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

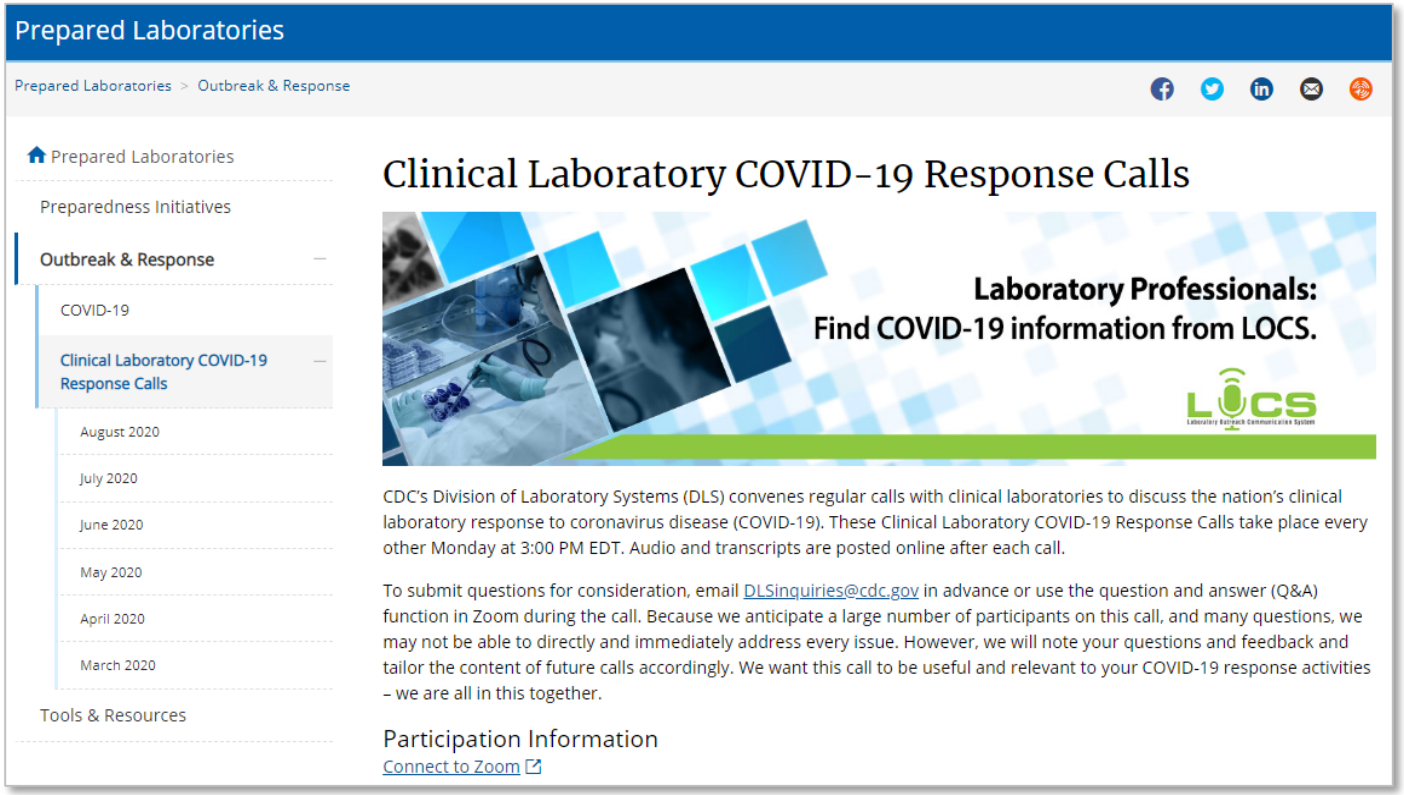
COVID-19 Resources for Laboratories

- **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

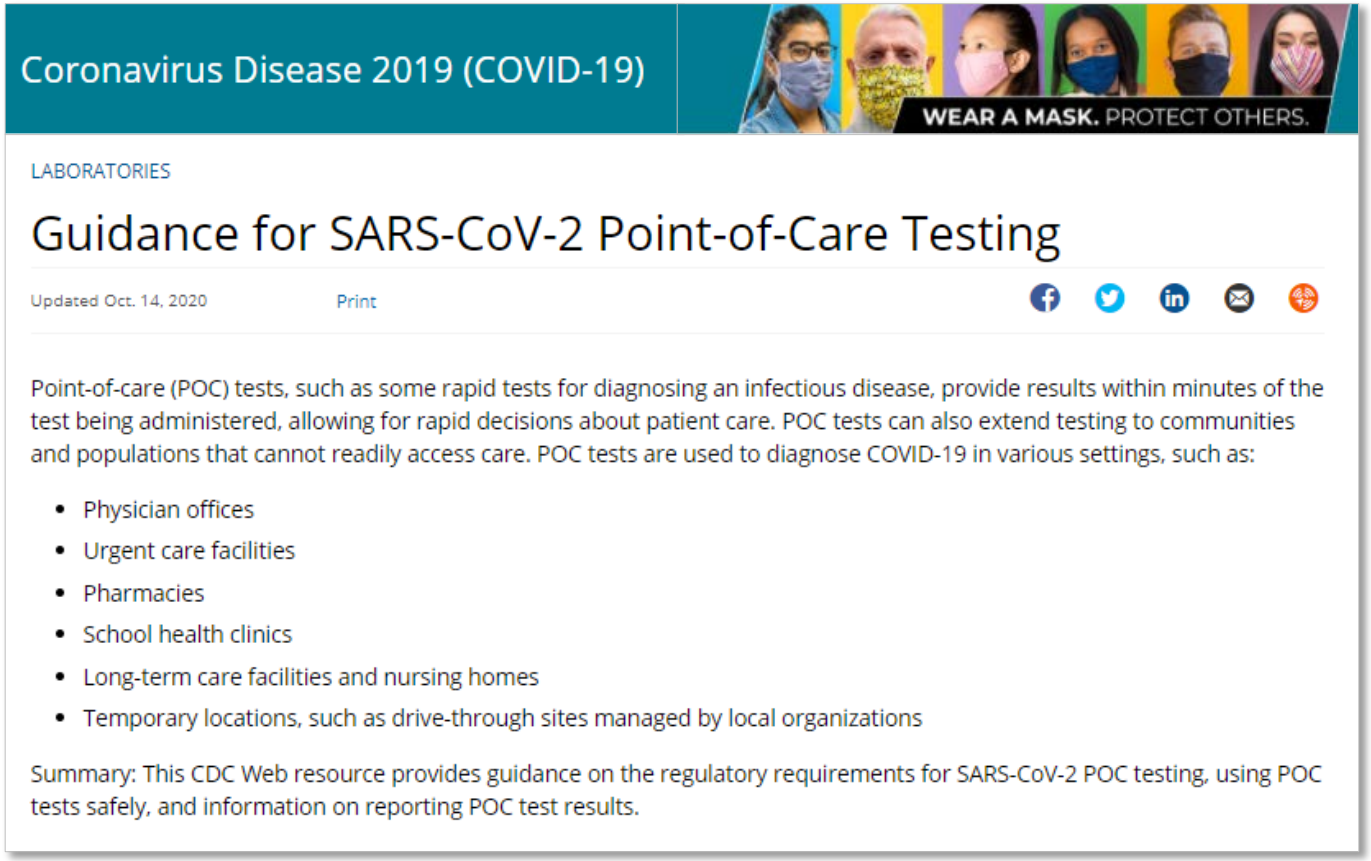
https://www.cdc.gov/csels/dls/preparedlabs/covid-19-clinical-calls.html

