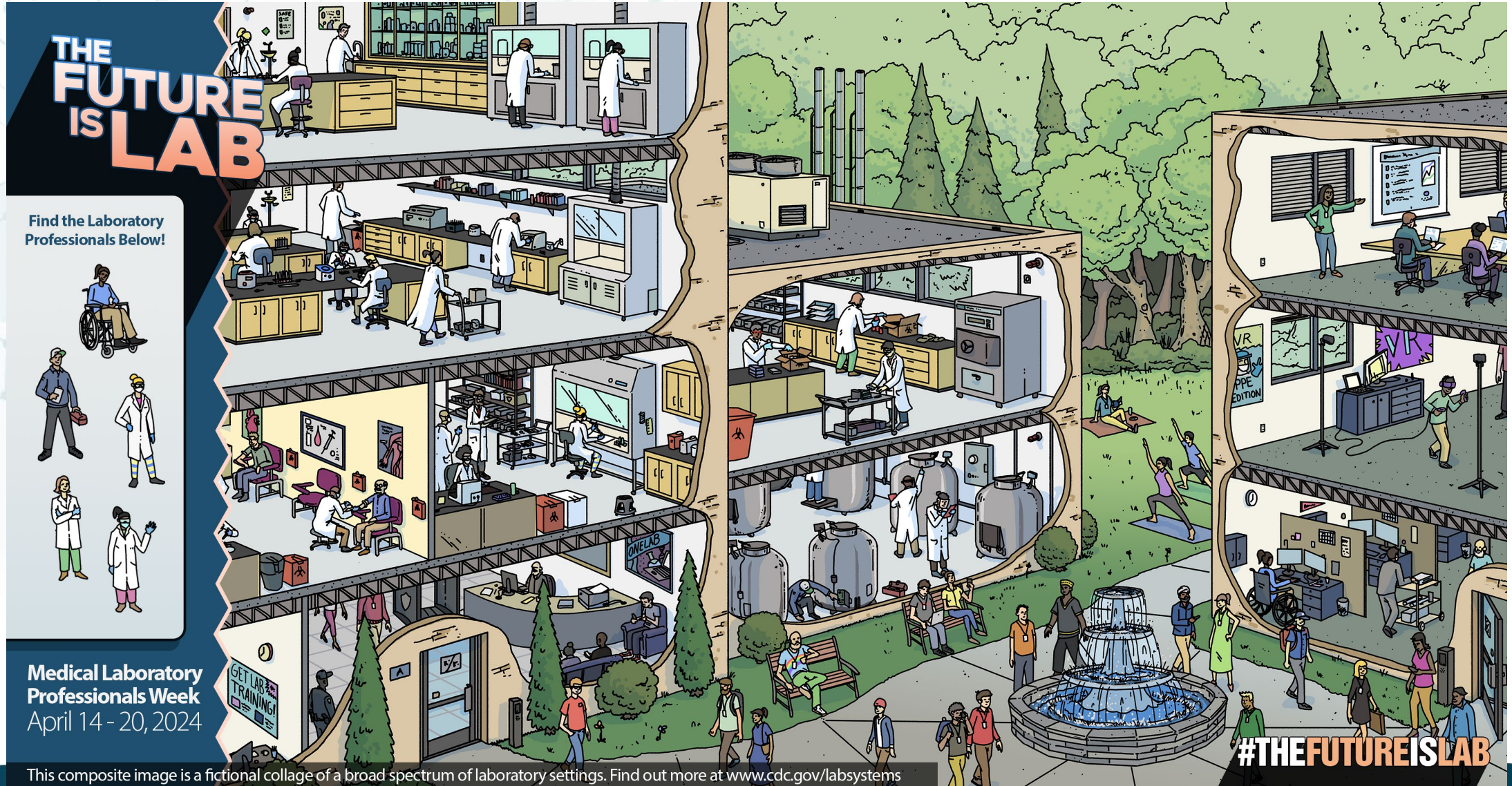


Thank you for joining, we'll begin the call momentarily.



Find the Laboratory Professionals Below!



Medical Laboratory Professionals Week
April 14 - 20, 2024

This composite image is a fictional collage of a broad spectrum of laboratory settings. Find out more at www.cdc.gov/labsystems

#THEFUTUREISLAB

Laboratory Outreach Communication System (LOCS) Call

Monday, June 17, 2024, at 3:00 P.M. ET

- **Welcome**
 - Sean Courtney, CDC Division of Laboratory Systems
- **Situational Update and Response to the Highly Pathogenic Avian Influenza A(H5N1) Outbreak in U.S. Dairy Cattle**
 - Charles (Todd) Davis and Marie Kirby, CDC Influenza Division
- **SARS-CoV-2 Viral Shedding and Rapid Antigen Test Performance Respiratory Virus Transmission Network, November 2022–May 2023**
 - Sarah (Lizzy) Smith-Jeffcoat, CDC Coronavirus and Other Respiratory Viruses Division

About DLS

Vision

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

Four Goal Areas



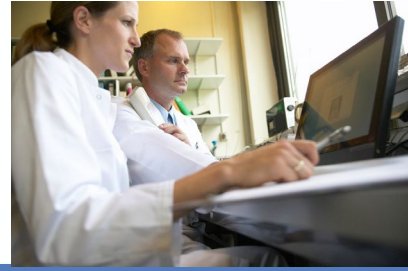
Quality Laboratory Science

- Improve the quality and value of laboratory medicine 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

DLS ECHO Biosafety Program

- Next session on **June 25, 12:00 PM ET**
 - **Topic:** Support - Communication and Documented Information
 - **Speakers:** Marian Downing RBP, CBSP, SM(NRCM) and Domenica Zimmerman
- For questions, contact DLSbiosafety@cdc.gov



Scan the QR code to register

www.cdc.gov/safelabs/resources-tools/echo-biosafety.html

We Want to Hear From You!

Training and Workforce Development

Questions about education and training?

Contact LabTrainingNeeds@cdc.gov



LOCS Calls

DLS Home > CDC's Laboratory Outreach Communication System (LOCS)

DLS Home

- About Us
- LIVD Mapping Tool for SARS-CoV-2 Tests
- Strengthening Clinical Laboratories
- CDC's Laboratory Outreach Communication System (LOCS)**
 - LOCS Messages Archive
 - LOCS Calls**
 - LOCS Calls Archive
 - CLCR Call Archive
 - LOCS Message Level Types
- Laboratory Communicators' Network
- Free Educational Materials for

CLCR calls are now LOCS calls!

Clinical Laboratory COVID-19 Response (CLCR) Calls are now Laboratory Outreach Communication System (LOCS) Calls. Find an archive of CLCR call audio files, transcripts, and slide presentations, [here](#).

CDC's Division of Laboratory Systems (DLS) convenes regular Laboratory Outreach Communication System (LOCS) calls with clinical laboratories and other audiences. The calls are an opportunity for CDC and other participants (such as federal partners and professional organizations) to provide updates and answer questions from the laboratory and testing community. These calls take place on the third Monday of each month at 3:00 PM Eastern time. DLS posts the audio, slides, and transcripts online after each call.

To submit questions for consideration, email 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.

On this page, you can find:

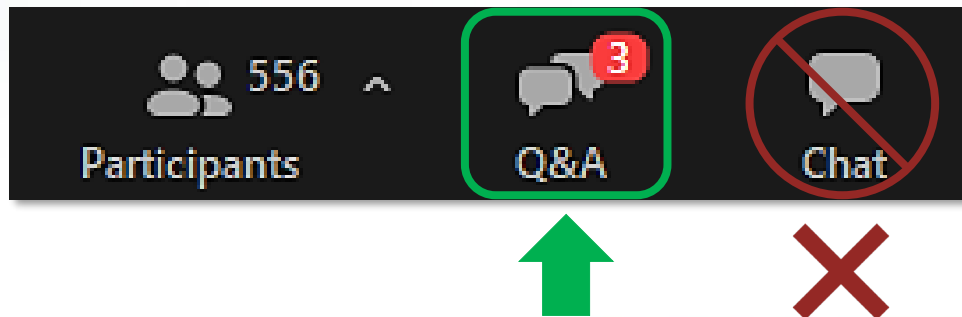
- LOCS Call information
- Transcripts
- Slides
- Audio Recordings

<https://www.cdc.gov/locs/calls>

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



Division of Laboratory Systems

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.



