

Clinical Laboratory COVID-19 Response Call

Monday, November 16th, 2020 at 3:00 PM ET

- **Welcome**

- Jasmine Chaitram, CDC Division of Laboratory Systems (DLS)

- **ASM's Clinical Microbiology Supply Shortage Collection (CMSSC) Tool: Identifying Lab Supply Shortages in Real Time**

- Melissa Miller, American Society for Microbiology (ASM)

- **Evaluating the Sofia SARS Antigen FIA for Asymptomatic and Symptomatic SARS-CoV-2 Testing on Two University Campuses – Wisconsin, Sep 29 - Oct 9, 2020**

- Ian Pray, Wisconsin Department of Health Services

- **FDA Update**

- Tim Stenzel, U.S. Food and Drug Administration (FDA)

Schedule for Clinical Laboratory COVID-19 Response Calls

The next call will be on **Monday, November 30rd**
from **3:00 PM to 4:00 PM ET**



We Want to Hear From You!

Training and Workforce Development

Questions about education and training?

Contact LabTrainingNeeds@cdc.gov



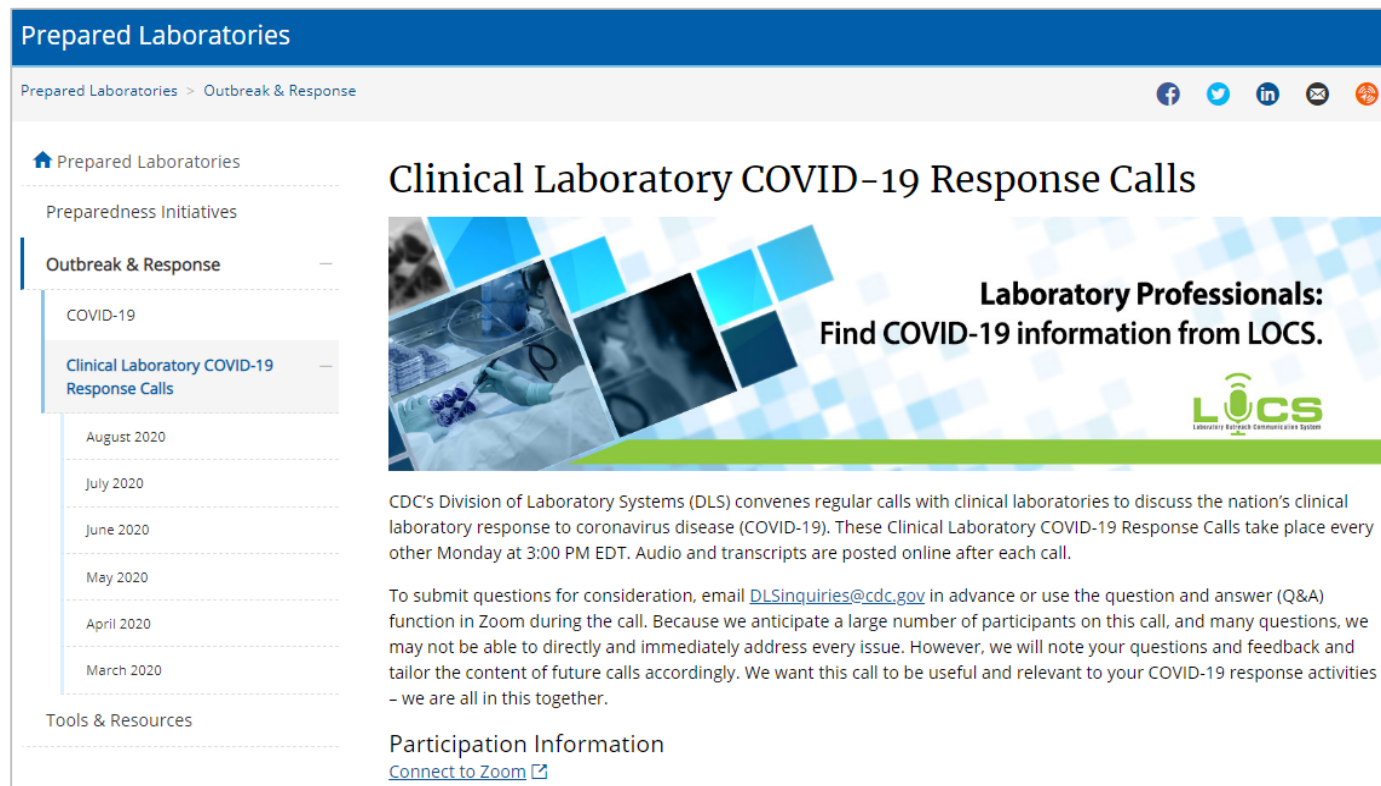
COVID-19 Resources for Laboratories

- **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/>

CDC Preparedness Portal

<https://www.cdc.gov/csels/dls/preparedlabs/covid-19-clinical-calls.html>

Find CLCR call information, transcripts, & audio recordings on the Preparedness Portal



The screenshot shows the 'Prepared Laboratories' section of the CDC website. The main heading is 'Clinical Laboratory COVID-19 Response Calls'. Below the heading is a banner image with the text 'Laboratory Professionals: Find COVID-19 information from LOCS.' and the LOCS logo. The page includes a sidebar with a navigation menu, a main content area with introductory text and a 'Participation Information' link, and a footer with social media icons.

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 Communication and Support System

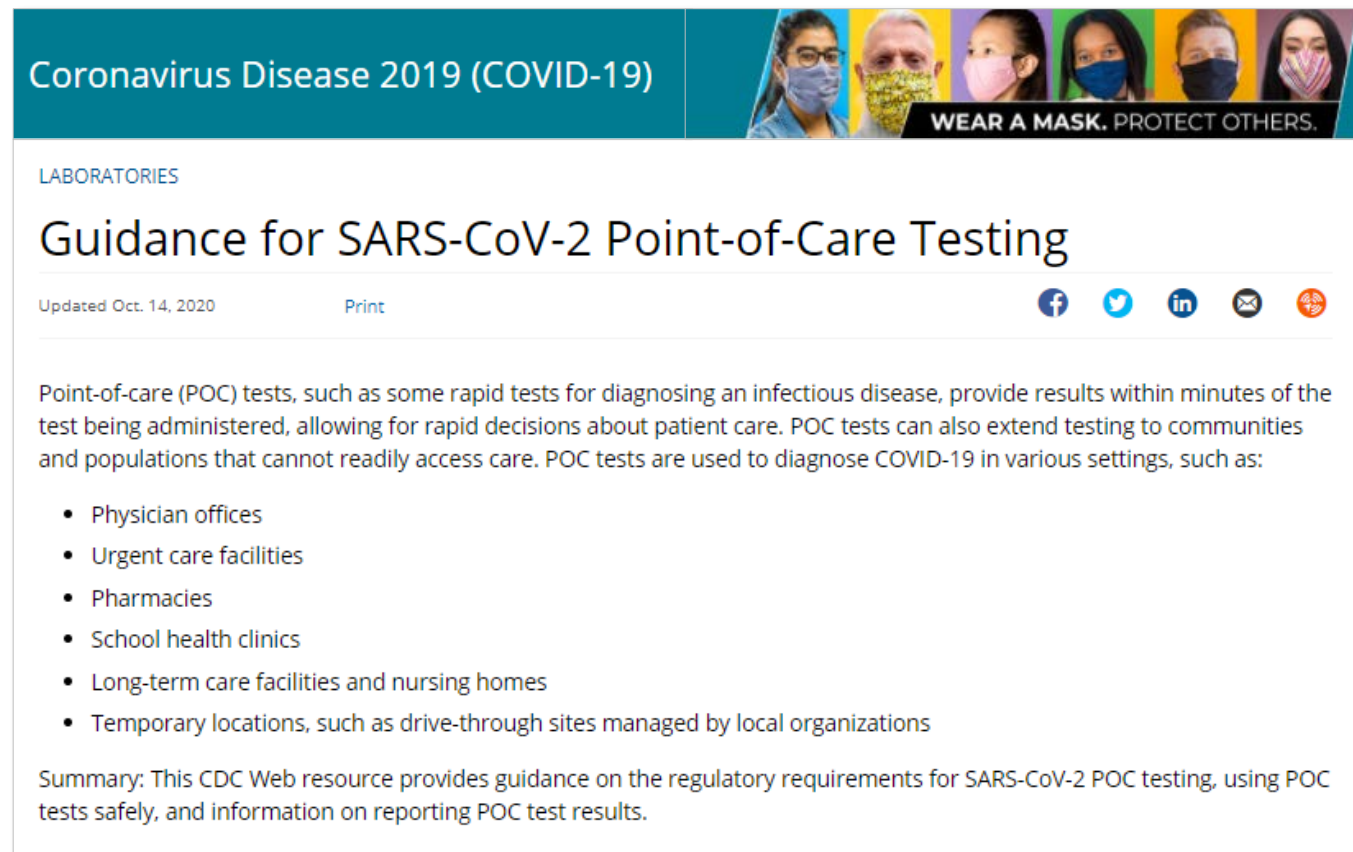
CDC's Division of Laboratory Systems (DLS) convenes regular calls with clinical laboratories to discuss the nation's clinical laboratory response to coronavirus disease (COVID-19). These Clinical Laboratory COVID-19 Response Calls take place every other Monday at 3:00 PM EDT. Audio and transcripts are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