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



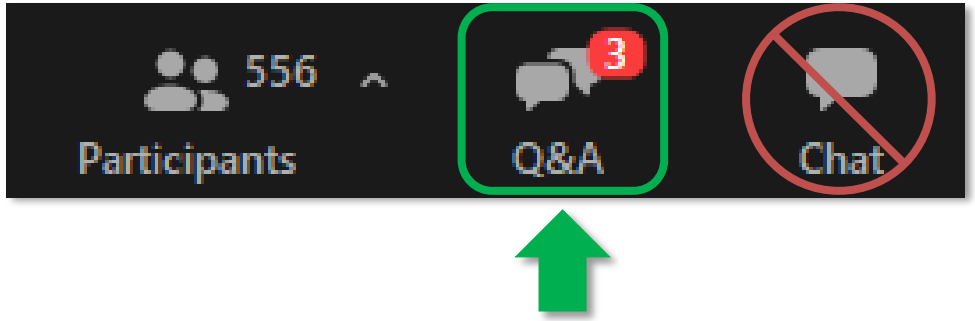
Guidance for SARS-CoV-2 Point-of-Care Testing

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



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

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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

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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).

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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

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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

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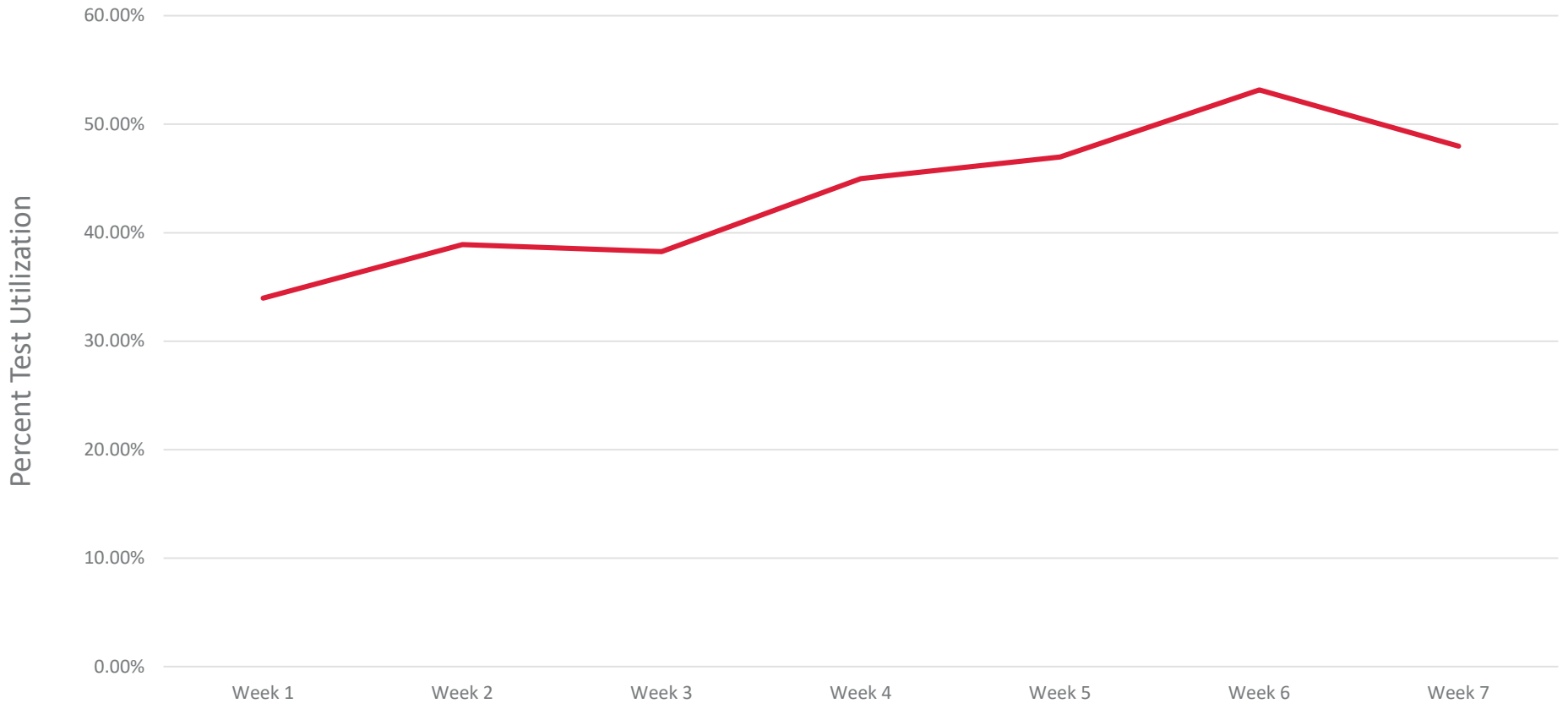
COVID-19 Test Utilization



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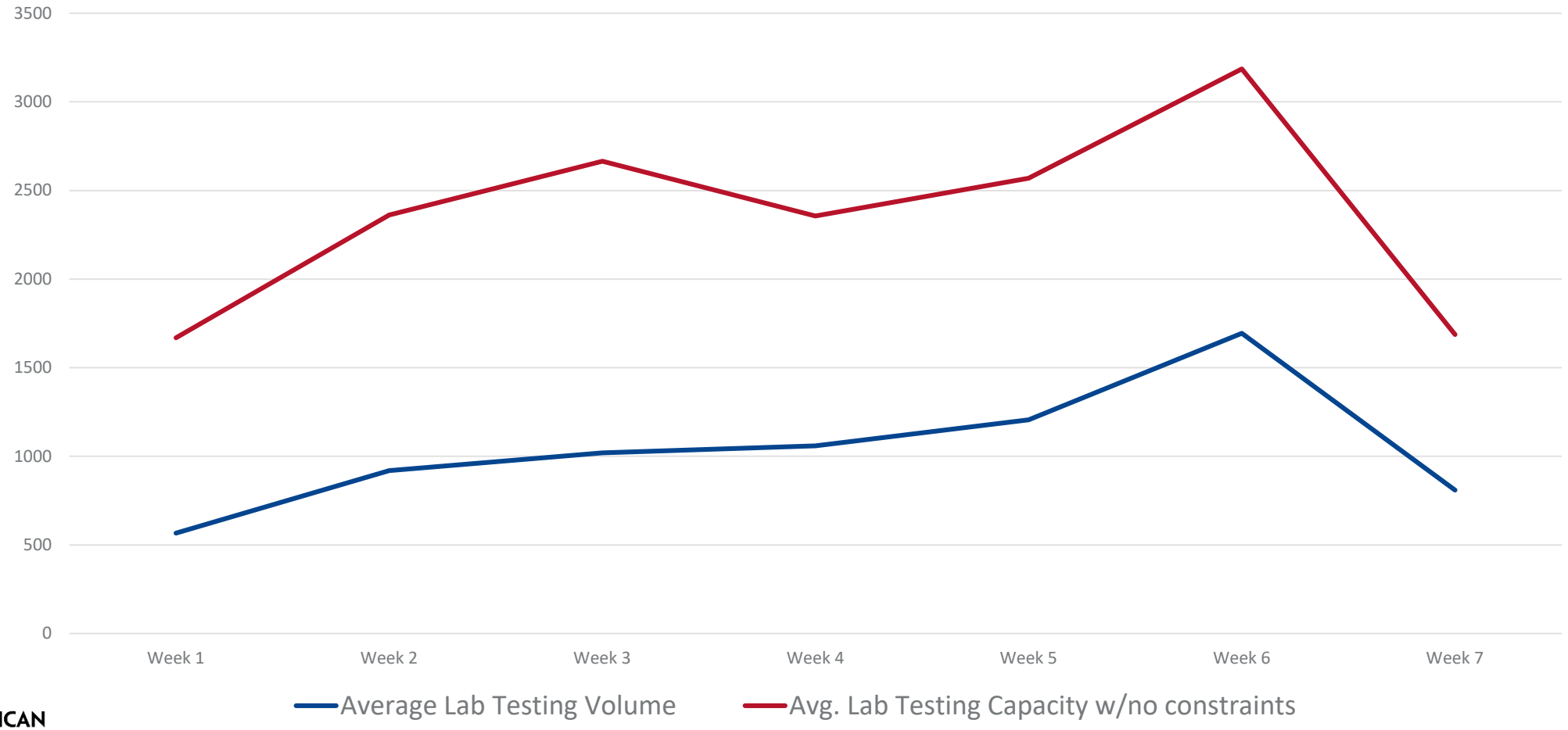
National Overview of U.S. Lab COVID-19 Testing