Situational Update and Response to the Highly Pathogenic Avian Influenza A(H5N1) Outbreak in U.S. Dairy Cattle

Todd Davis

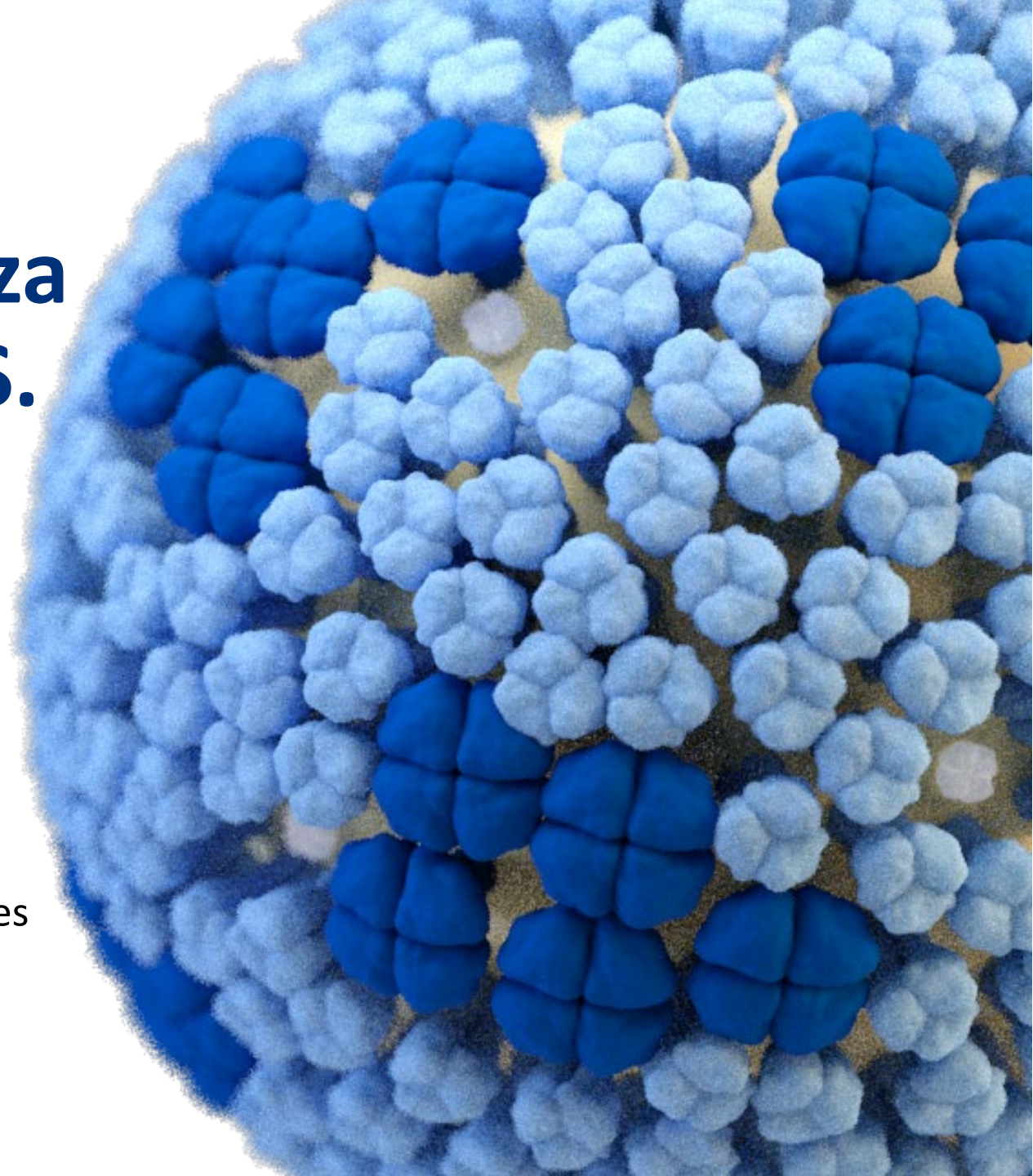
Branch Chief (acting)

Virology, Surveillance, and Diagnosis Branch

Influenza Division

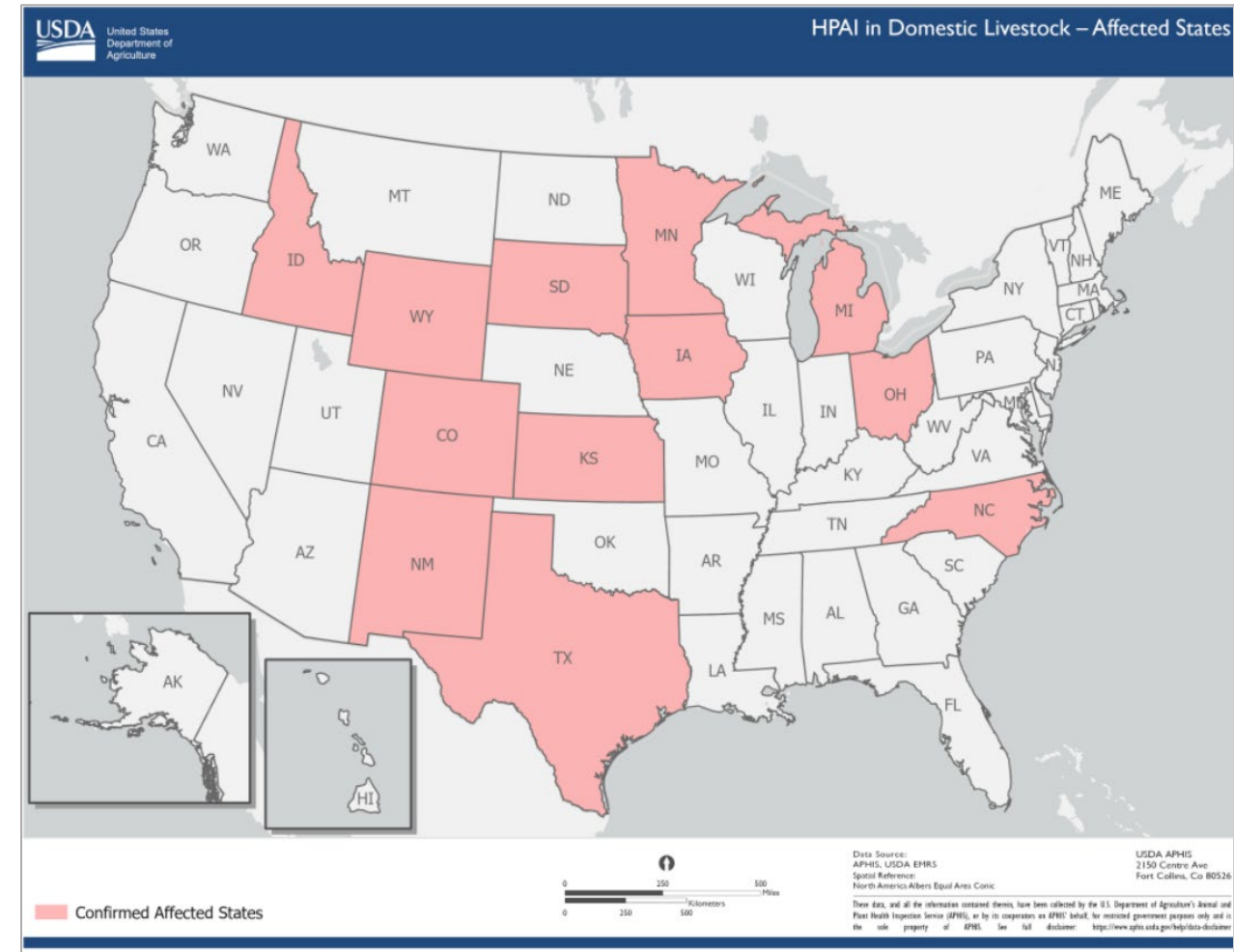
National Center for Immunization and Respiratory Diseases

Centers for Disease Control and Prevention



H5N1 in U.S. Cattle, 2024

- As of June 13, 2024, USDA has confirmed HPAI in dairy herds in **95** farms across **12** states:
 - CO (5), ID (22), IA (2), KS (4), MI (25), MN (3), NC (1), NM (8), OH (1), SD (5), TX (18), **WY (1)**
- Other animal species reported on dairy premises:
 - 5 wild birds (2 TX farms)
 - 6 wild foxes (1 NM, 1 MI farm)
 - 11 cats (3 MI, 3 NM, 1 OH, 3 TX farms)
 - 1 racoon (NM)
 - 2 opossums (MI)
- WI & MN to require neg H5N1 test for lactating dairy cattle in fairs & exhibitions



Monitoring of Exposed Persons

Monitoring Strategies

- Active outreach to states with positive cattle herds
- Human monitoring and testing in states
- Enhanced influenza surveillance
- Planned epidemiologic studies

Since Feb 2022

- CDC and state and local health departments actively monitor people exposed to infected birds, poultry or other animals for 10 days after exposure
 - At least 9,500 people monitored and
 - At least 350 people tested for novel influenza A

Current outbreak (2024)