To submit questions for consideration, email DLInquiries@cdc.gov 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](#)

Guidance for SARS-CoV-2 Point-of-Care Testing

<https://www.cdc.gov/coronavirus/2019-ncov/lab/point-of-care-testing.html>



The screenshot shows the top portion of a CDC webpage. At the top left, it says "Coronavirus Disease 2019 (COVID-19)". To the right is a banner with six diverse people wearing face masks and the text "WEAR A MASK. PROTECT OTHERS." Below this, the word "LABORATORIES" is displayed. The main title of the page is "Guidance for SARS-CoV-2 Point-of-Care Testing". Underneath the title, it says "Updated Oct. 14, 2020" and "Print". There are social media sharing icons for Facebook, Twitter, LinkedIn, Email, and Print. The main text begins with "Point-of-care (POC) tests, such as some rapid tests for diagnosing an infectious disease, provide results within minutes of the test being administered, allowing for rapid decisions about patient care. POC tests can also extend testing to communities and populations that cannot readily access care. POC tests are used to diagnose COVID-19 in various settings, such as:" followed by a bulleted list of settings. At the bottom, there is a "Summary" section.

Coronavirus Disease 2019 (COVID-19)

WEAR A MASK. PROTECT OTHERS.

LABORATORIES

Guidance for SARS-CoV-2 Point-of-Care Testing

Updated Oct. 14, 2020 Print

Point-of-care (POC) tests, such as some rapid tests for diagnosing an infectious disease, provide results within minutes of the test being administered, allowing for rapid decisions about patient care. POC tests can also extend testing to communities and populations that cannot readily access care. POC tests are used to diagnose COVID-19 in various settings, such as:

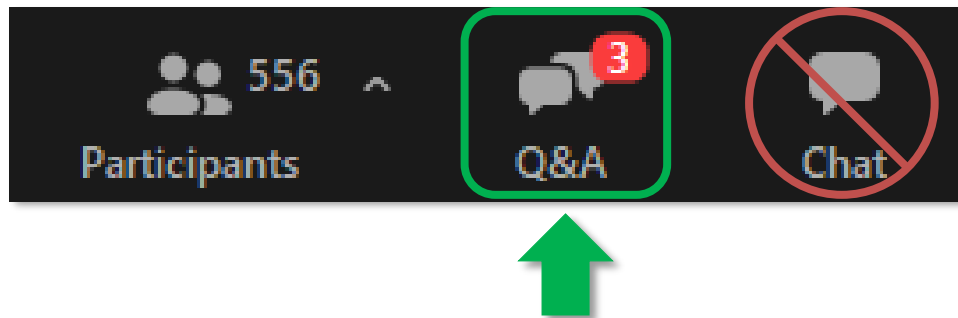
- Physician offices
- Urgent care facilities
- Pharmacies
- School health clinics
- Long-term care facilities and nursing homes
- Temporary locations, such as drive-through sites managed by local organizations

Summary: This CDC Web resource provides guidance on the regulatory requirements for SARS-CoV-2 POC testing, using POC tests safely, and information on reporting POC test results.

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**

ASM's Clinical Microbiology Supply Shortage Collection (CMSSC) Tool

Identifying Lab Supply Shortages in Real Time



AMERICAN
SOCIETY FOR
MICROBIOLOGY



Shortages of COVID-19 testing kits and other supplies

Tracking lab supply shortages to make data-driven decisions

- ASM, in partnership with the Association for Supply Chain Management (ASCM), developed an online platform to track supply shortages in clinical labs
- Began collecting data from CLIA-certified labs on September 11th
 - A survey was issued weekly to our national network of 300 labs
- We continue to monitor COVID-19 and non-COVID testing supplies to identify shortages in real-time
- Lack of supplies significantly hinders day-to-day laboratory operations



A ripple effect of shortages – Beyond COVID-19 testing

Due to supply chain issues, many labs can't perform routine tests

- **47.4%** face shortages of testing supplies for **detection of routine bacteria** (including the bacteria causing strep throat, pneumonia, bronchitis and urinary tract infections)
- **57.1%** face shortage of supplies for the **molecular detection of sexually transmitted infections**
- **15.4%** face shortages for supplies for **mycobacteria testing**
- **50.0%** face a shortage of supplies for **routine fungal testing** (ranging from superficial, localized skin conditions to deeper tissue infections to serious lung, blood or [systemic](#) diseases).



Advocating for clinical labs

ASM has been a leading voice on addressing supply shortages.

- **Provided Input on FDA Regulations/EUAs**
 - Worked directly with FDA in [Feb-March](#) to allow CLIA-certified labs to use their own tests.
- **Among the First to Sound the Alarm**
 - Published statements as early as [March](#) calling for increased funding to address shortages.
 - Issued [letter](#) to White House Task Force urging transparency of resource allocation.
- **Leading Data Collection**
 - Developed an online platform to monitor and report laboratory shortages and demand
- **Calling on Congress to Provide Continued Relief for COVID-19**
 - Advocated for emergency supplemental appropriations and renewal of PHE declaration



