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)
The next call will be on **Monday, November 30**\(^{rd}\) 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

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

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

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
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

1,686

47.9%

Average Lab Testing Volume (Past 7 Days)

Average Lab Testing Capacity without Resource Constraints

Testing Capacity Utilization

Locations of Labs Testing Below Full
COVID-19 Test Utilization
National Overview of U.S. Lab COVID-19 Testing

Week 1 Week 2 Week 3 Week 4 Week 5 Week 6 Week 7

Average Lab Testing Volume Avg. Lab Testing Capacity w/no constraints
COVID-19 Laboratory Developed Tests (LDT) Testing Supply Shortages
COVID-19 Commercial Molecular Assay Testing
Supply Shortages

Average % of Labs with Supply Shortage

Kits and consumables
IVD Instruments
Control Materials

Week 1 | Week 2 | Week 3 | Week 4 | Week 5 | Week 6 | Week 7
Non-COVID-19 Laboratory Testing Supplies Shortages

Avg. % of Labs with Supply Shortages

- Bacteria
- Mycobacteria
- Fungal
- Parasitic
- STI

Week 1 | Week 2 | Week 3 | Week 4 | Week 5 | Week 6 | Week 7
Non-COVID-19 Laboratory Testing Supplies Shortages

Average # of Days of Testing Remaining w/Current Supplies

Week 1  Week 2  Week 3  Week 4  Week 5  Week 6  Week 7

- bacteria
- Mycobacteria
- Fungal
- Parasitic
- STI
Where Can I Access This Data?

Updated data will be available on Tuesday, November 17.

Visit: https://asm.org/supplydata
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, Gerencio Fajardo, Dena Bushman, Miranda Delahoy, John-Paul Biguouette, Glen Abedi, Blake Cherney
* = Presenter

data.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**
Background – Wisconsin summary

Data are provisional – do not distribute

Source: [https://www.dhs.wisconsin.gov/covid-19/cases.htm](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

Overall (N=1098)

Asymptomatic (N=871)

≥1 symptom (N=227)

CSTE COVID-19 clinical criteria (N=148)

Data are provisional – do not distribute
## Sensitivity, specificity, PPV, and NPV of Sofia SARS Antigen FIA compared to RT-PCR

### Symptomatic (≥1 symptom)

<table>
<thead>
<tr>
<th>Antigen</th>
<th>RT-PCR</th>
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<tbody>
<tr>
<td></td>
<td>Positive</td>
<td>Negative</td>
<td>Total</td>
<td>Positive</td>
<td>Negative</td>
</tr>
<tr>
<td>Positive</td>
<td>32</td>
<td>2</td>
<td>34</td>
<td>7</td>
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</tr>
<tr>
<td>Negative</td>
<td>8</td>
<td>185</td>
<td>193</td>
<td>10</td>
<td>840</td>
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<tr>
<td>Total</td>
<td>40</td>
<td>187</td>
<td>227</td>
<td>17</td>
<td>854</td>
</tr>
</tbody>
</table>

- **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

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<tr>
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<tr>
<td>Positive</td>
<td>7</td>
<td>14</td>
<td>21</td>
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<tr>
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<td>11</td>
<td>841</td>
</tr>
<tr>
<td>Total</td>
<td>17</td>
<td>854</td>
<td>871</td>
<td>42</td>
<td>842</td>
</tr>
</tbody>
</table>

- **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%)

Data are provisional – do not distribute
Sensitivity, specificity, PPV, and NPV of Sofía 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

Data are provisional – do not distribute
For more information, contact CDC
1-800-CDC-INFO (232-4636)

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)
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

COVID-19 Frequently Asked Questions

COVID-19 Updates

FDA Townhall Meetings

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**
This box being opened by an American Hero
#lovetheLab
#labprofessionalsrock

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