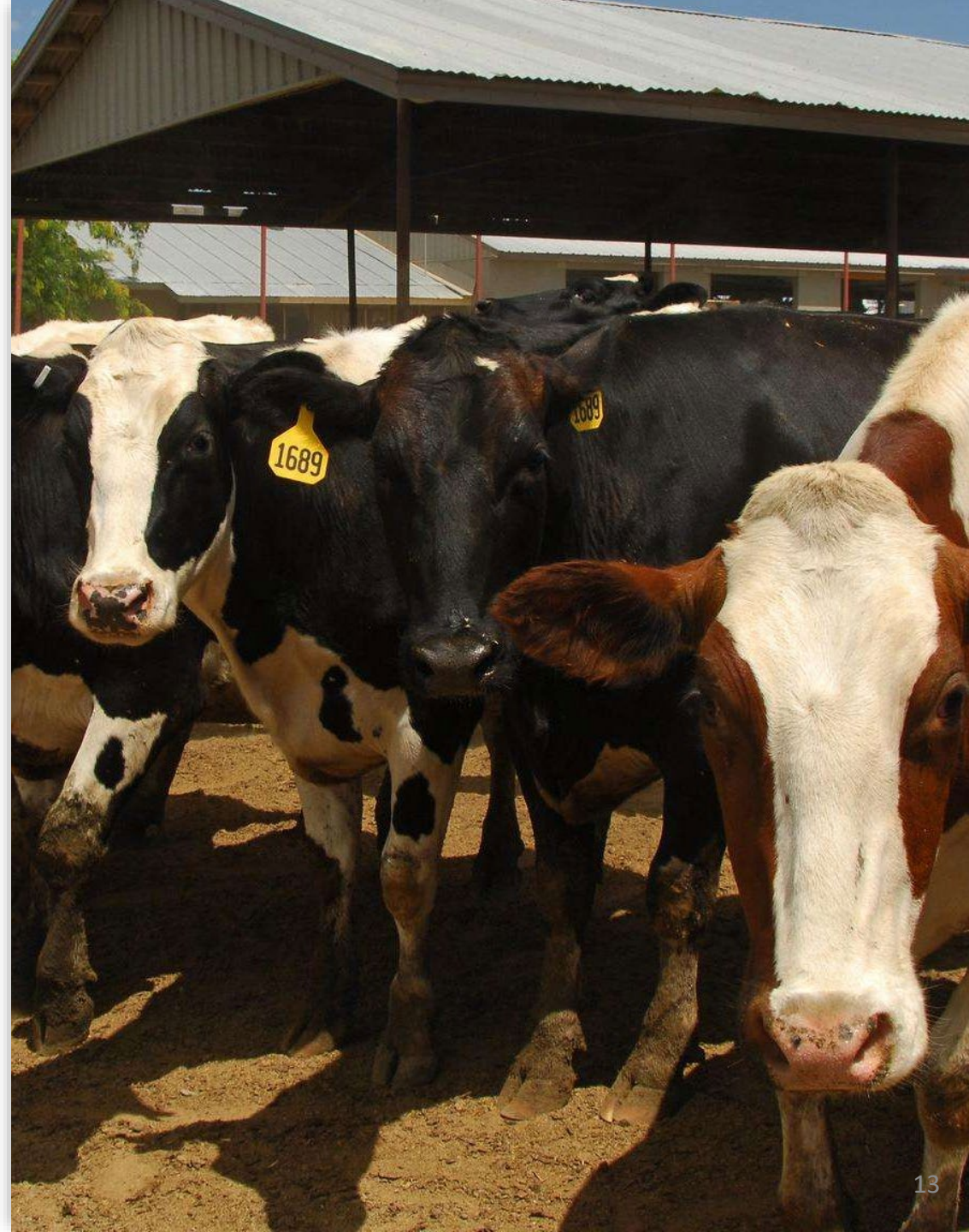
- >550 people actively monitored
- Additional persons passively monitored
- States and CDC have tested >45 persons
- **Three cases identified; all recovered**

The screenshot shows the CDC website page for 'Highly Pathogenic Avian Influenza A(H5N1) Virus in Animals: Interim Recommendations for Prevention, Monitoring, and Public Health Investigations'. The page is titled 'Influenza (Flu)' and 'Avian Flu > Information for Specific Groups'. The main content area features a 'Summary' section with the text: 'The purpose of this guidance is to outline CDC's recommendations for preventing exposures to highly pathogenic avian influenza (HPAI) A(H5N1) viruses, infection prevention and control measures including the use of personal protective equipment, testing, antiviral treatment, patient investigations, monitoring of exposed persons, including persons exposed to sick or dead wild and domesticated animals and livestock with suspected or confirmed infection with highly pathogenic avian influenza (HPAI) A(H5N1) virus, and antiviral chemoprophylaxis of exposed persons. These recommendations are based on information available as of March 2024 and will be updated as needed when new information becomes available.' A 'Background' section is also visible. On the right side, there is a 'On This Page' section with links to 'Summary', 'Background', 'Recommendations for the Public', 'Recommendations for Farmers', 'Recommendations for Clinicians', 'Recommendations for State Health Departments', and 'Recommendations for Surveillance and Testing'. The left sidebar contains a navigation menu with items like 'Avian Flu', 'Current Situation', 'Bird Flu in Birds', 'Bird Flu in Pets and Other Animals', 'Bird Flu in People', 'Avian Influenza Type A Viruses', 'Prevention and Antivirals', 'Information for Specific Groups', 'Backyard Flock Owners', and 'Information for People Exposed to'.

[How CDC is monitoring influenza data to better understand the current avian influenza A \(H5N1\) situation in people | Avian Influenza \(Flu\)](#)

H5N1 Human Cases

- Three human cases of HPAI A(H5N1) virus infection associated with dairy cattle
 - April 1 – Texas announced
 - May 22 – Michigan announced
 - May 30 – Michigan announced
- All cases were in adults working at commercial dairy farms
 - No relationship to each other
 - Three different farms
- Two had conjunctivitis, one mild ILI
 - Not hospitalized, all recovered
 - Isolation recommended
- No human-to-human transmission
- Viruses remain



Epidemiologic Investigations

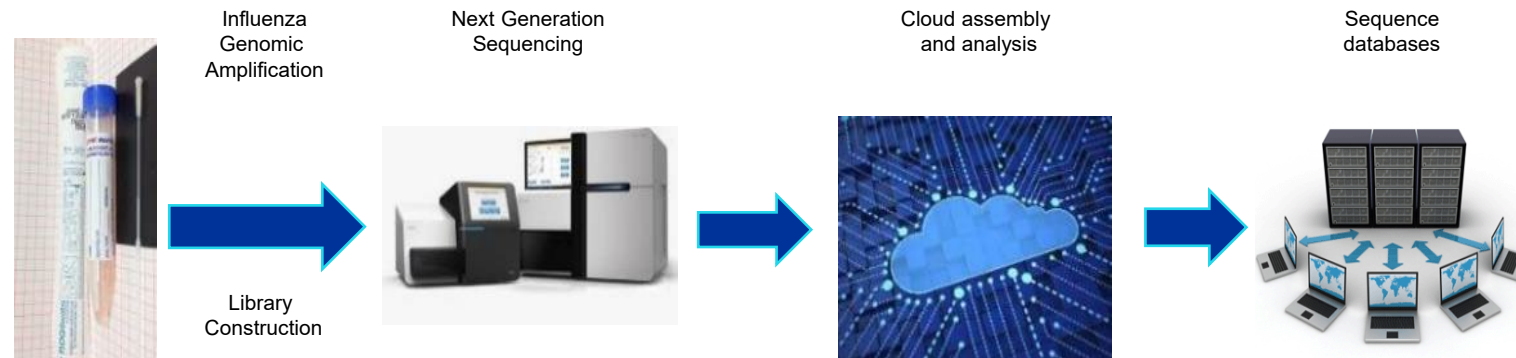
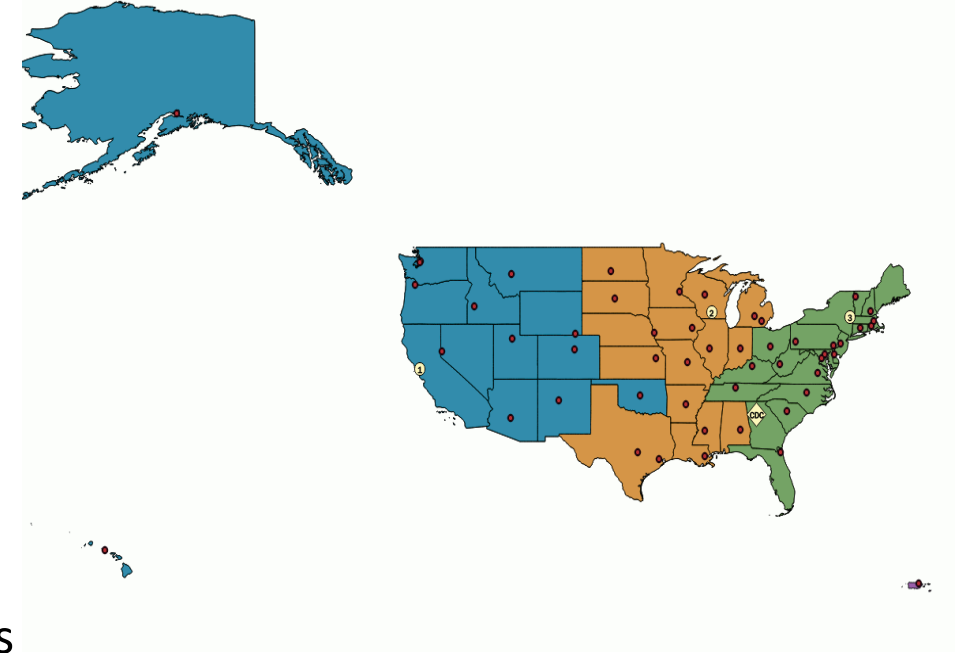
- Working with health and agricultural partners at local, state and federal level, as well as with affected farms
- Important public health questions
 - Is there evidence of infection with HPAI A(H5N1) virus in exposed populations?
 - If we find infections, what is the spectrum of illness and rate of asymptomatic infections?
 - What are the types of exposure to HPAI A(H5N1) virus on farms/dairies?
 - Are any behaviors associated with human infections with HPAI A(H5N1) virus or protection from infection?
- Assess risk for symptomatic and asymptomatic infection through specimen collection and a survey to assess exposures