National Overview & Survey Participants

National Overview of U.S. Laboratory COVID-19 Testing

809

**Average Lab
Testing Volume
(Past 7 Days)**

1,686

**Average Lab Testing Capacity
without Resource Constraints**

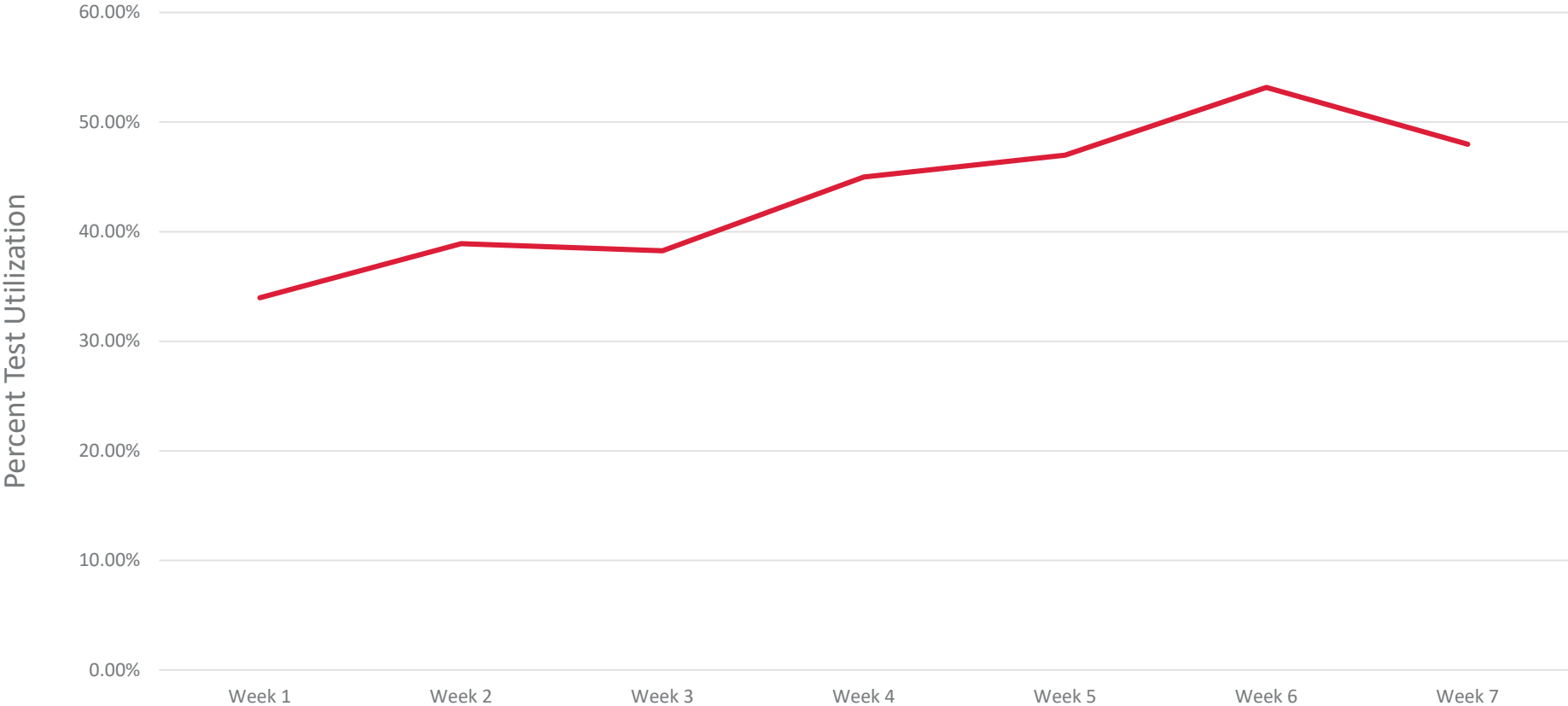
47.9%

**Testing Capacity
Utilization**

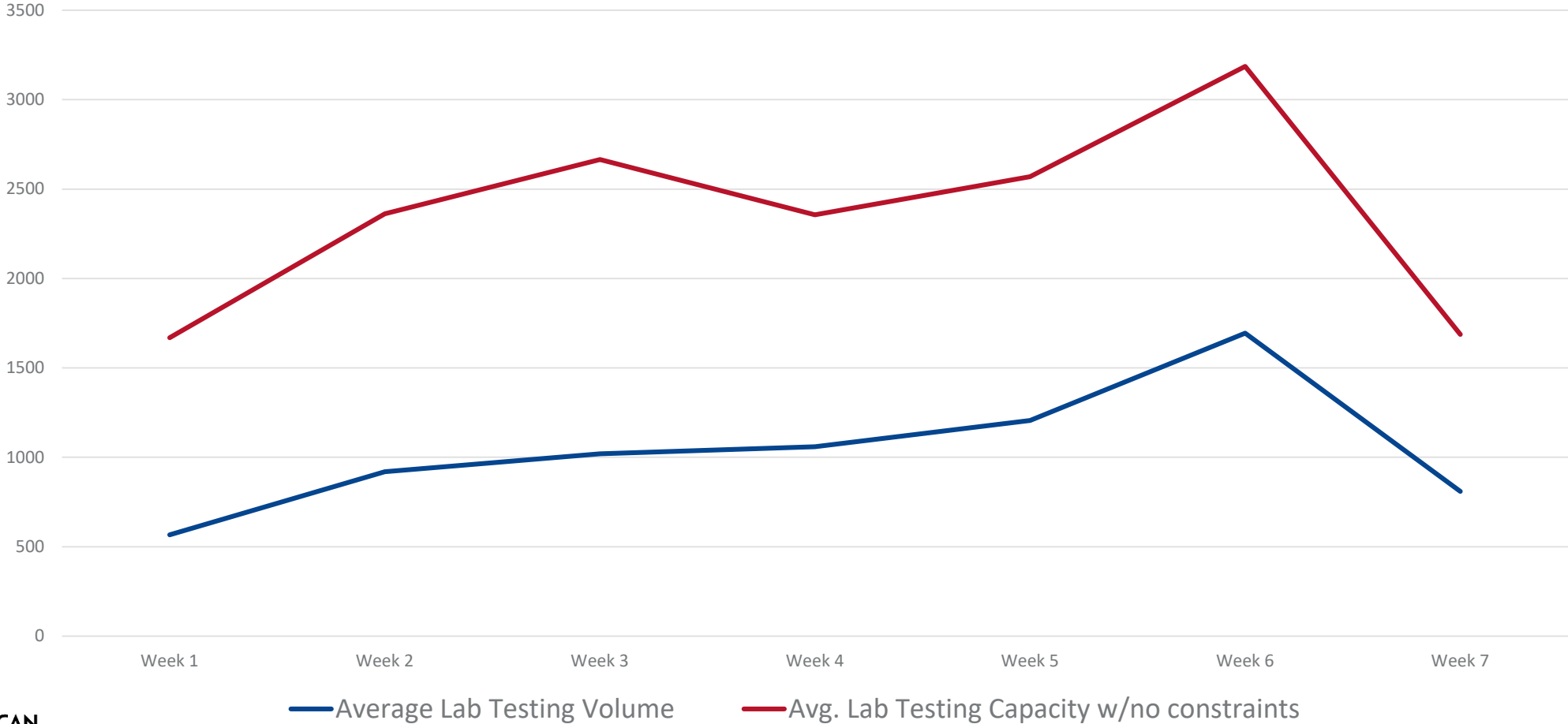