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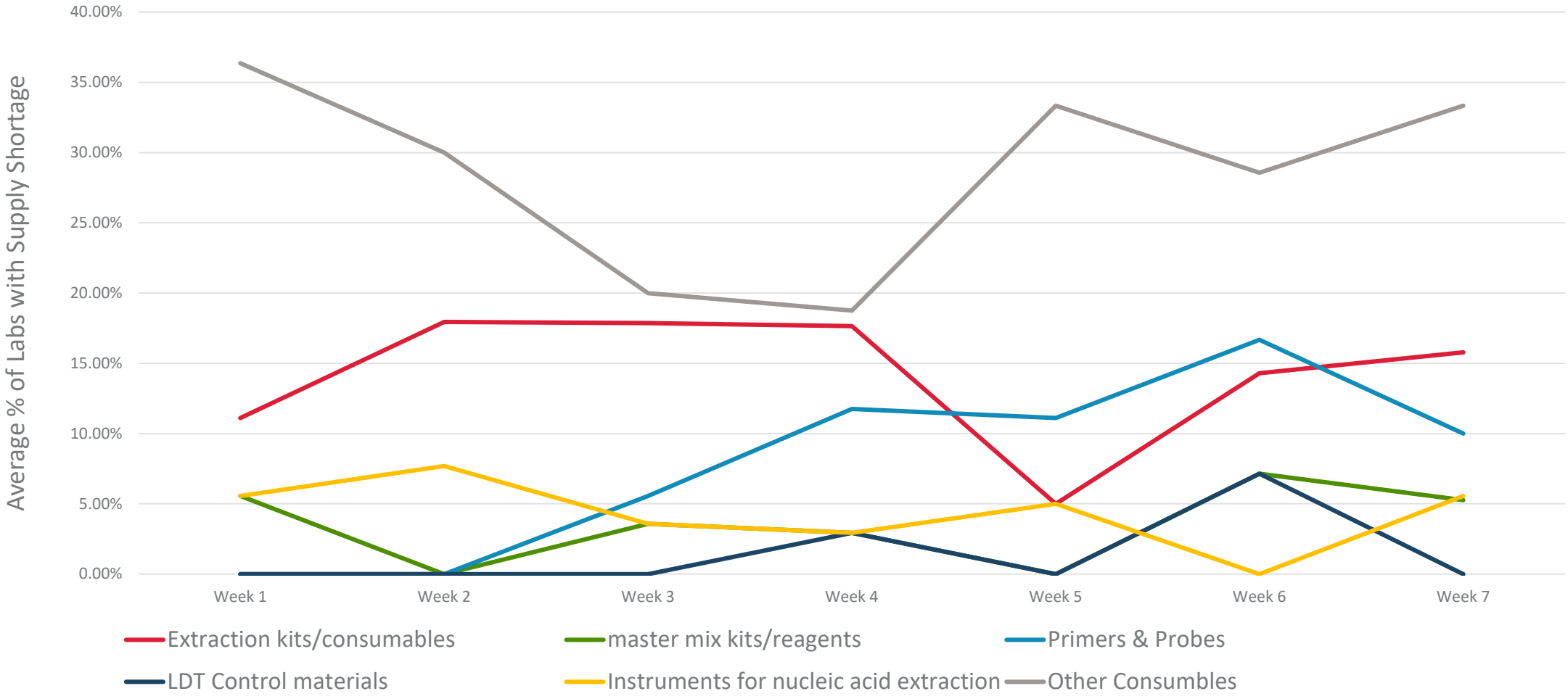
COVID-19 Laboratory Developed Tests (LDT) Testing Supply Shortages



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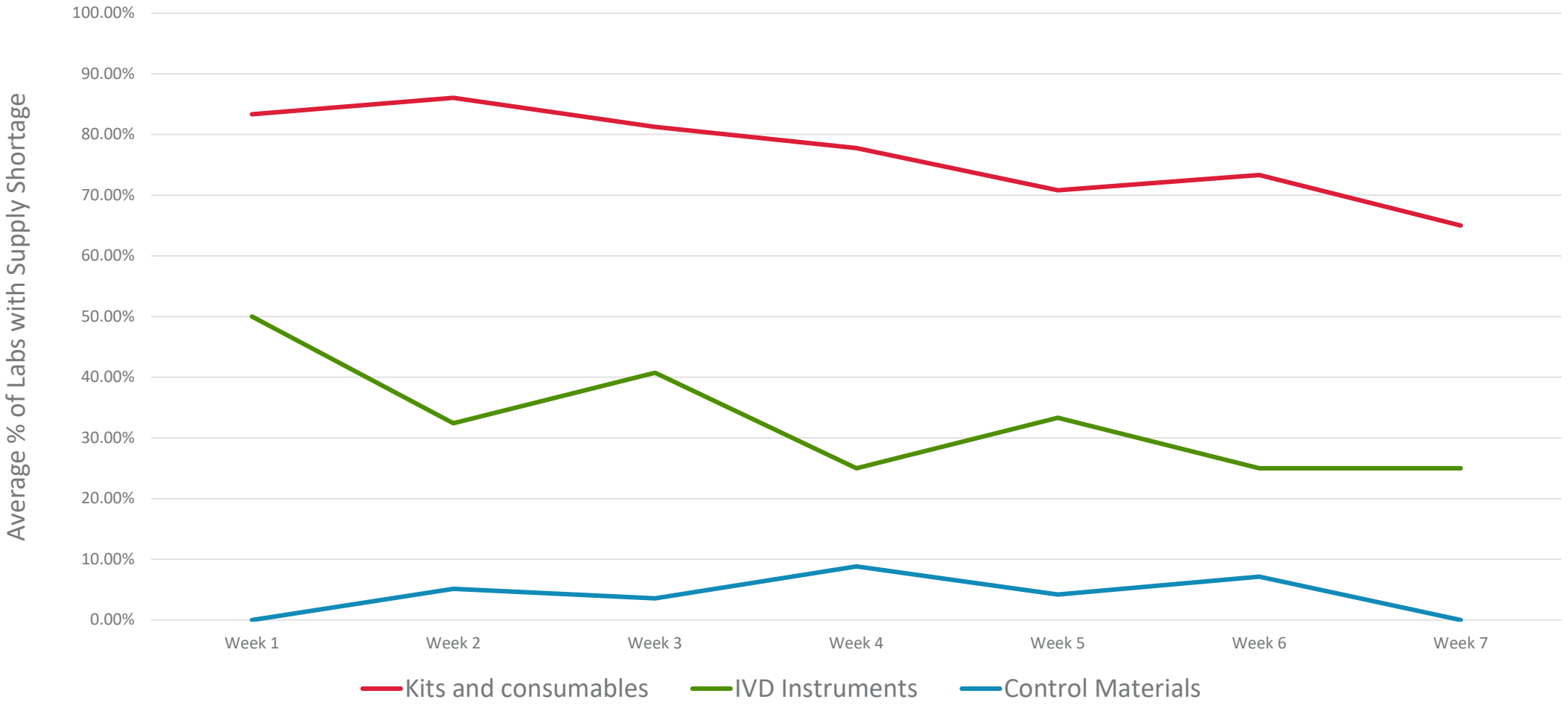
COVID-19 Commercial Molecular Assay Testing Supply Shortages