Enhanced summer surveillance - Epidemiology

1. Symptom monitoring among **workers and others with recent exposures** to HPAI A/H5 infected animals on farms or other locations
2. Conduct **outreach and education to people exhibiting animals** (specifically swine, cattle and avian species) **at or attending agricultural fairs.**
3. Encourage **ongoing influenza testing (preferably RT-PCR) of individuals with compatible illness throughout the summer**, particularly for persons with recent history of relevant exposures
4. Enhance surveillance for novel influenza A detection among **severely ill patients** by subtyping influenza A positive specimens from patients **hospitalized or in the ICU.**
5. Enhance surveillance for novel influenza A detections in the community by maintaining the flow of influenza positive specimens to and subtyping of influenza A positives by public health laboratories and **investigation of unexplained clusters of respiratory illness.**
6. Monitor influenza surveillance data for any **unexpected patterns.**
7. Local **data anomaly** detection and investigation.

Expanded Influenza Genomics and Analysis Capacity

- CDC sequences ~6,000 viruses each year
- National Influenza Reference Centers (NIRCS)
 - Wisconsin State Lab of Hygiene
 - New York Department of Health
 - California Department of Public Health
- Expansion to additional state and local public health labs
 - Influenza Sequencing Centers (ISCs)
 - Colorado, Florida, Hawaii, Massachusetts, Minnesota, Texas



Enhanced summer surveillance - Laboratory

CDC requests commercial laboratories continue to send the following specimens to PHLs as soon as possible for further testing and characterization.

1. Influenza A positive specimens that are subtype negative on tests designed to provide an influenza subtyping result **and confirmed upon retest.**
2. Influenza A positive specimens that are subtype influenza A(H1) and not influenza A(H1)pdm09 on tests designed to provide an influenza subtyping result **and confirmed upon retest.**

Acceptable sample types for use of CDC's A/H5 assay:

- Human upper respiratory specimens from patients with signs and symptoms of respiratory infection
- Human lower respiratory tract specimens from patients with signs and symptoms of respiratory infection
- Paired nasopharyngeal/ conjunctival specimens

Enhanced Surveillance to subtype more samples

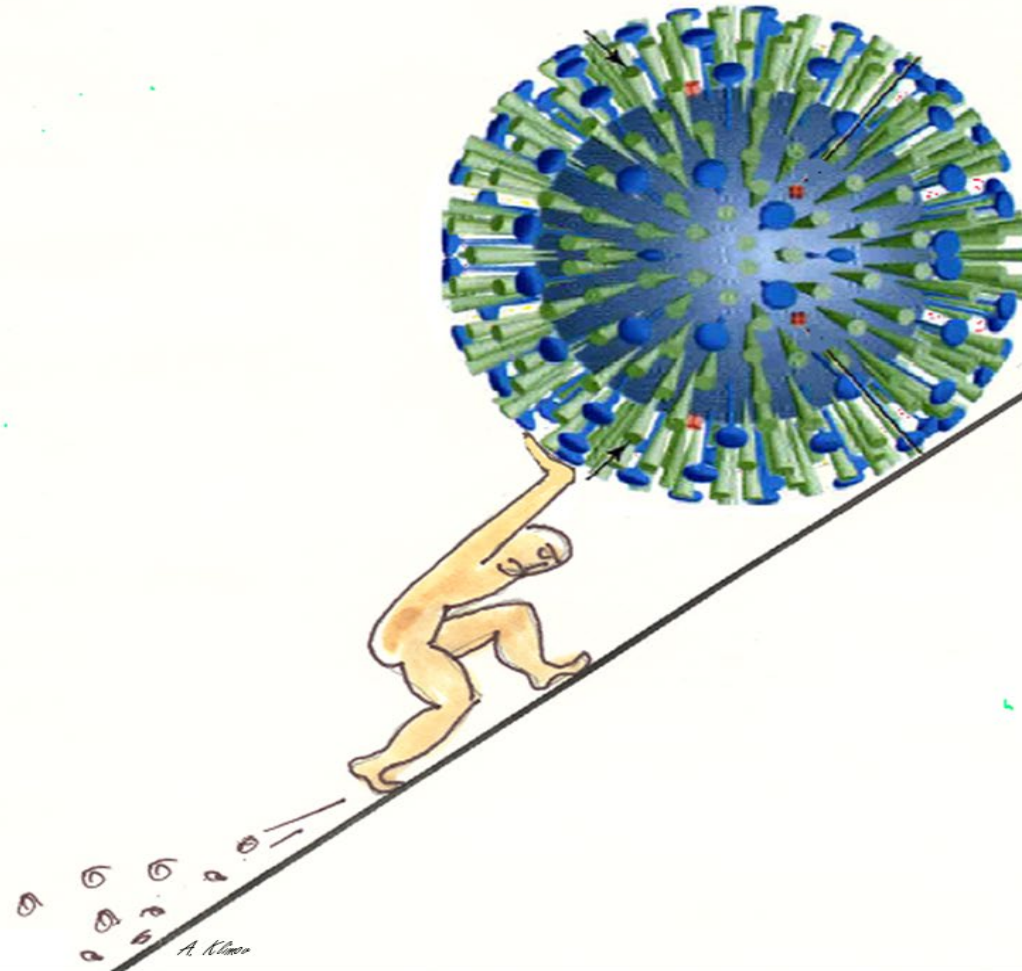
- Influenza A and B positive specimens that have not undergone influenza subtyping
 - Determine an appropriate number of samples each month
 - Samples that meet the established assay cutoff of your testing method to identify positive samples.
 - Determine a process by which samples will be submitted to state and local public health laboratories or national reference laboratories for subtyping

Diagnostic testing

- **FDA granted enforcement discretion for the use of conjunctival swabs with the CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel, Influenza A/H5 Subtyping Kit**
 - Public health laboratories may use of conjunctival swabs with this test
 - Must be paired testing of conjunctival specimens with testing of a nasopharyngeal swab
 - Using swabs and transport media currently included in the current CDC test's instructions for use
 - PHLs must perform in-house verification performance studies; CMS guidelines.
- USDA/APHIS issued a temporary exemption of H5 avian influenza viruses as a Select Agent for 3 years
- Call to Industry to seek proposals for the OTA (Other Transaction Authority) to develop commercial H5 assays is live at www.sam.gov.
 - [CDC Open Call to Industry – Influenza A\(H5\) Diagnostic Test Development and Validation](#)
- Drafting recommendations/protocol for conjunctival sample collection methods for healthcare providers
- Working with FDA to consider addition of Universal Transport Media for sample collection of specimens tested by CDC's H5 assay

Thank you!

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.



SARS-CoV-2 viral shedding and rapid antigen test performance

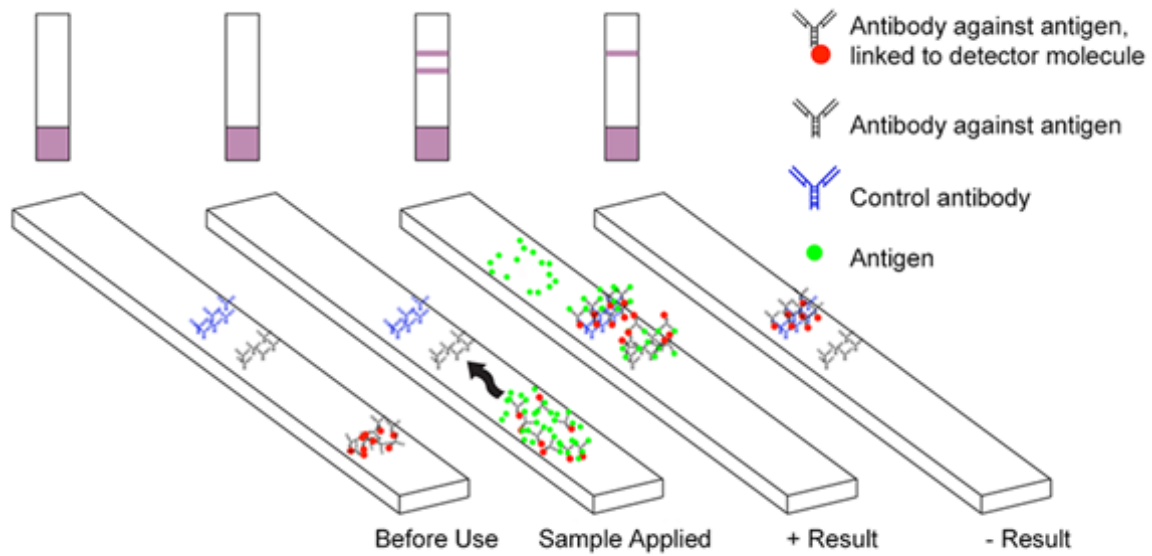
Respiratory Virus Transmission Network, November 2022–May 2023