Locations of Labs Testing Below Full



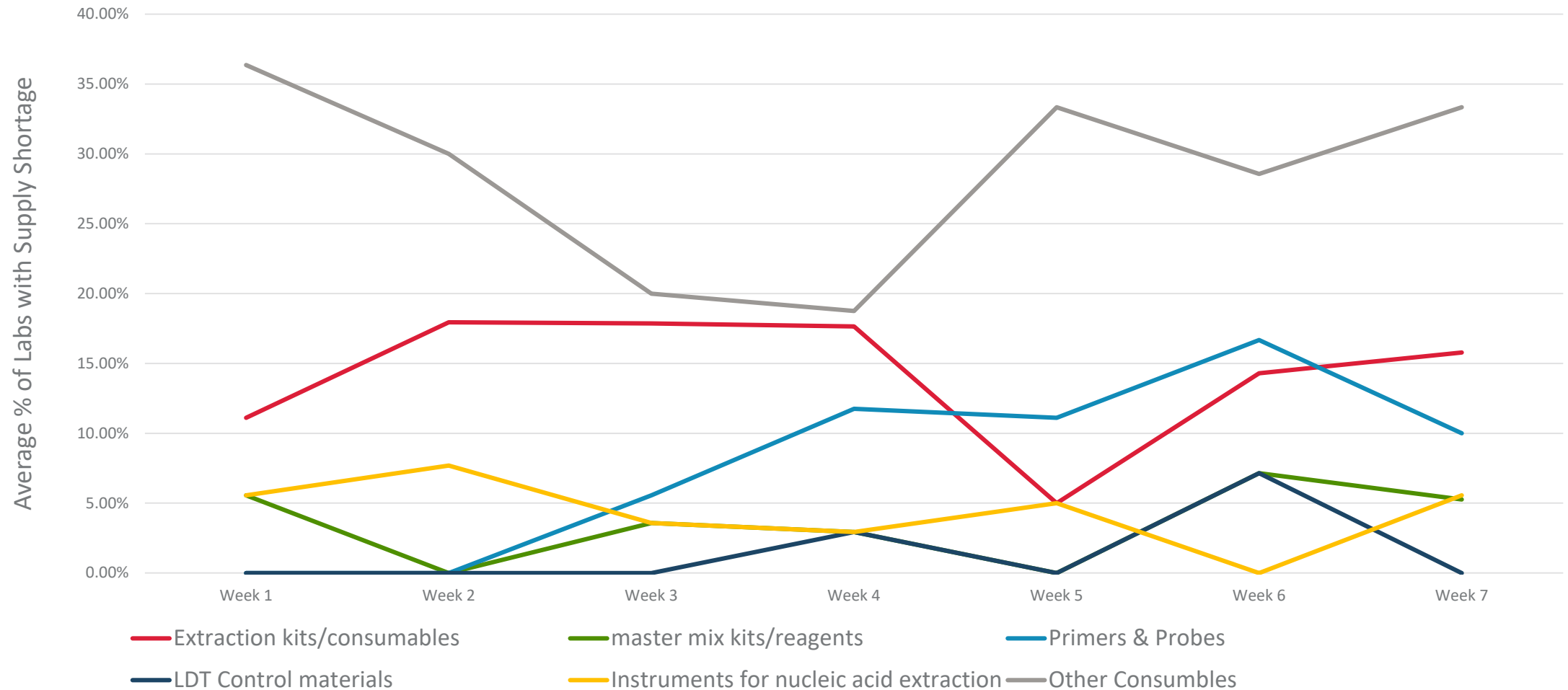
COVID-19 Test Utilization



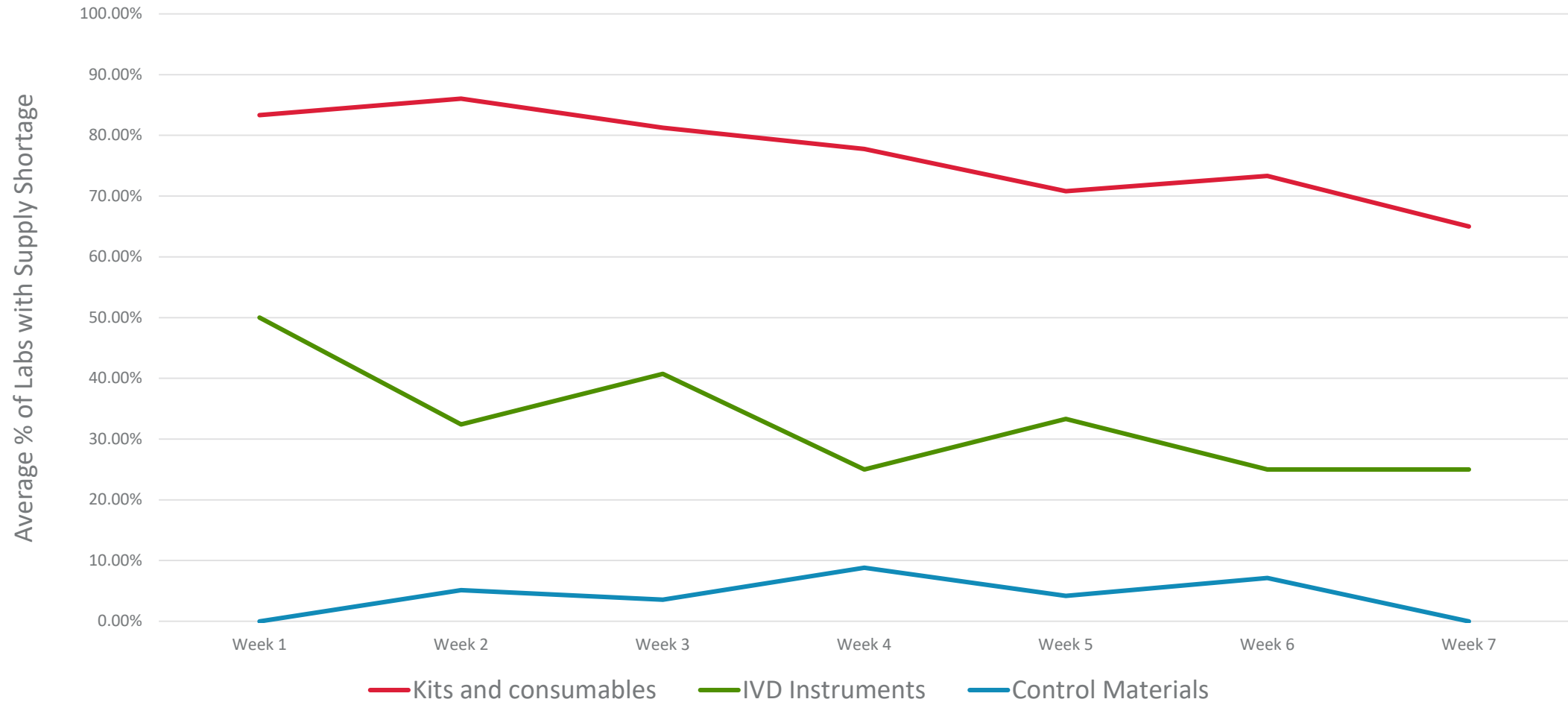
National Overview of U.S. Lab COVID-19 Testing



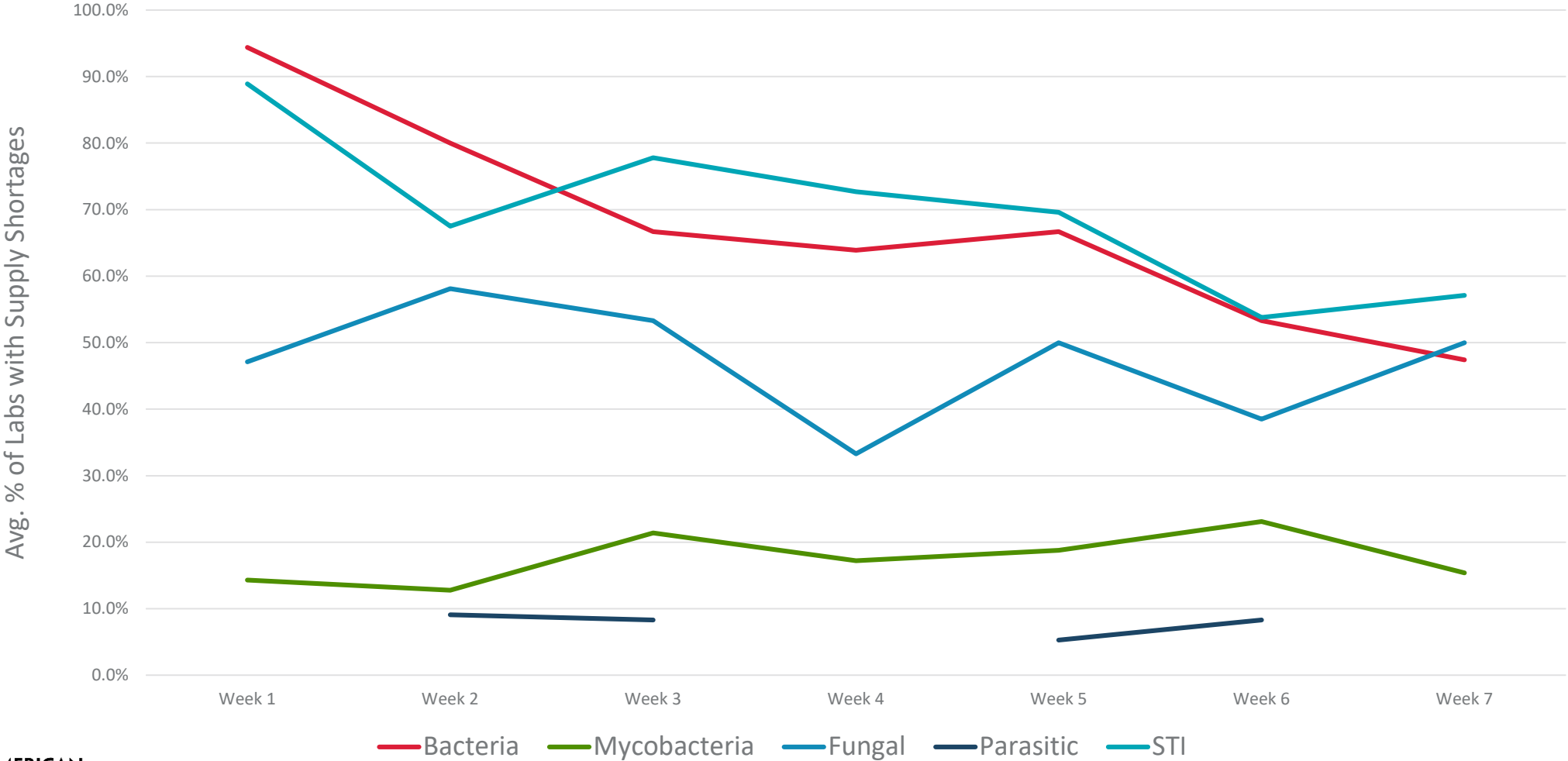
COVID-19 Laboratory Developed Tests (LDT) Testing Supply Shortages