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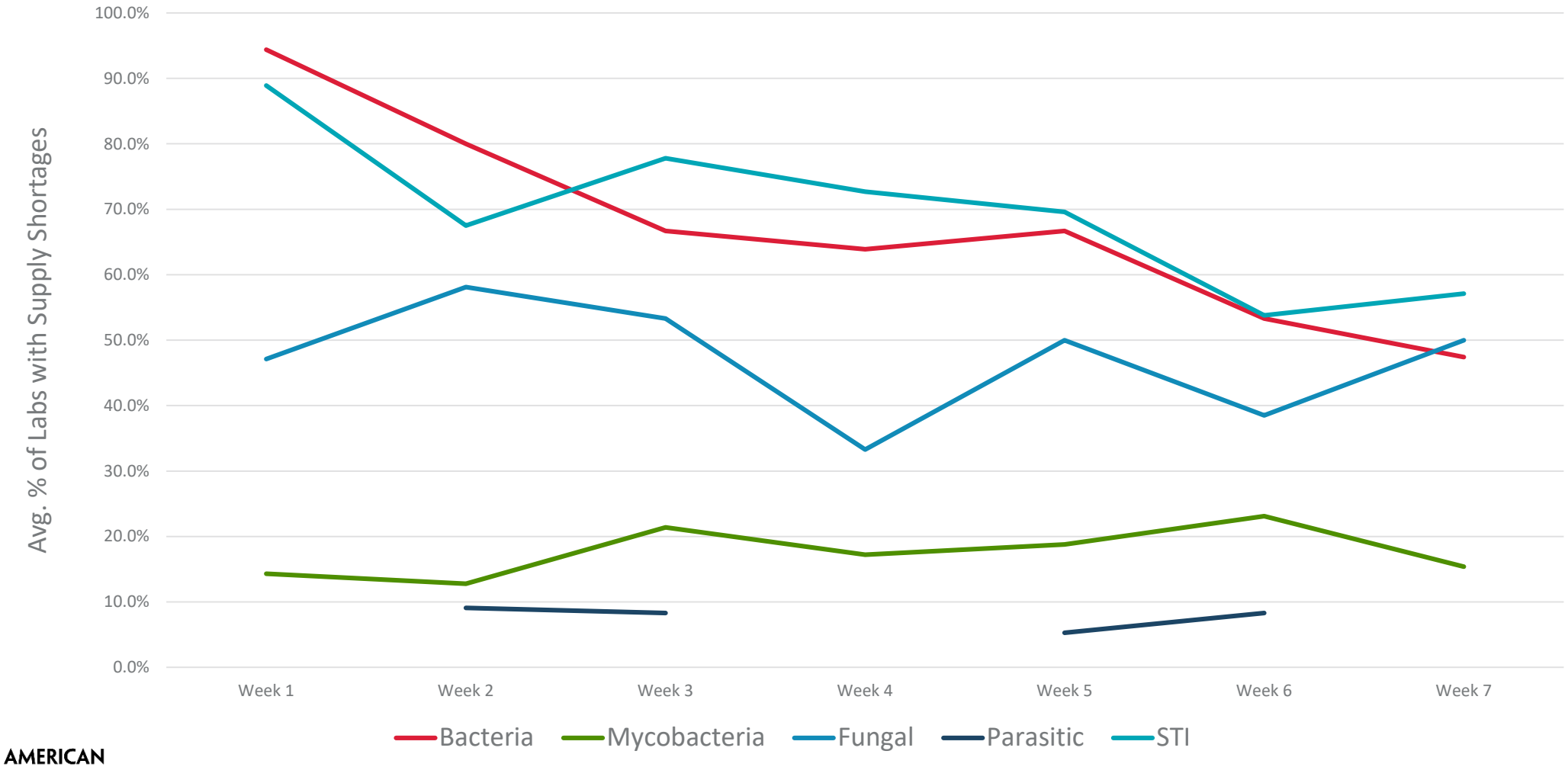
Non-COVID-19 Laboratory Testing Supplies Shortages



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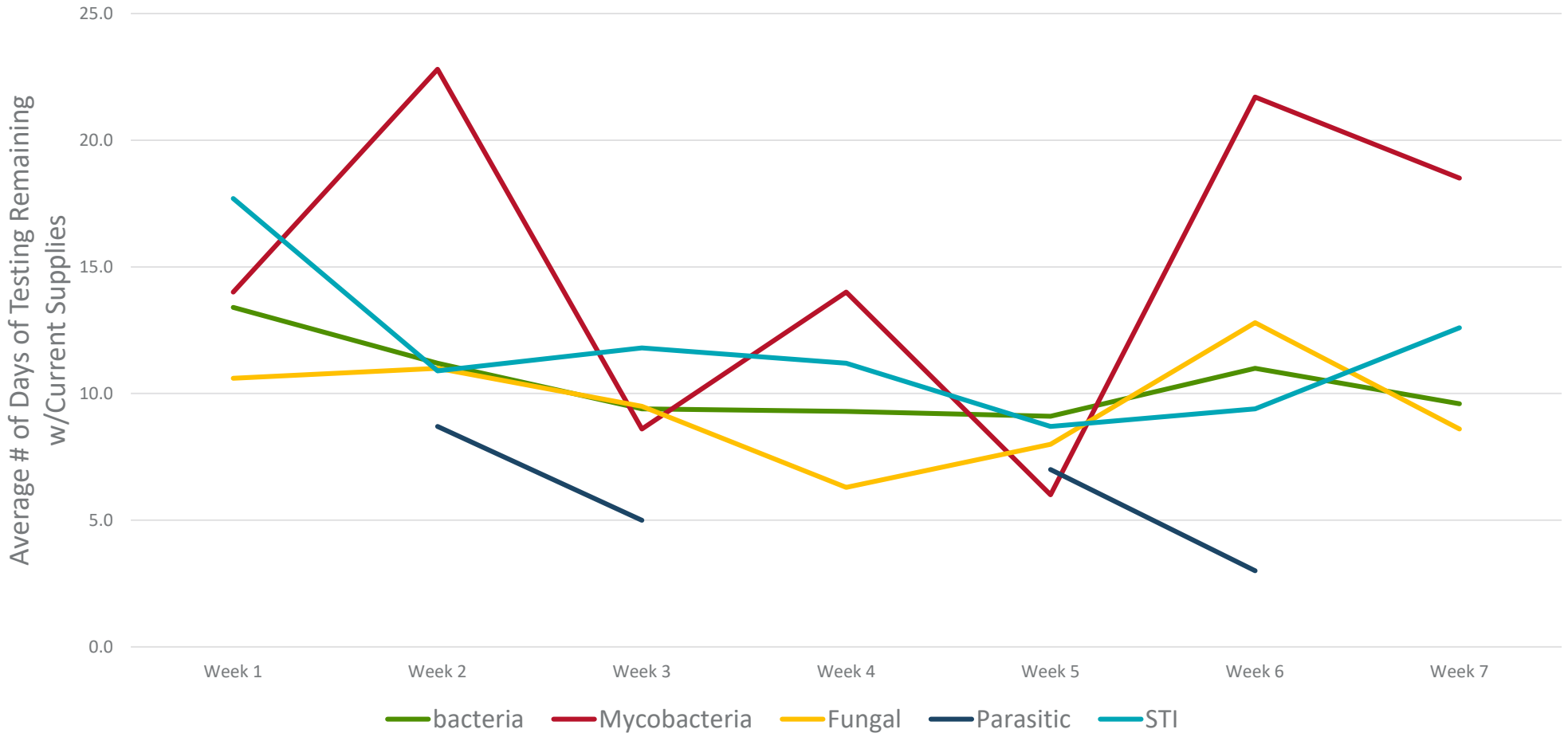
Non-COVID-19 Laboratory Testing Supplies Shortages