Lizzy Smith-Jeffcoat, MPH

Epidemiology Branch, CORVD, NCIRD, CDC

CDC's Laboratory Outreach Communication System Call
June 17, 2024

Background



Adapted from: Ian M. Campell, https://commons.wikimedia.org/wiki/File:Diagnostic_Medical_Dipstick.png

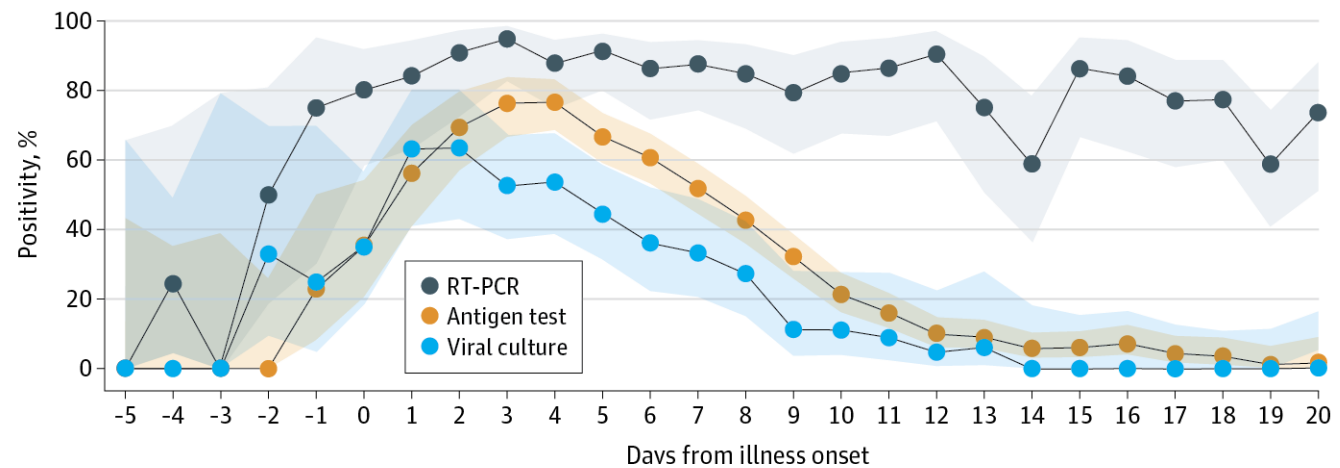


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Background

- Previous studies have shown that rapid antigen tests are less sensitive than RT-PCR, but closely correlate with viral culture
- Role and performance of antigen tests in diagnosing SARS-CoV-2 has been questioned as variants and population immunity have evolved

Comparison of Home Antigen Testing With RT-PCR and Viral Culture During the Course of SARS-CoV-2 Infection, January–April 2021



Objective: To reevaluate the performance characteristics of SARS-CoV-2 antigen tests with those of RT-PCR and viral culture during early 2023

Respiratory Virus Transmission Network

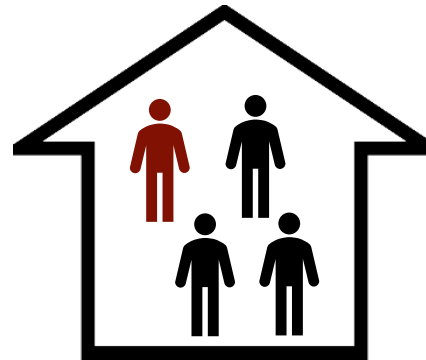
Antigen/culture sub-study

Individuals testing
positive for SCV2

Symptomatic

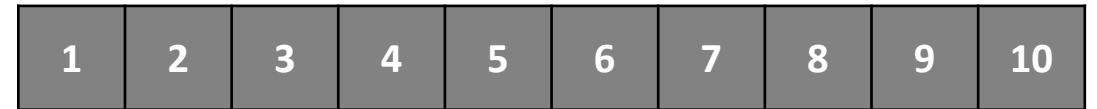


0-6 days post-onset/test



HH enrolled

Specimens sent to central testing lab



Daily symptom diaries
2 x Daily nasal swabs

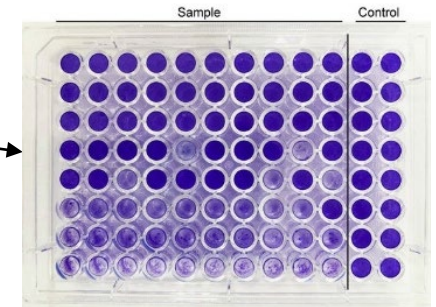
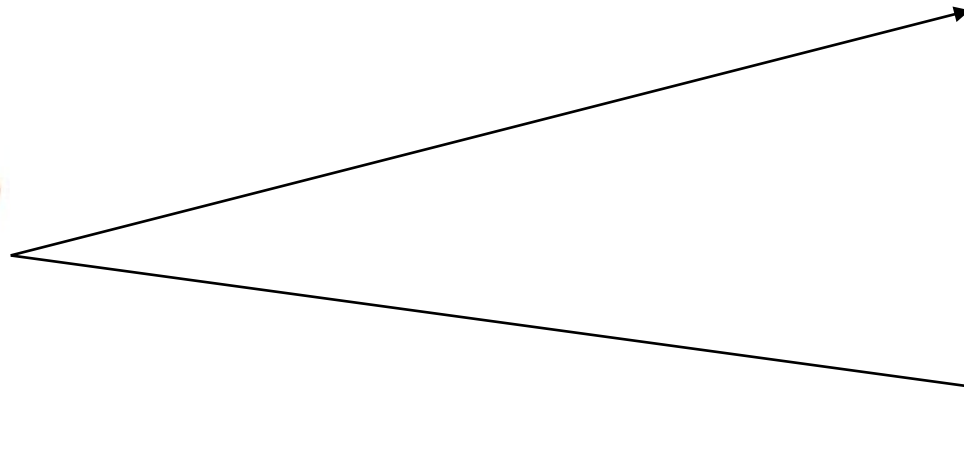
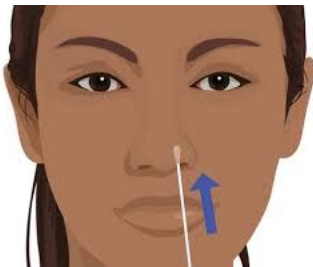
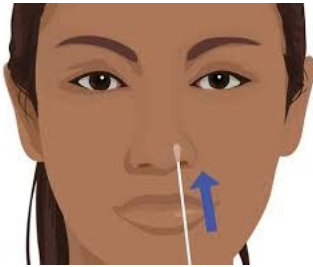
**Baseline
participant
surveys**