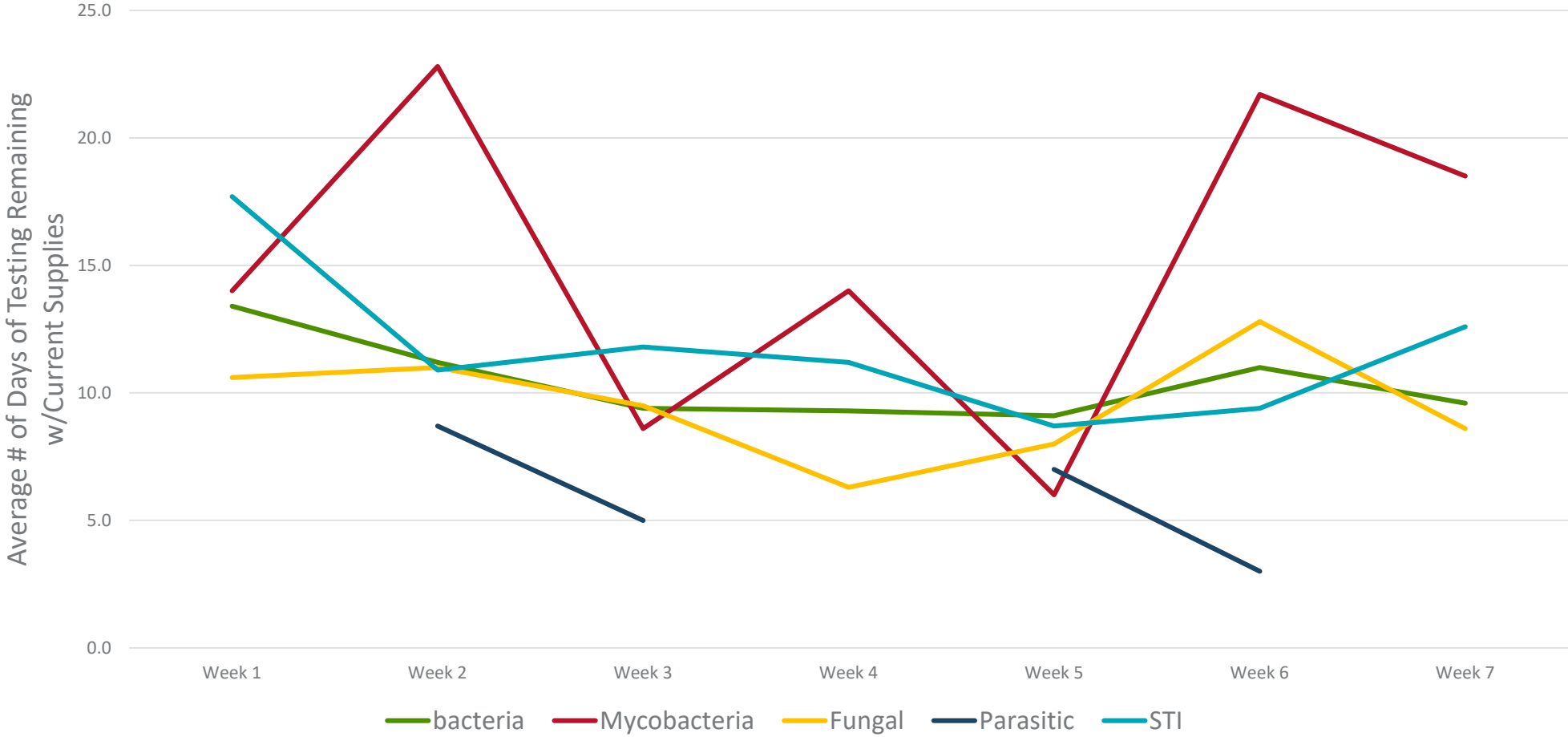
COVID-19 Commercial Molecular Assay Testing Supply Shortages



Non-COVID-19 Laboratory Testing Supplies Shortages



Non-COVID-19 Laboratory Testing Supplies Shortages



Where Can I Access This Data?

Updated data will be available on Tuesday, November 17.

Visit: <https://asm.org/supplydata>

Thank You!

Questions? Contact Us.

- clinmicro@asmusa.org
- 202-942-9225
- ASM
- Clinical and Public Health Microbiology Committee
- 1752 N Street NW
- Washington, DC 20036



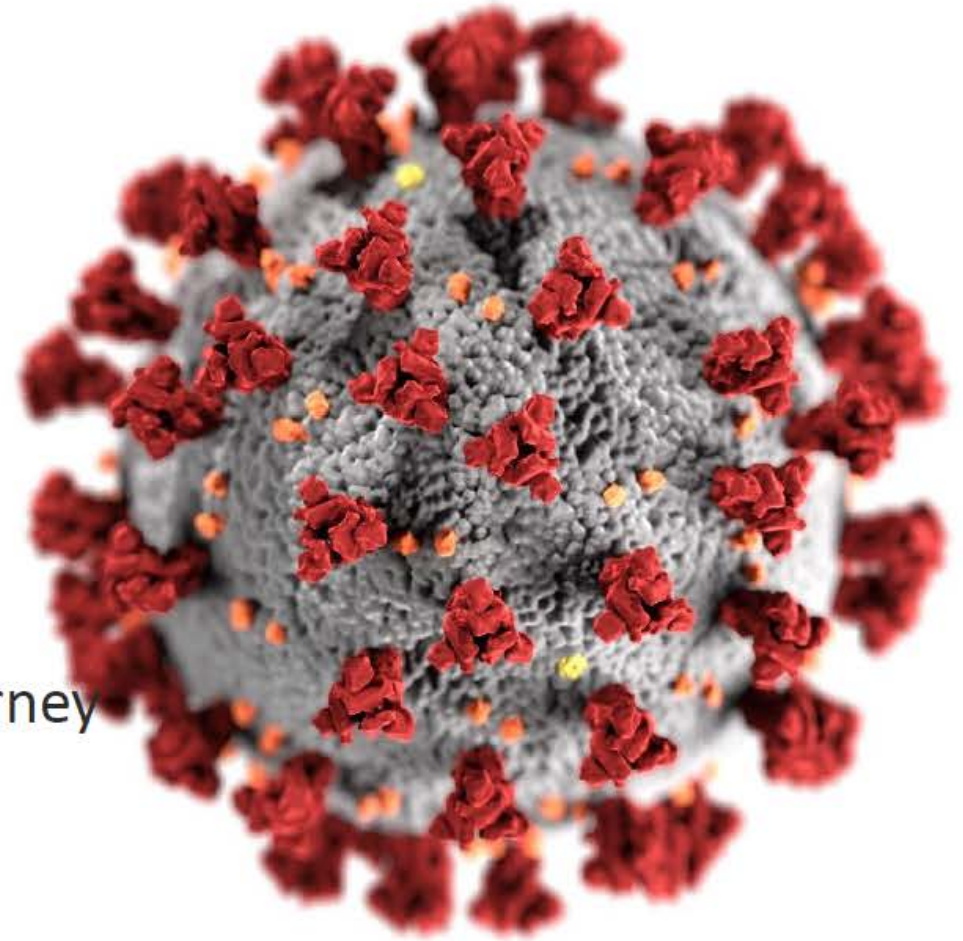
Evaluating the Sofia SARS Antigen FIA for asymptomatic and symptomatic SARS-CoV-2 testing on two university campuses — Wisconsin, Sep 29–Oct 9, 2020

Clinical Laboratory COVID-19 Response Call Monday, November 16, 2020

CDC COVID-19 Epi Studies Deployment Team:

Ian Pray*, Laura Ford, Marie Killerby, Christine Lee, Motria Caudill, Dustin Currie, Marie Kirby, Geroncio Fajardo, Dena Bushman, Miranda Delahoy, John-Paul Biguette, Glen Abedi, Blake Cherney

*= Presenter



Data are provisional – do not distribute

cdc.gov/coronavirus

Background – SARS-CoV-2 Antigen Testing

- Benefits: Point-of-care, low-cost, rapid (~15 minutes)
- FDA Emergency Use Authorization:
 - Symptomatic, within 5-7 days of onset
 - 97% sensitive; 100% specific (Sofia)
- Current widespread use for asymptomatic screening
 - College campuses
 - Nursing homes
 - Other populations