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Where Can I Access This Data?

Updated data will be available on Tuesday, November 17.

Visit: https://asm.org/supplydata

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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

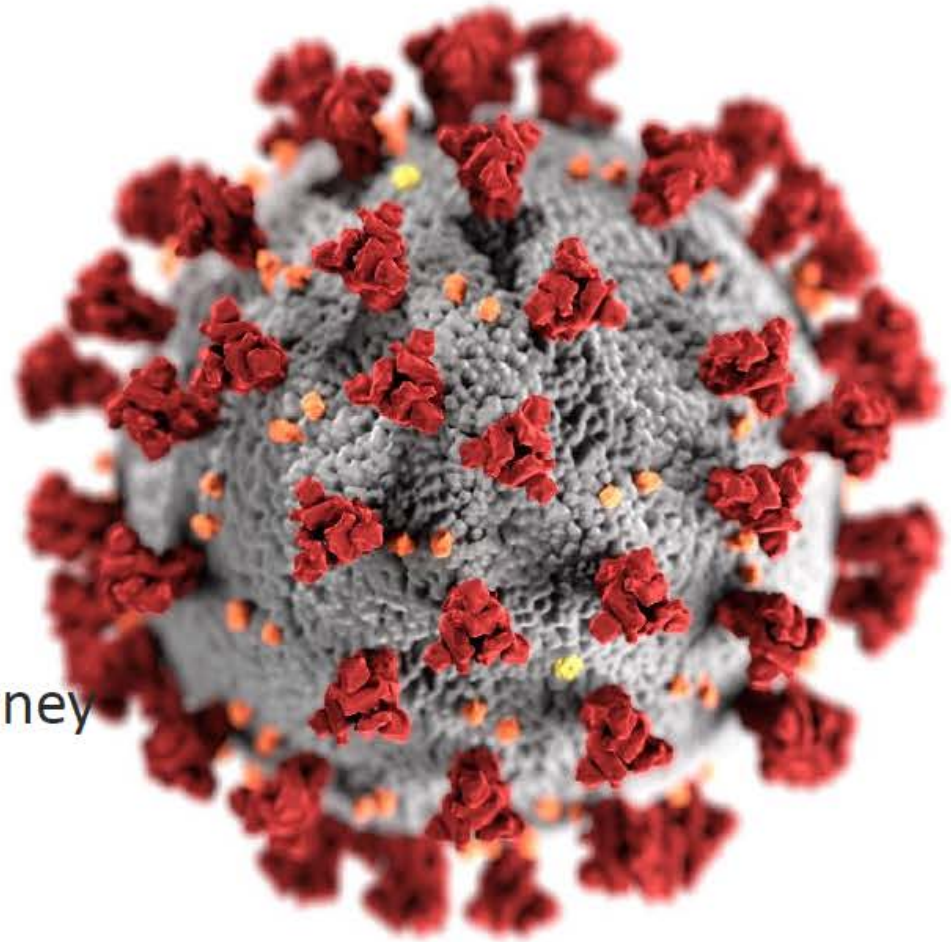
Clinical Laboratory COVID-19 Response Call

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 Biguoette, 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

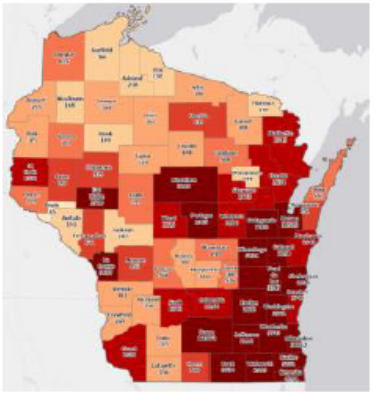
Objective

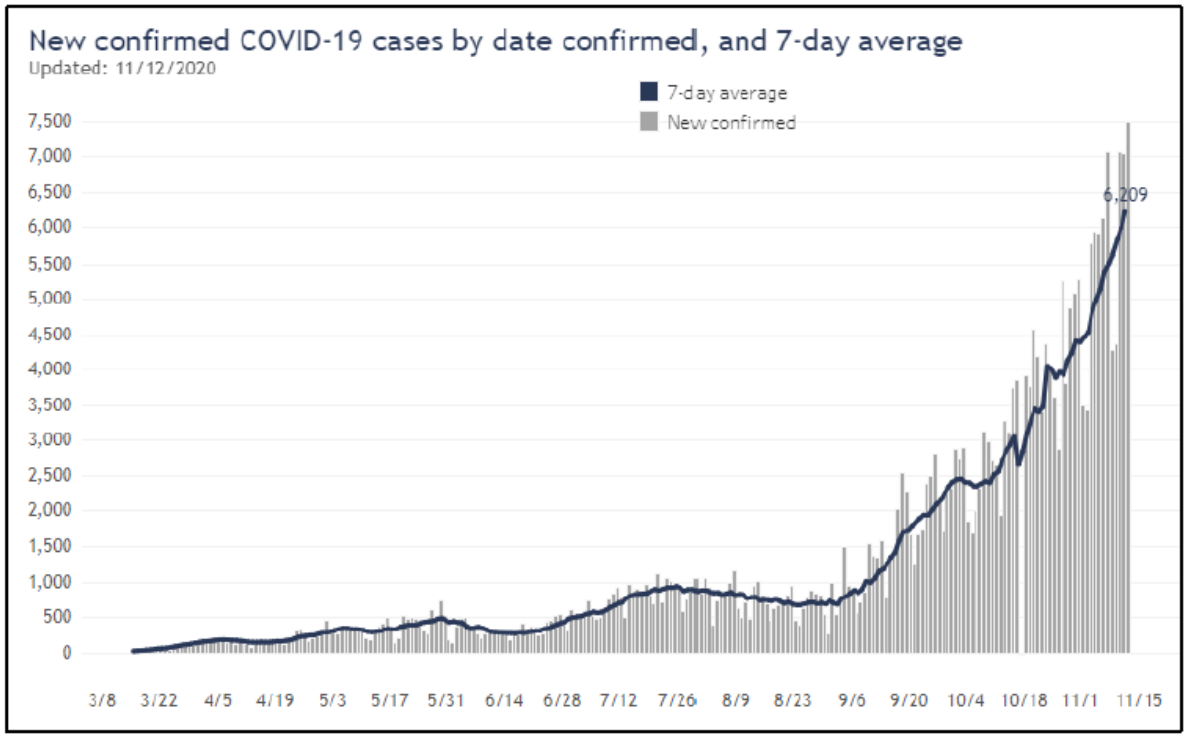
- Evaluate the diagnostic performance of the **Sofia SARS Antigen Fluorescent Immunoassay (FIA)** compared to real time RT-PCR and viral culture in asymptomatic and symptomatic persons in **university population**