Asymptomatic

Respiratory Virus Transmission Network

Antigen/culture sub-study

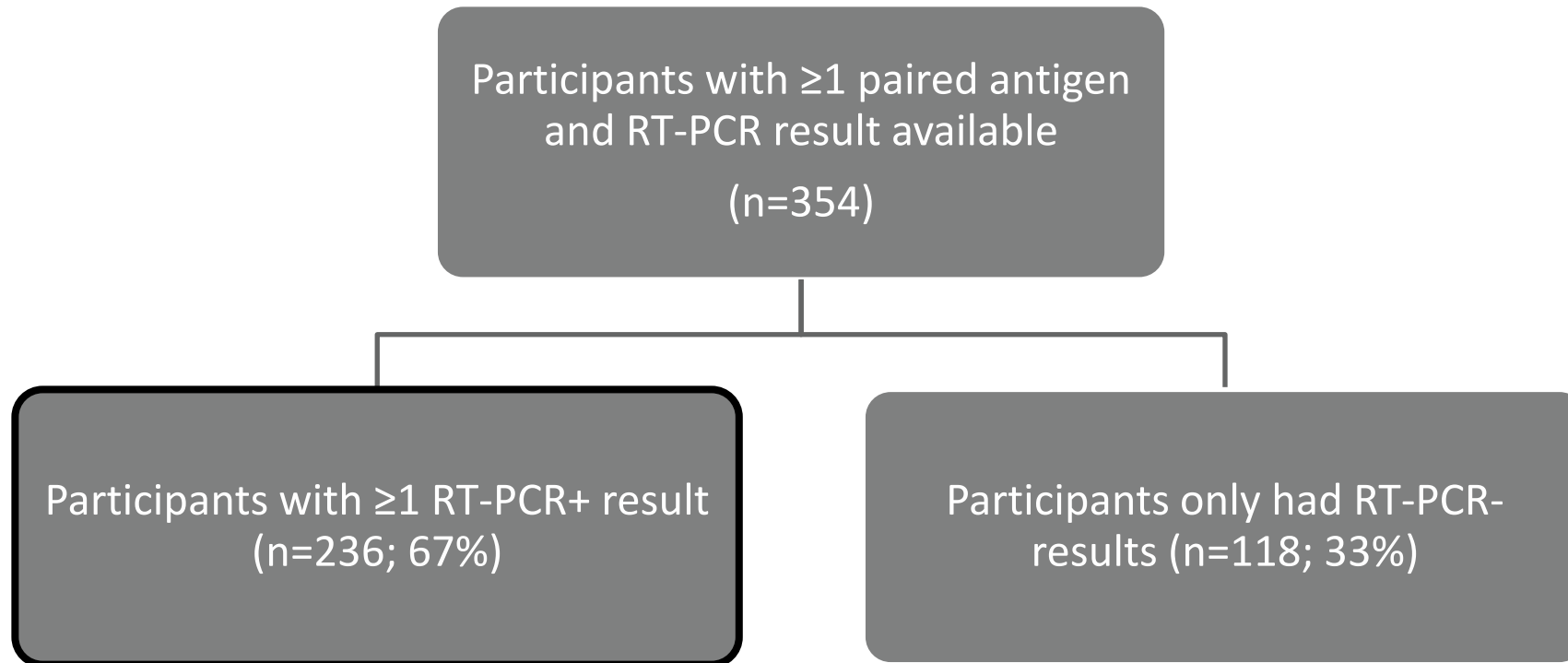
2 x nasal swabs for
10 days



Statistical Methods

- **Onset defined as first day of symptoms or, if asymptomatic, day of positive test**
- **Viral shedding**
 - Percentage of positive rapid antigen, RT-PCR, and viral culture results each day post onset
 - Wilson score intervals to calculate 95% CI
- **Antigen test sensitivity**
 - Two references:
 - 1) same-day positive RT-PCR result
 - 2) same-day positive culture result
 - Stratified by symptom status, presence of fever or cough, and presence of fever alone
 - Cluster-robust bootstrapping to calculate 95% CI

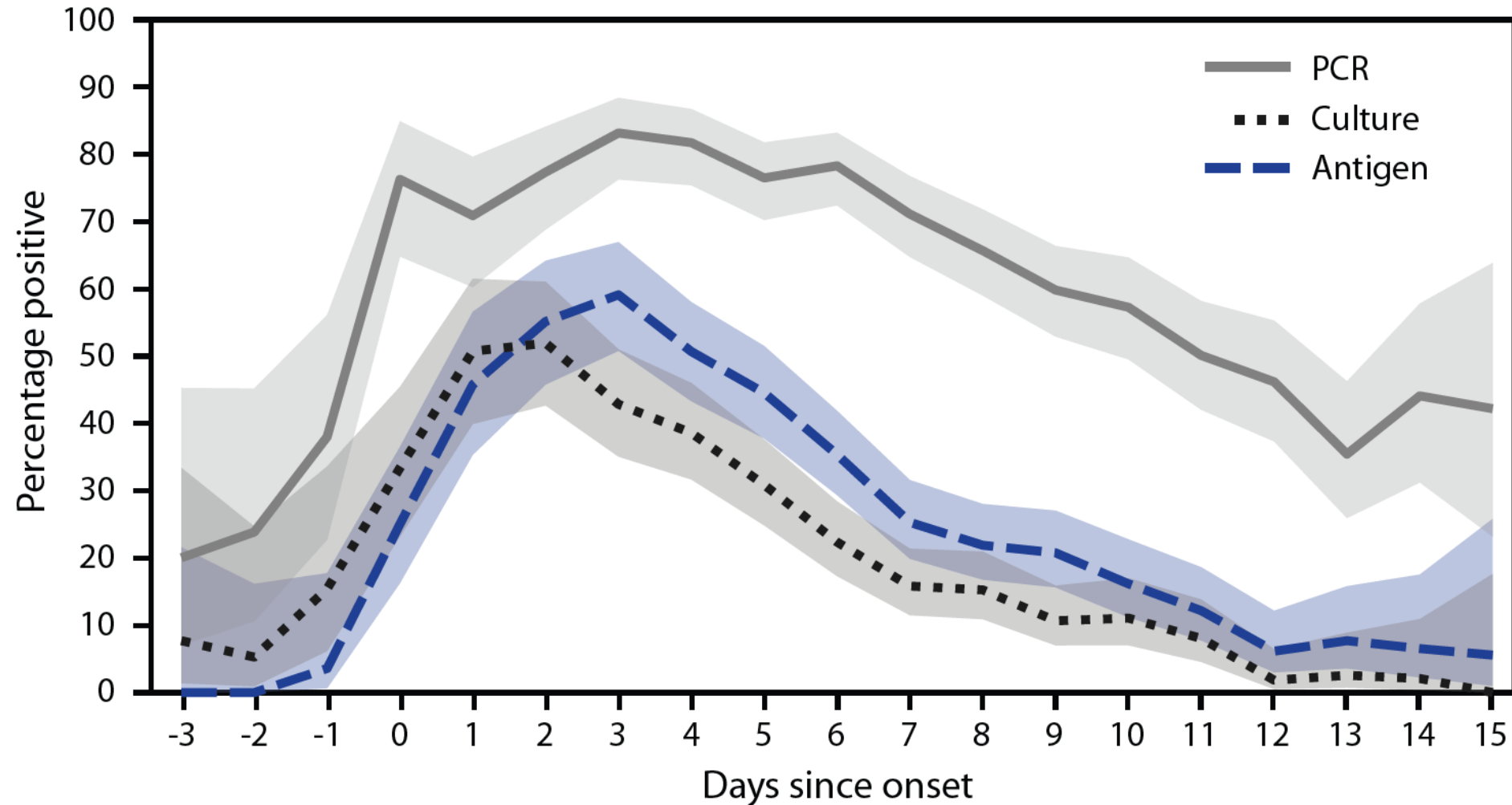
Analytic Population



Participant Characteristics

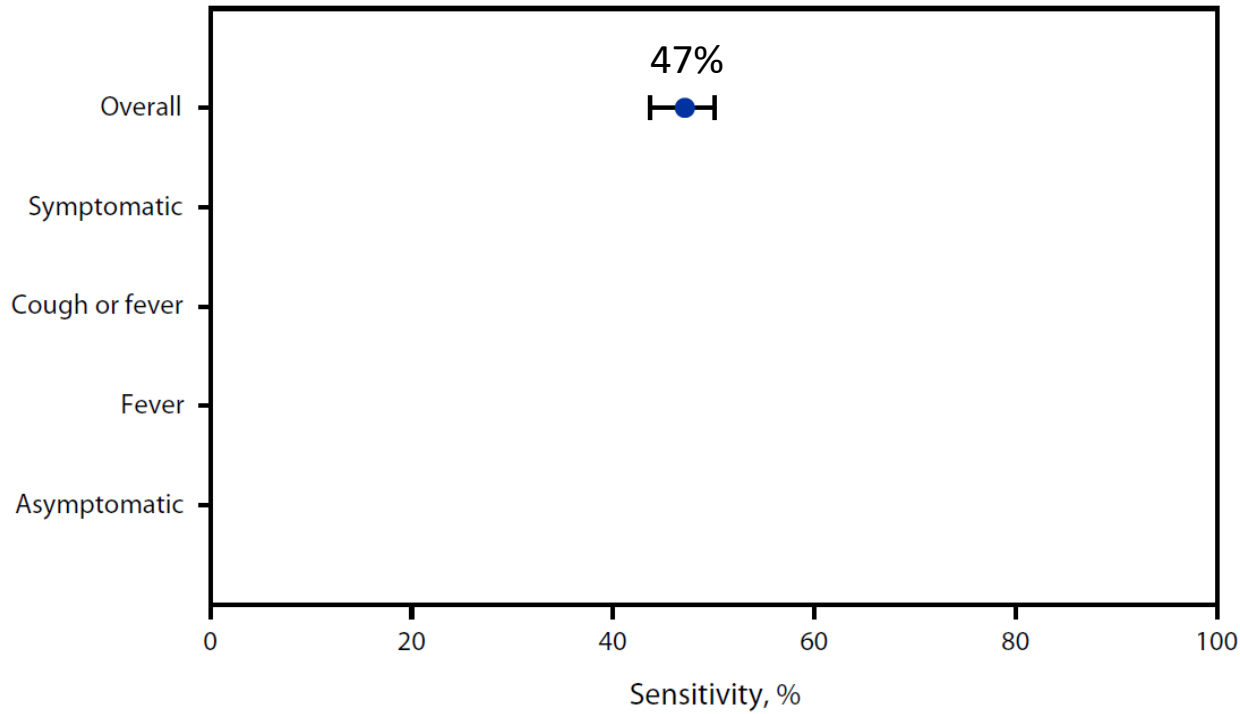
Characteristic	N = 236¹
Age at enrollment, years	36 (17, 50)
Female gender	140 (59%)
Race/ethnicity	
White, Non-Hispanic	133 (56%)
Hispanic/Latino	69 (29%)
Black, Non-Hispanic	17 (7.2%)
Other	14 (5.9%)
Unk/Refused	3 (1.3%)
Social Vulnerability Index	0.43 (0.19, 0.80)
Any chronic medical condition	110 (47%)
Any COVID-19 symptom	219 (93%)
Any prior COVID (self-reported or anti-N)	102 (43%)
Vaccinated \leq 12 month before enrollment	92 (40%)