Data are provisional – do not distribute

Objective

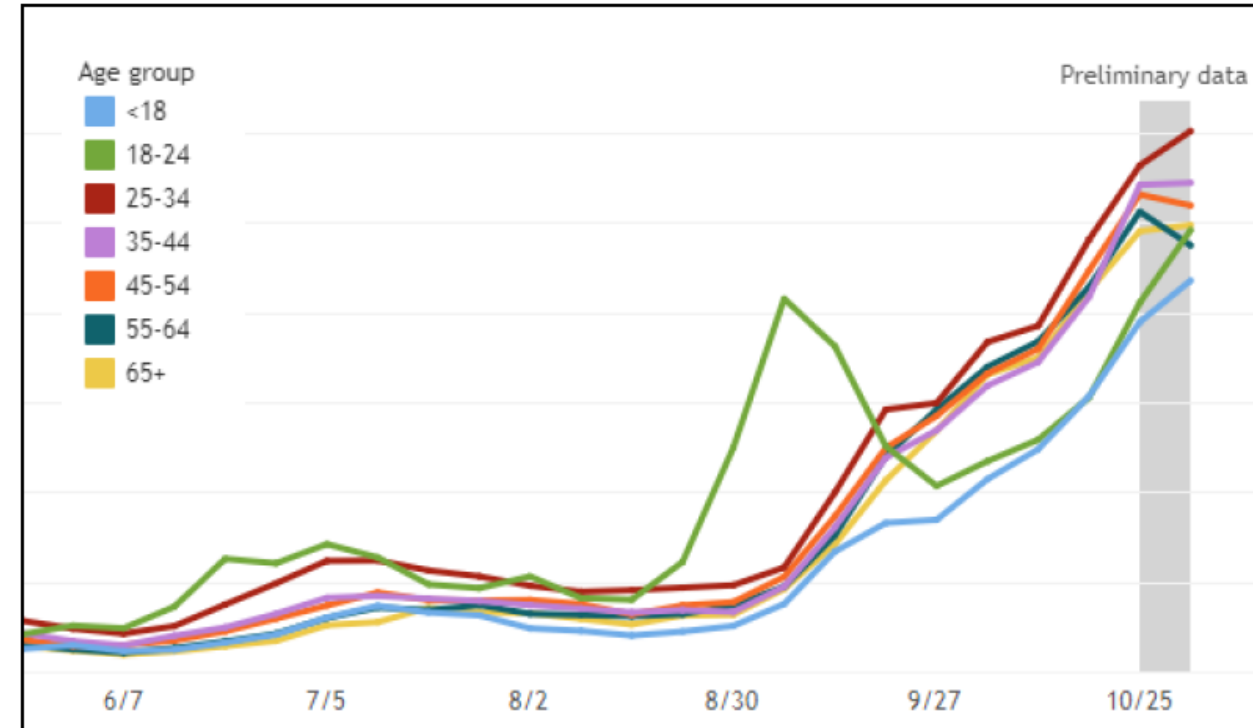
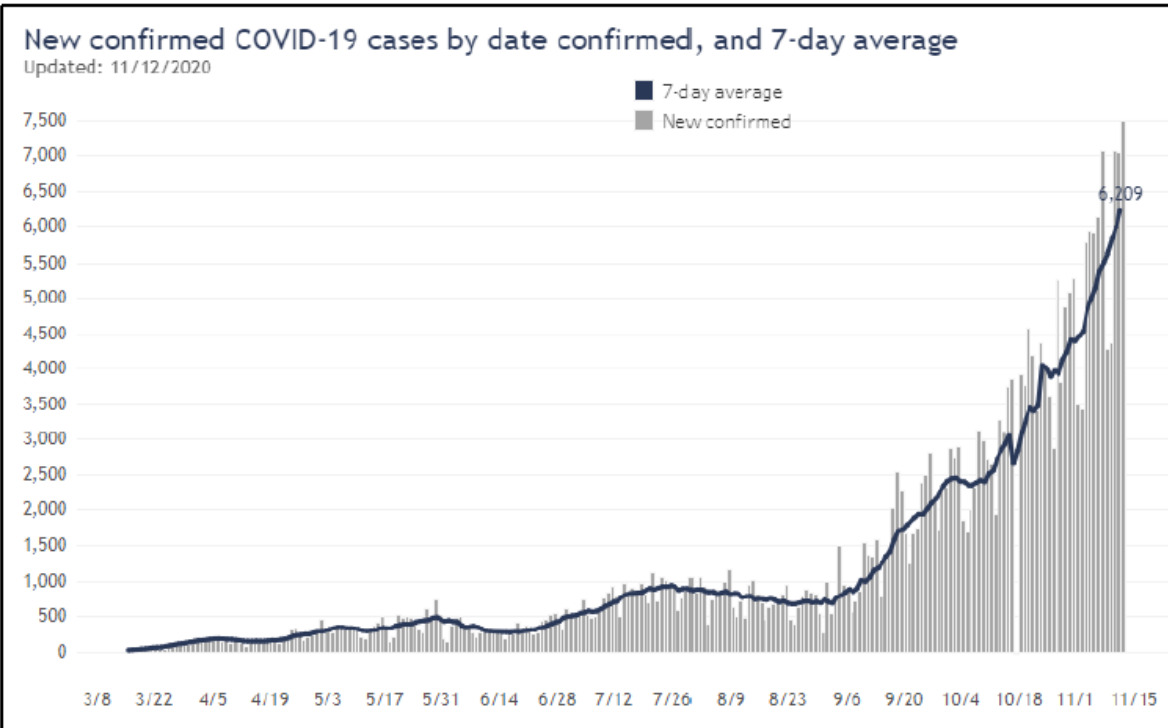
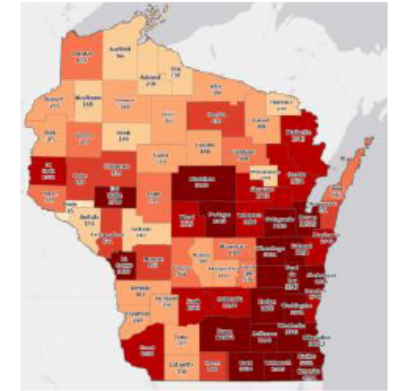
- Evaluate the diagnostic performance of the **Sofia SARS Antigen Fluorescent Immunoassay (FIA)** compared to real time RT-PCR and viral culture in asymptomatic and symptomatic persons in **university population**

Sofia 2 SARS Antigen FIA



Data are provisional – do not distribute

Background – Wisconsin summary



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Source: <https://www.dhs.wisconsin.gov/covid-19/cases.htm>

Antigen evaluation methods

- Routine surveillance testing and quarantine testing
- Questionnaire
 - Demographics
 - Symptoms
 - Exposure and quarantine dates
- Paired nasal swabs (Sofia antigen and RT-PCR)
 - Simultaneous swabs of each nostril
(Right/Left → Left/Right)
- 1,098 paired samples analyzed from students (90.5%)
staff (7.5%) or other university affiliates (2.0%)



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Demographics and symptoms on the date of nasal swab (N=1,098)



41.3% (453)
male



90.5% (994)
students



70.3% (761)
live in the residence halls



79.3% (871)
asymptomatic



20.7% (227)
≥ 1 symptom

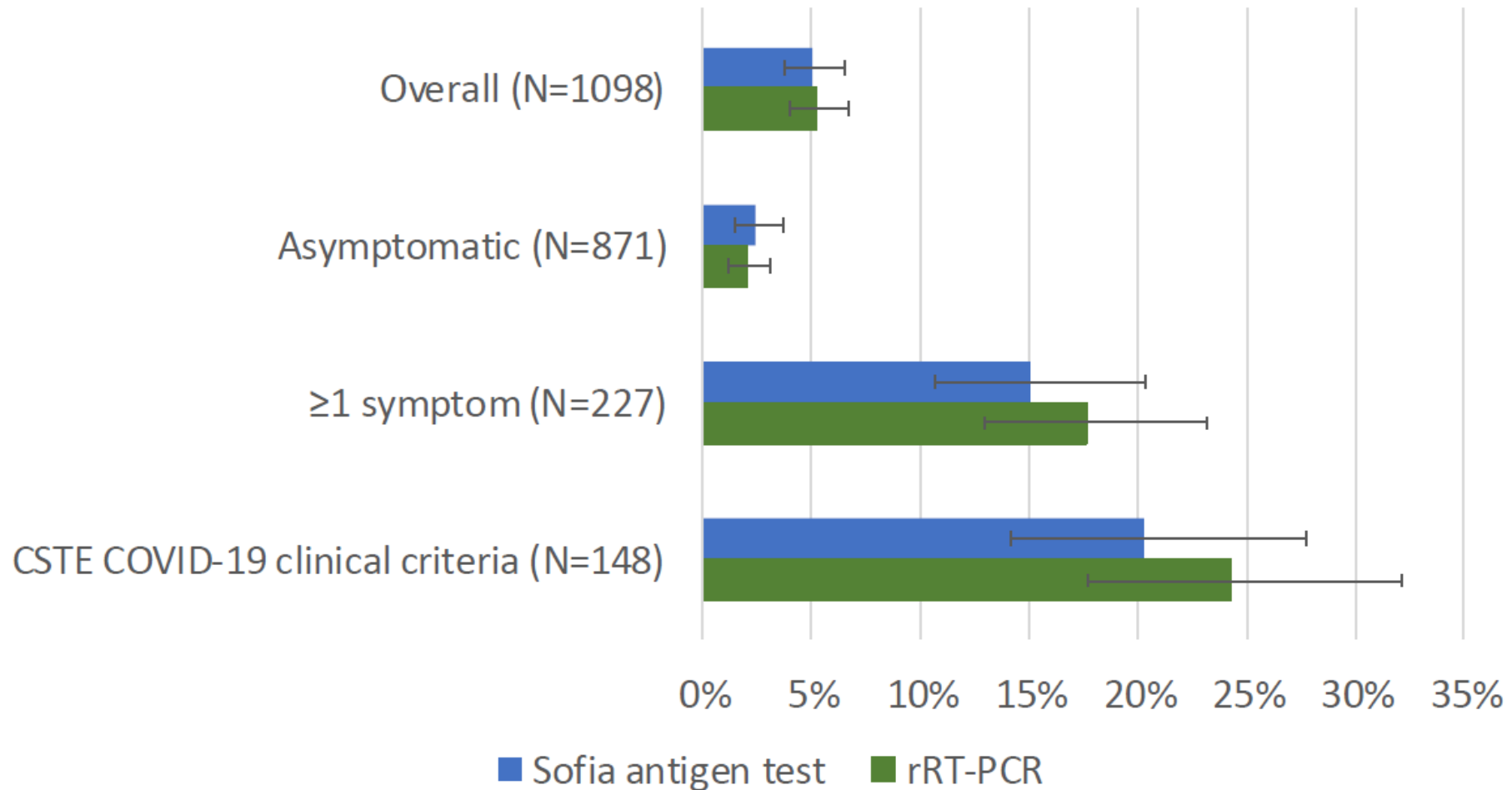


13.5% (148)
CSTE clinical criteria for
COVID-19

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Test positivity by symptoms



Data are provisional – do not distribute



Sensitivity, specificity, PPV, and NPV of Sofia SARS Antigen FIA compared to RT-PCR