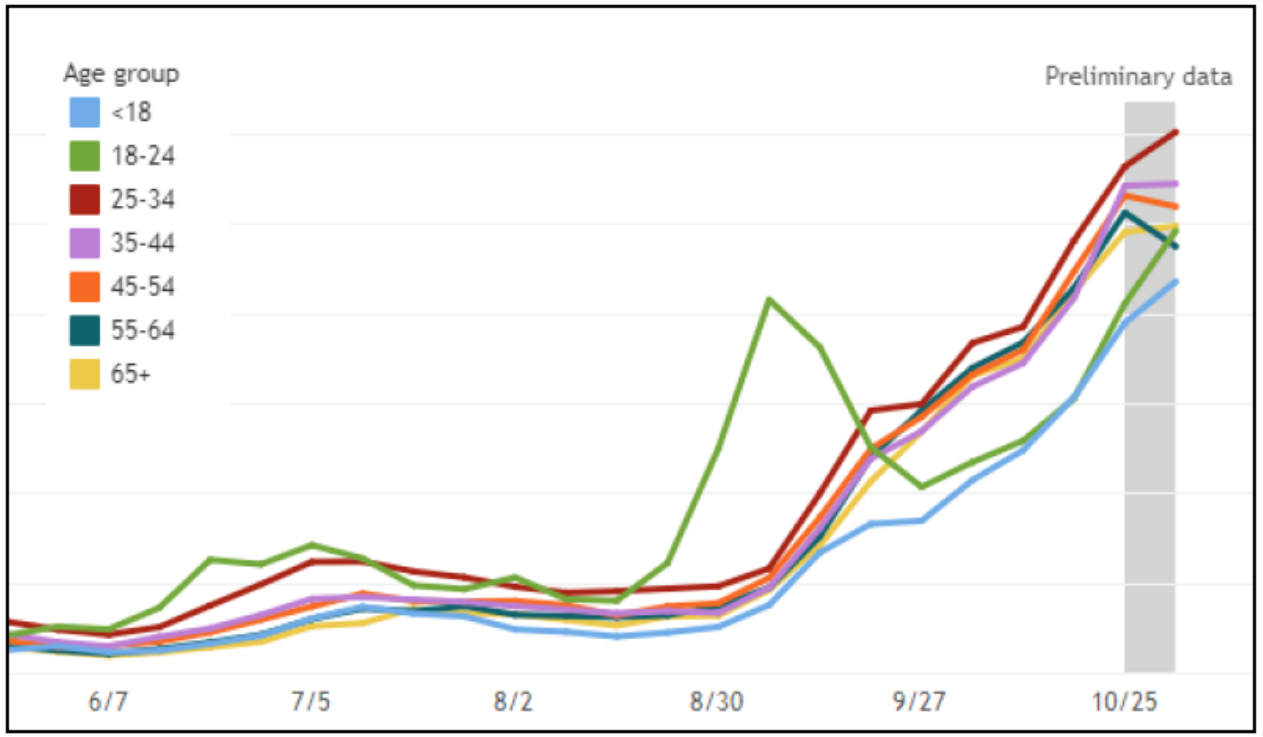
Sofia 2 SARS Antigen FIA

Data are provisional – do not distribute

Background – Wisconsin summary







Data are provisional – do not distribute

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%)

Data are provisional – do not distribute

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

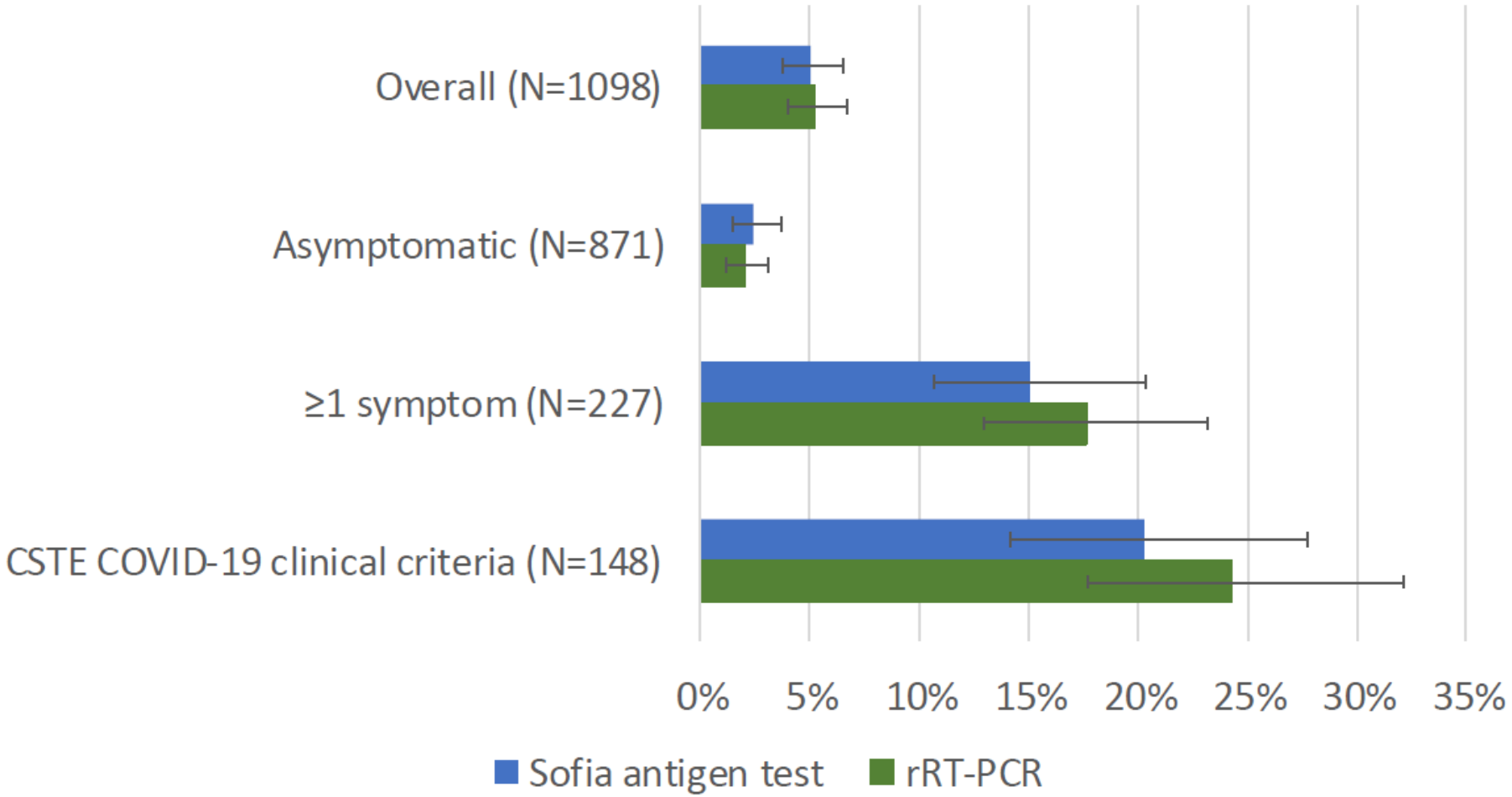
79.3% (871)
asymptomatic

20.7% (227)
≥ 1 symptom

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

Data are provisional – do not distribute

Test positivity by symptoms



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

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

- **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%)