SARS-CoV-2 viral shedding by RT-PCR, rapid antigen, and viral culture tests

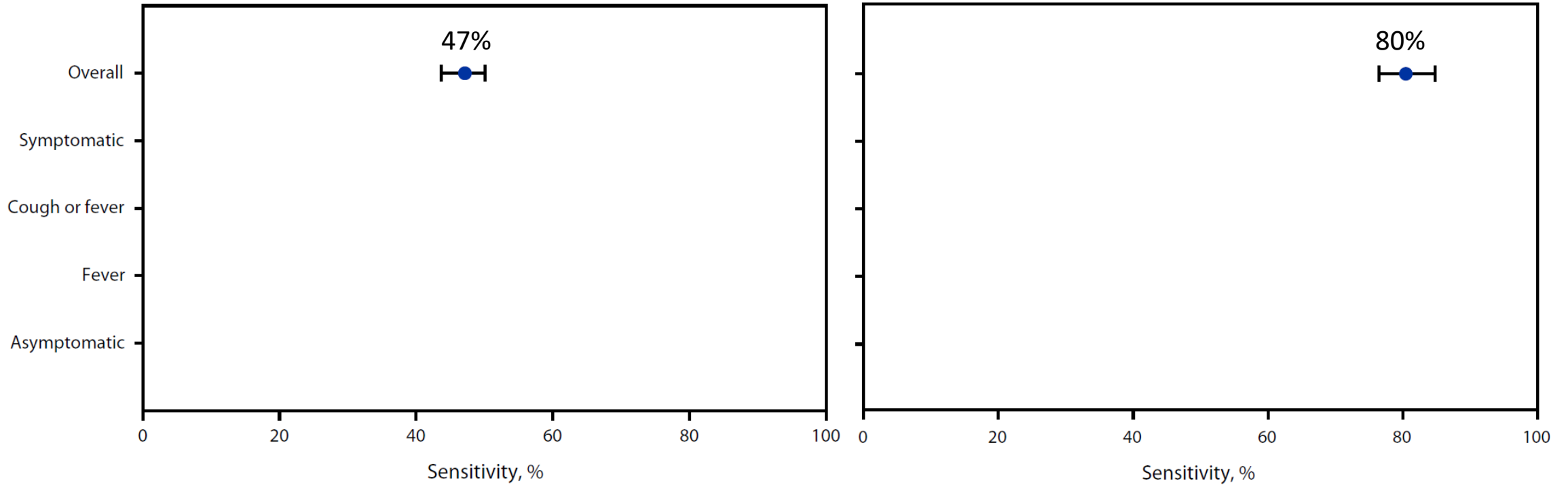


Rapid antigen test sensitivity

Compared to RT-PCR

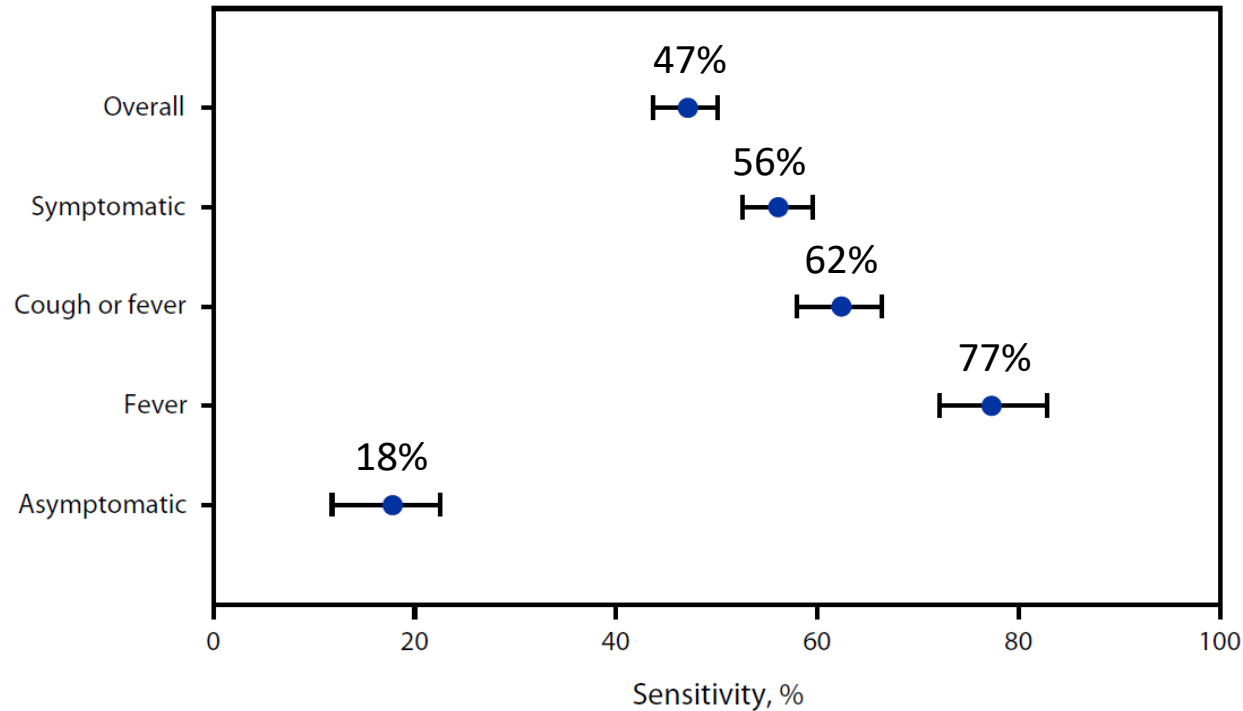


Compared to culture

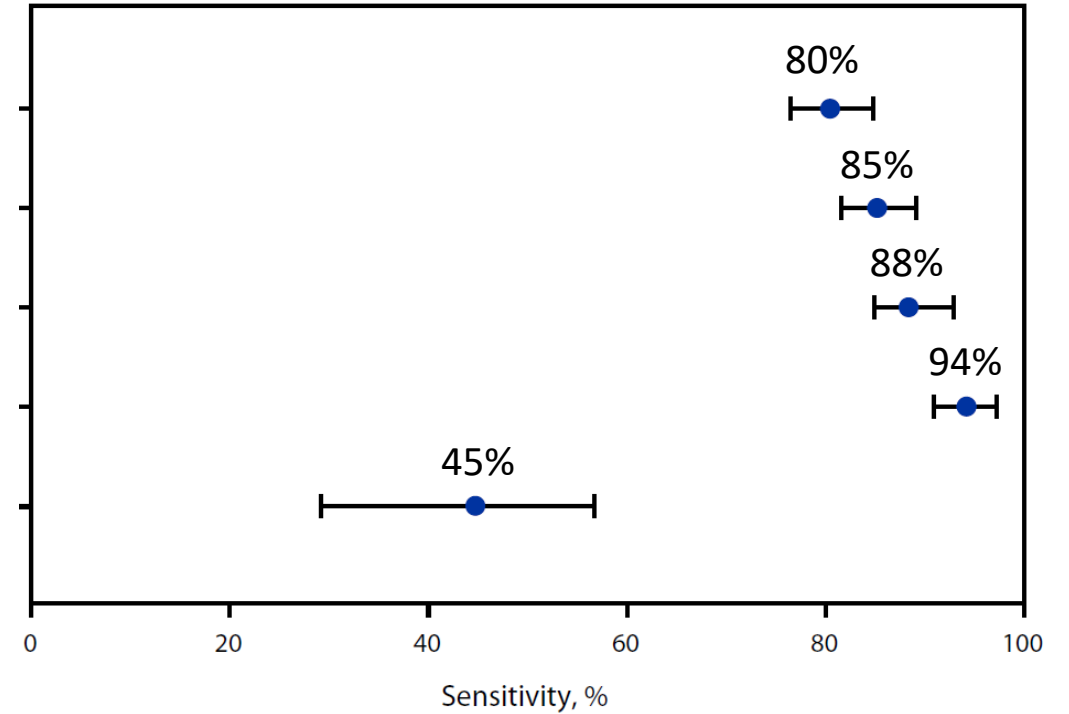


Rapid antigen test sensitivity

Compared to RT-PCR



Compared to culture



Conclusions

- **Rapid antigen and viral culture detected similar proportion of infections, but detection by RT-PCR was higher**
- **Rapid antigen tests remain less sensitive than RT-PCR (47%), but similar to viral culture (80%)**
- **Rapid antigen test sensitivity was higher when symptoms were present**

Public Health Implications

- **Findings are similar, but context is different**
 - High population immunity
 - Lower hospitalization and death rates
 - Several outpatient antiviral treatments available
- **Patients at higher risk for severe illness and eligible for antiviral treatments would benefit from RT-PCR or other high sensitivity diagnostic soon after symptom onset**
 - If not available, follow FDA's serial antigen testing recommendations

Thank you!