Symptomatic (≥ 1 symptom)			
Antigen	RT-PCR		
	Positive	Negative	Total
Positive	32	2	34
Negative	8	185	193
Total	40	187	227

Asymptomatic			
Antigen	RT-PCR		
	Positive	Negative	Total
Positive	7	14	21
Negative	10	840	850
Total	17	854	871

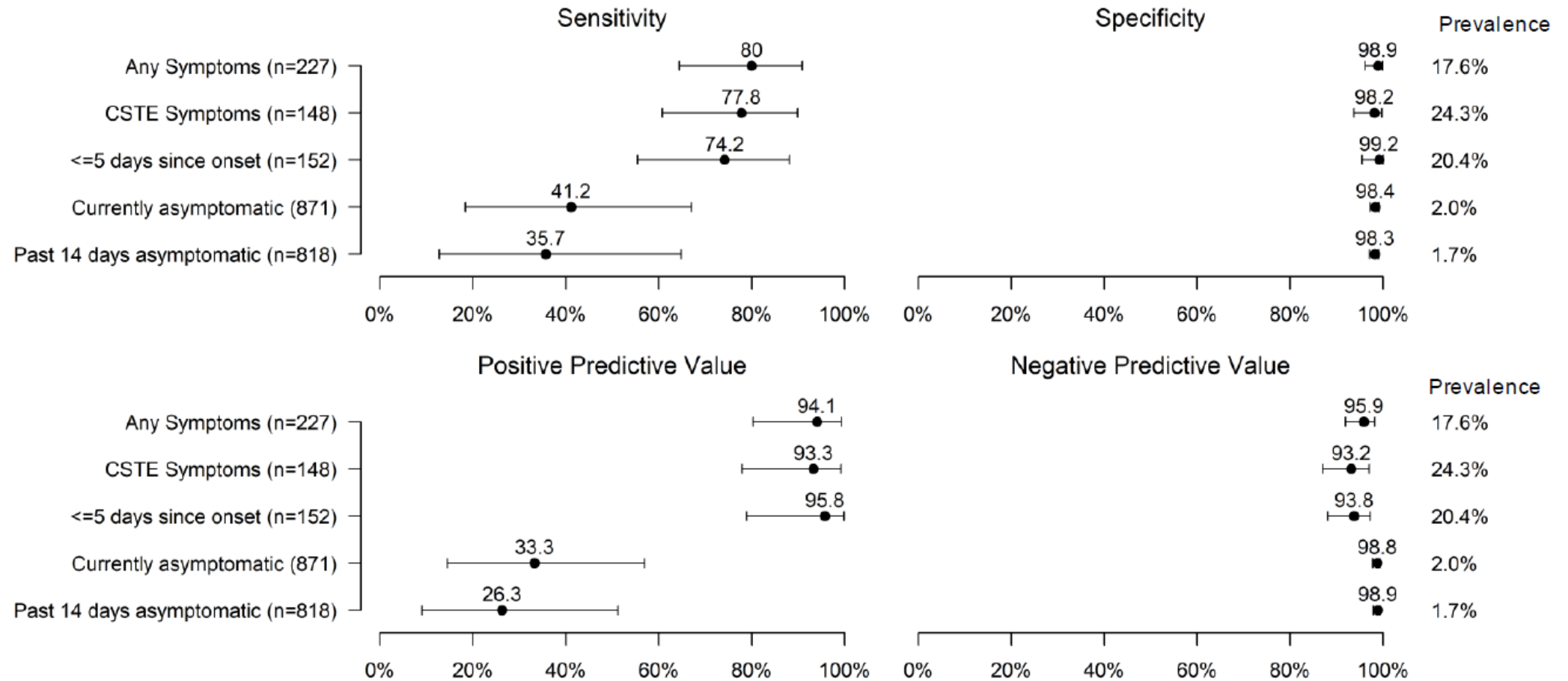
- **Sensitivity:** 80.0% (95% CI 64.4%-90.9%)
- **Specificity:** 98.9% (95% CI 96.2%-99.9%)
- **PPV:** 94.1% (95% CI 80.3%-99.3%)
- **NPV:** 95.9% (95% CI 92.0%-98.2%)

- **Sensitivity:** 41.2% (95% CI 18.4%-67.1%)
- **Specificity:** 98.4% (95% CI 97.3%-99.1%)
- **PPV:** 33.3% (95% CI 14.6%-57.0%)
- **NPV:** 98.4% (95% CI 97.8%-99.4%)

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Sensitivity, specificity, PPV, and NPV of Sofia SARS Antigen FIA compared to RT-PCR

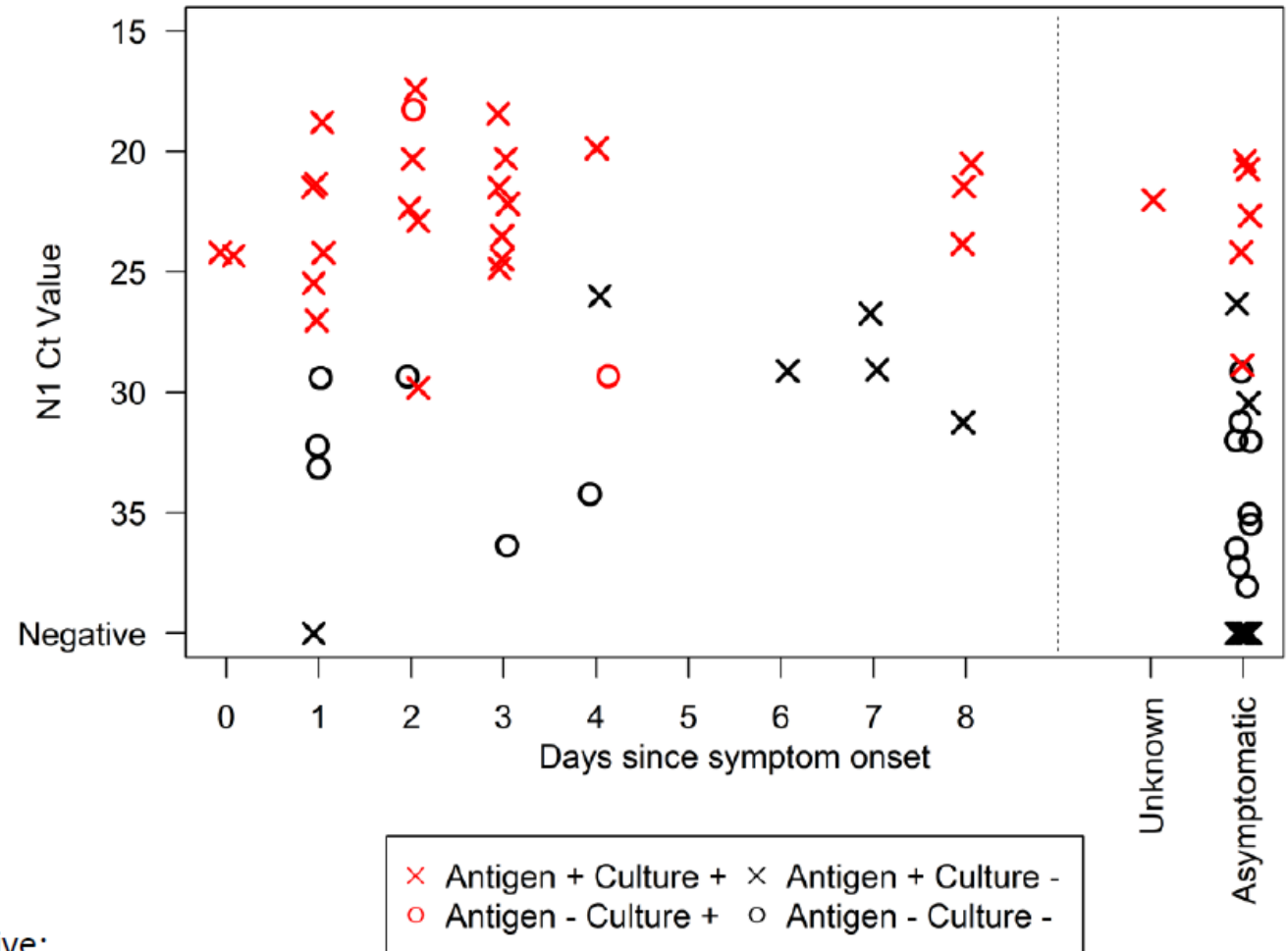


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Viral culture and Ct values among positive specimens