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

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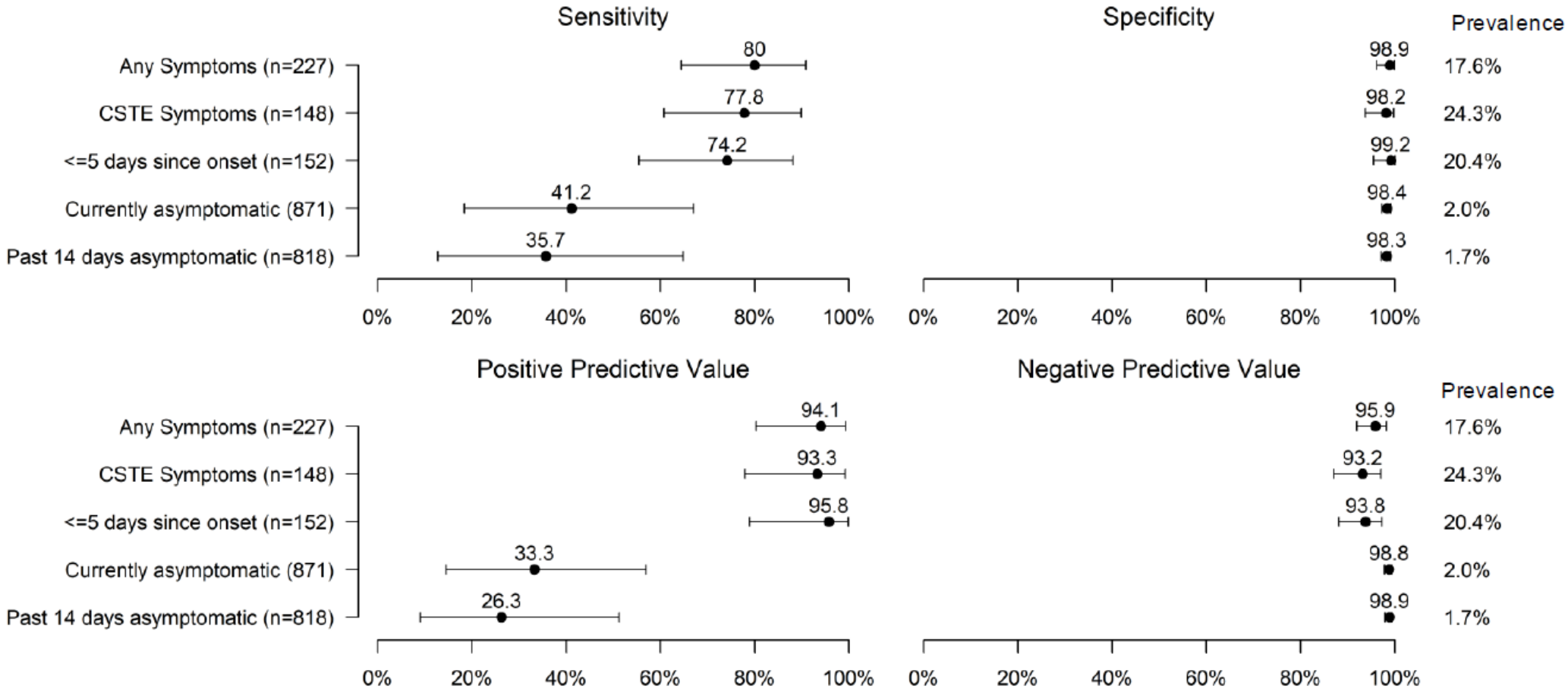
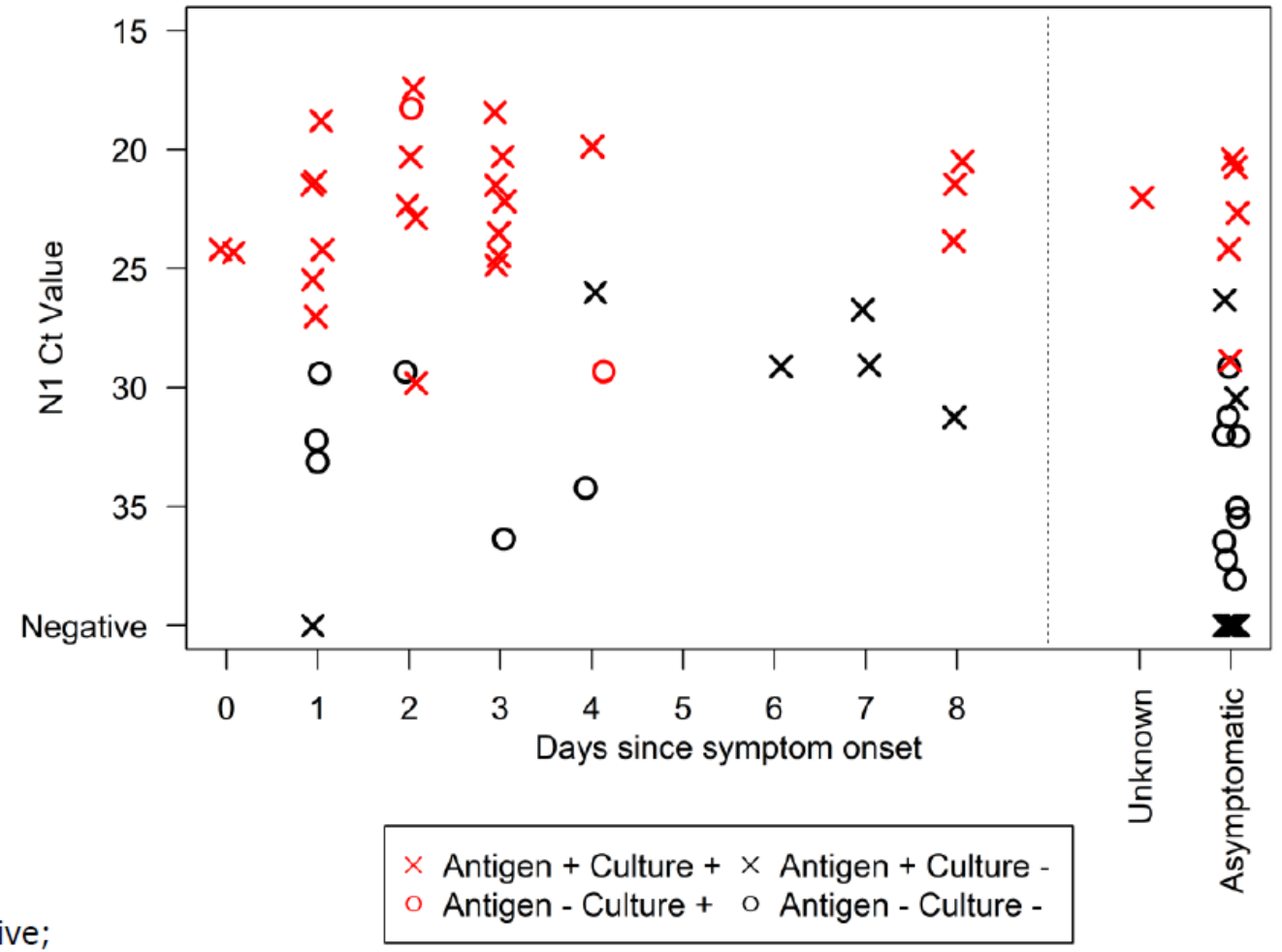
Sensitivity, specificity, PPV, and NPV of Sofia SARS Antigen FIA compared to RT-PCR