Questions?

Lizzy Smith-Jeffcoat, uyi7@cdc.gov

- CDC RVTN Team

- Lexie Mellis
- Jessica Biddle
- Hannah Kirking
- Phil Salvatore

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 cdc.gov

- RVTN Collaborating Institutions

- Vanderbilt University Medical Center
- Columbia University/New York-Presbyterian Hospital
- Marshfield Clinic Research Institute
- University of Arizona
- Children's Hospital Colorado
- Emory University

- RVTN Participants

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the U.S. Centers for Disease Control and Prevention.



Next Scheduled Call

Monday, July 15
3 PM - 4 PM ET



<https://www.cdc.gov/locs/calls>

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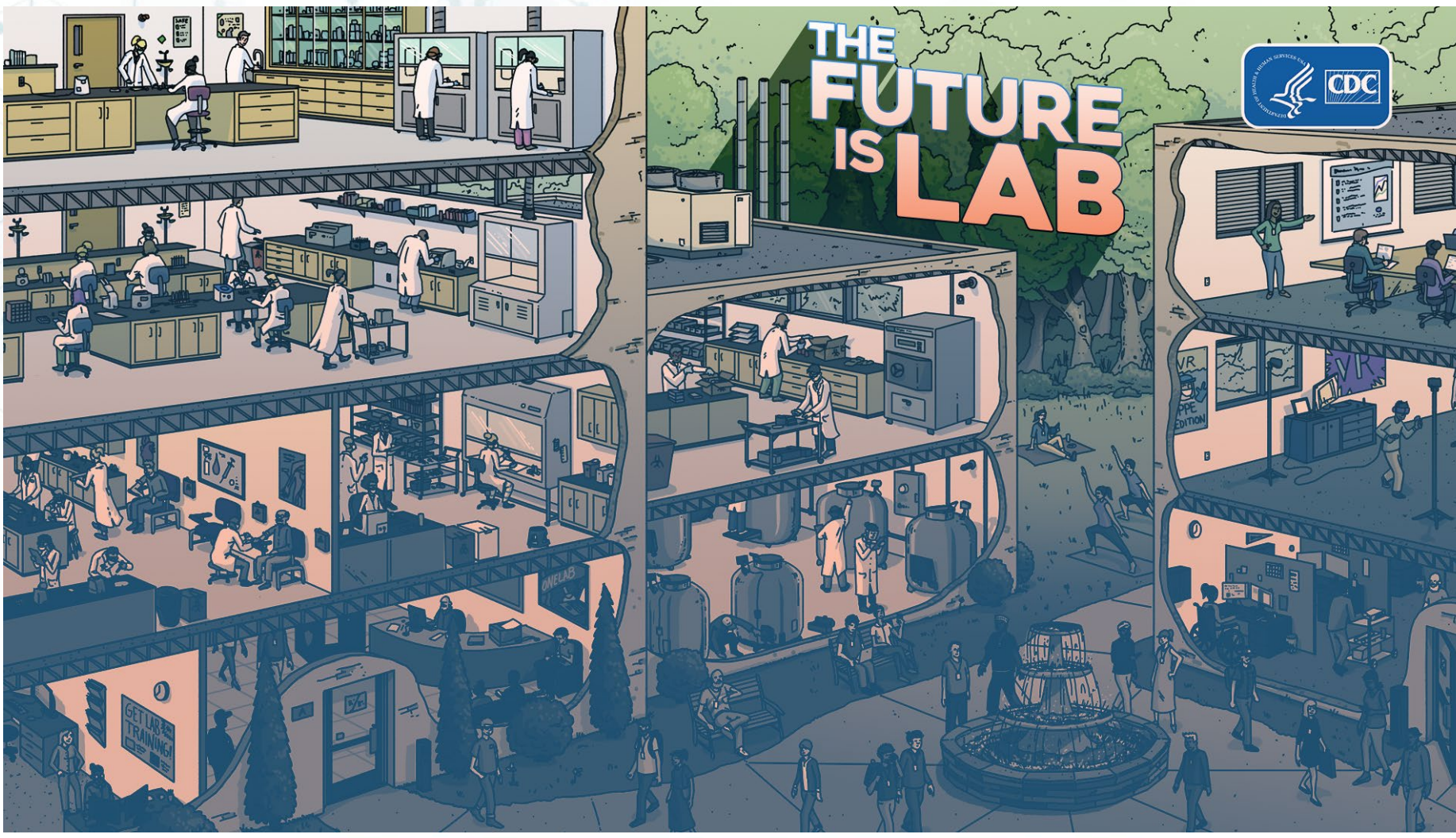
<https://twitter.com/cdcgov>

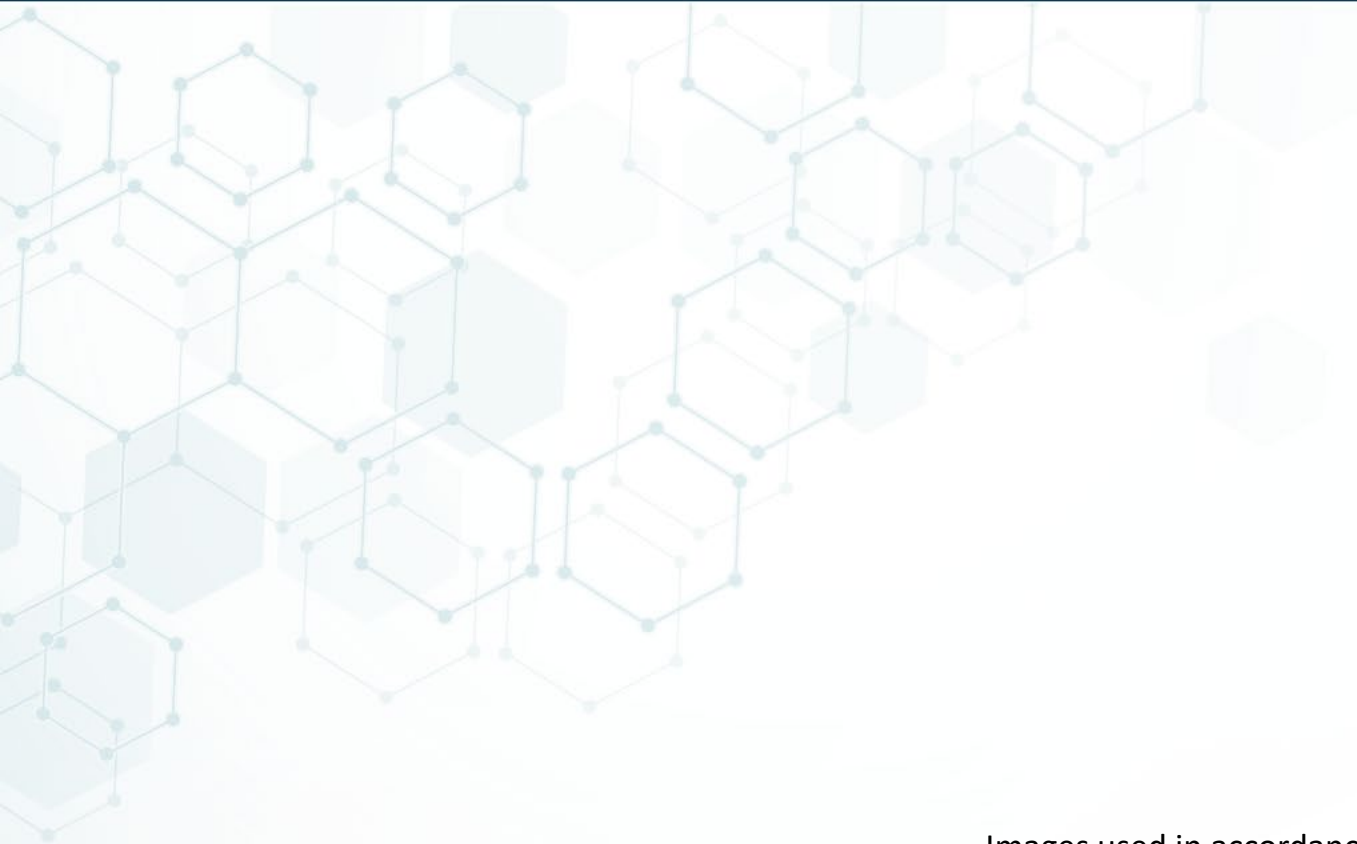
<https://www.instagram.com/cdcgov>



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

Thank You For Your Time!





For more information, contact CDC
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