- 34/73 (46.6%) antigen or RT-PCR positive specimens were culture positive.
 - 32/39 (82%) concordant positives (RT-PCR+/antigen+) were culture positive
 - 2/8 (25%) false negatives* from symptomatic participants were culture positive.
 - 0/10 (0%) false negatives* specimens from asymptomatic participants were culture positive.
 - 0/16 false positives* were culture positive



*False negative = antigen negative / PCR positive;

*False positive = antigen positive / PCR negative

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Summary

- Sofia antigen test had **lower sensitivity** (80.0%) and **lower specificity** (98.9%) than reported in EUA data (96.7%; 100%) in symptomatic individuals
- For asymptomatic screening, sensitivity was **41.2%** (7/17) and positive predictive value was **33.3%** (7/21)
- Virus recovery was possible from **2 of 18 false negative** antigen results
- Testing strategies should consider **confirmatory molecular testing** for:
 - **Negative antigen results in symptomatic persons** when COVID-19 is suspected
 - **Positive antigen results in asymptomatic persons** where pre-test probability is low

Data are provisional – do not distribute

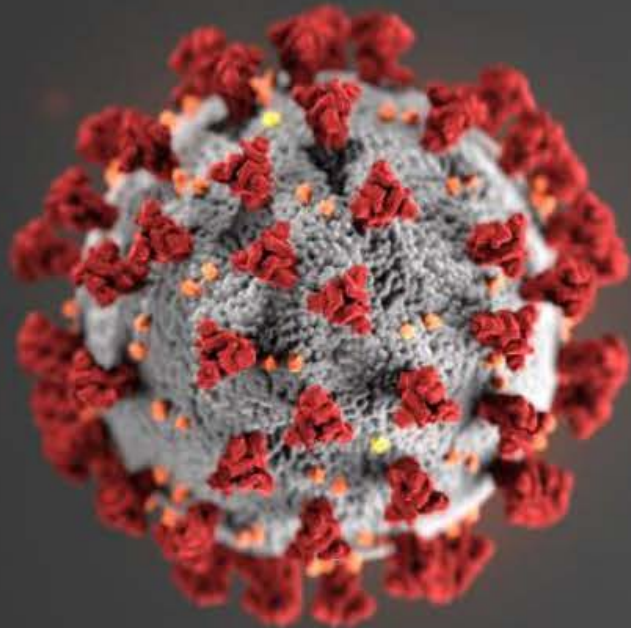


Acknowledgments

- CDC COVID-19 Response Team
- CDC Epi Studies Team
- CDC Surge Laboratory Group
- University of Wisconsin-Oshkosh
- University Health Services, University of Wisconsin-Madison
- University of Wisconsin Veterinary Diagnostic Laboratory
- Wisconsin State Laboratory of Hygiene
- Winnebago County Health Department
- Wisconsin Department of Health Services

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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.



FDA Update

Tim Stenzel

U.S. Food and Drug Administration (FDA)



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

Food and Drug Administration (FDA)

- **COVID-19 Emergency Use Authorization (EUA) Information for Medical Devices**

<https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>

- **COVID-19 In Vitro Diagnostic EUAs**

<https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas>

- **COVID-19 Frequently Asked Questions**

<https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/coronavirus-disease-2019-covid-19-frequently-asked-questions>

- **COVID-19 Updates**

<https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#2019-ncov>

- **FDA Townhall Meetings**

<https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/virtual-town-hall-series-immediately-effect-guidance-coronavirus-covid-19-diagnostic-tests-06032020>

- **Independent Evaluations of COVID-19 Serological Tests**

<https://open.fda.gov/apis/device/covid19serology/>

Food and Drug Administration (FDA)

- **COVID-19 Diagnostic Development**

CDRH-EUA-Templates@fda.hhs.gov

- **Spot Shortages of Testing Supplies: 24-Hour Support Available**

1. Call 1-888-INFO-FDA (1-888-463-6332)

2. Then press star (*)

- **FDA MedWatch**

<https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program>

CDC Social Media



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

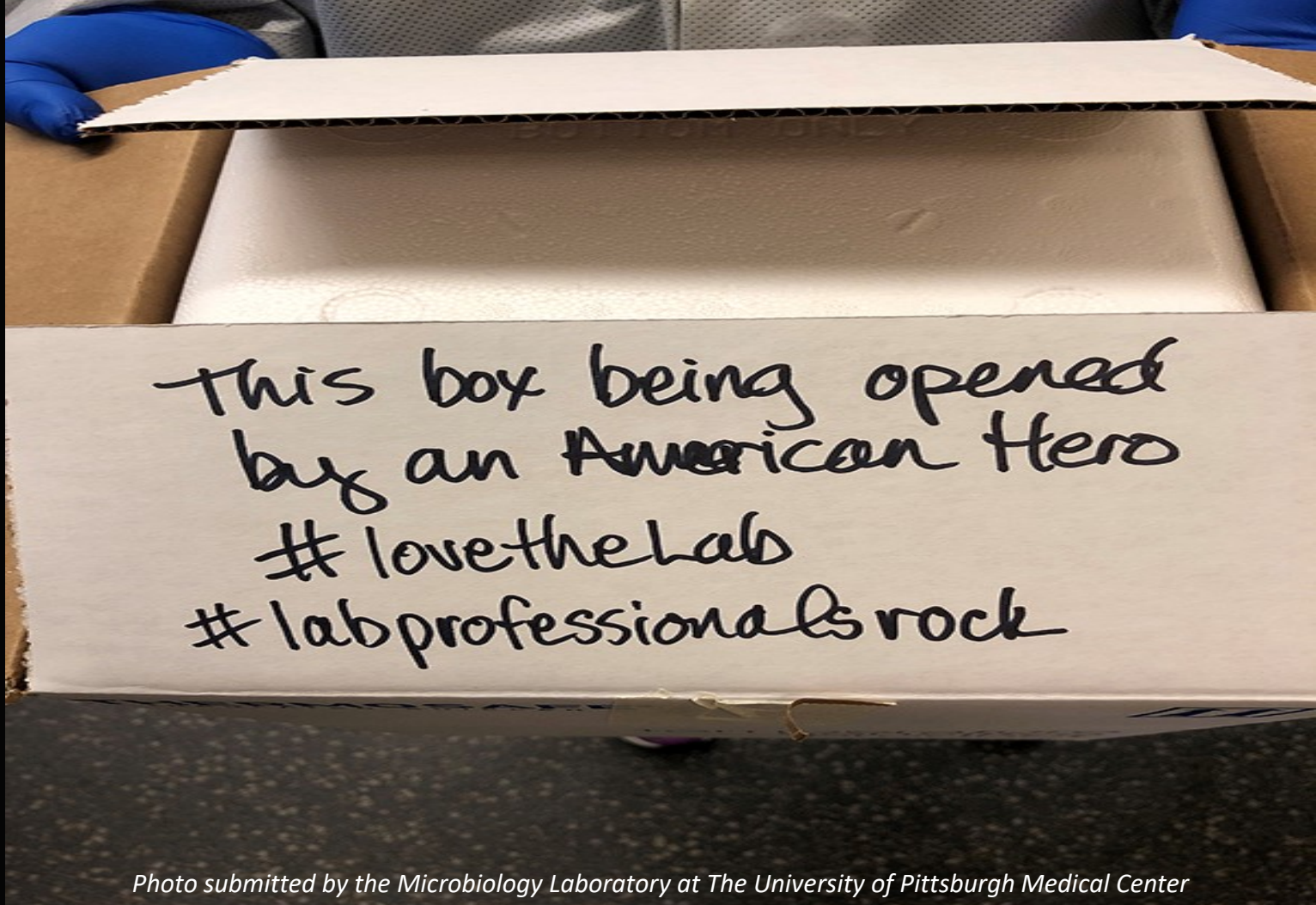


<https://twitter.com/cdcgov>



<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