Data are provisional – do not distribute

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

Data are provisional – do not distribute

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)

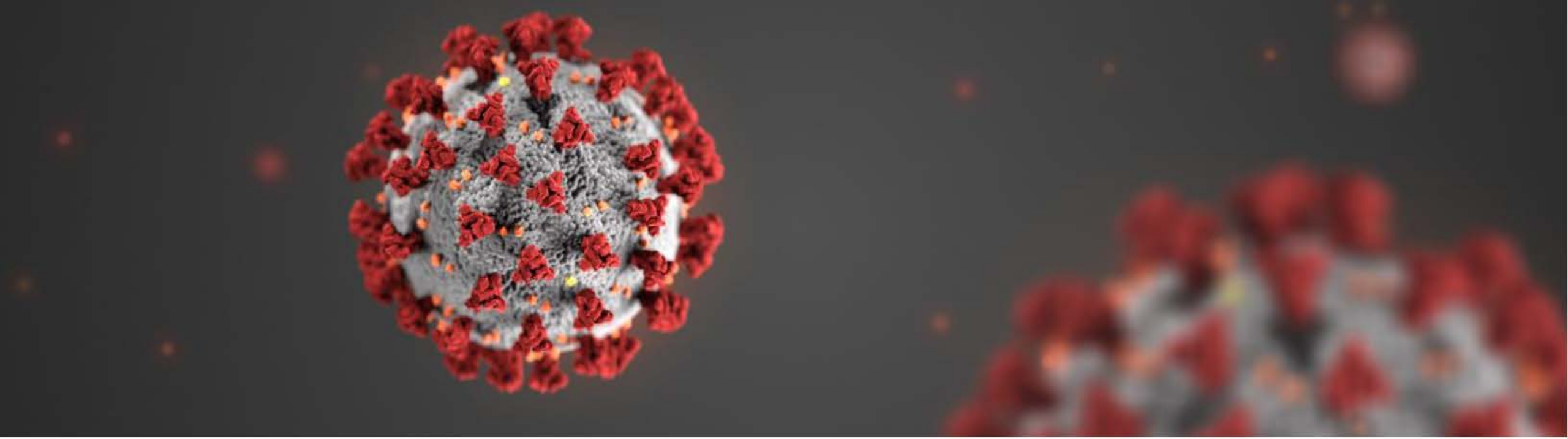
- Virus recovery was possible from **2 of 18 false negative** antigen results

- 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



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

FDA Update

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

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/

U.S. FOOD & DRUG ADMINISTRATION

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

U.S. FOOD & DRUG ADMINISTRATION

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Thank You For Your Time!

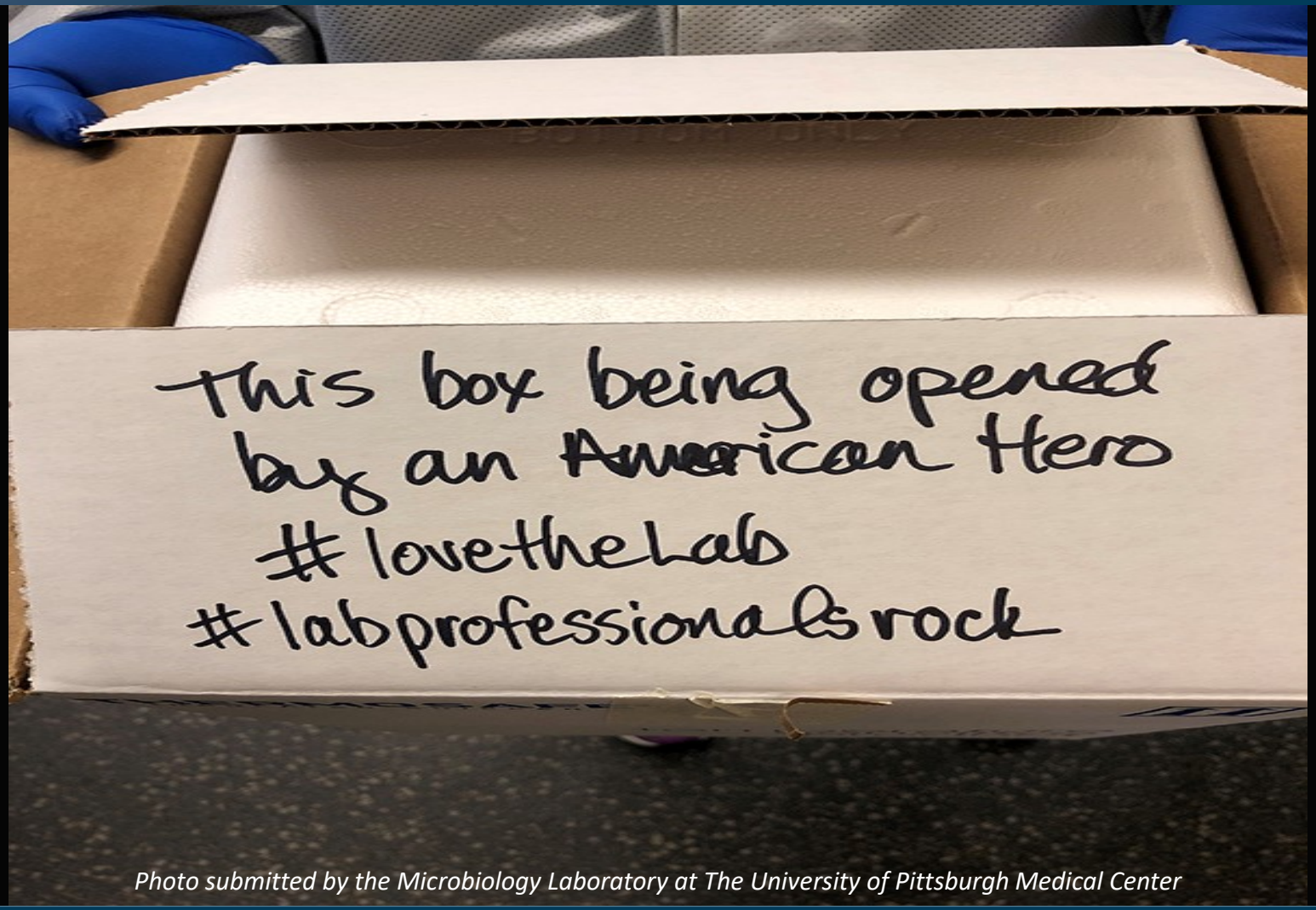

Photo submitted by the Microbiology Laboratory at The University of Pittsburgh Medical Center