Clinical Laboratory COVID-19 Response Call  
Monday, March 21, 2022, at 3:00 PM ET

- Welcome  
  - Jasmine Chaitram, CDC Division of Laboratory Systems (DLS)
- Antigen Testing Guidance Update  
  - Reynolds (Ren) Salerno, CDC Division of Laboratory Systems (DLS)
- HHS Reporting Requirements  
  - Jason Hall, CDC Data, Analytics, and Visualization Task Force
- Key Findings for SARS-CoV-2 Testing Using Rapid Antigen Tests from RADx Clinical Studies Core  
  - Apurv Soni, University of Massachusetts Chan Medical School
- FDA Update  
  - Tim Stenzel, US Food and Drug Administration (FDA)
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
Find CLCR call information, transcripts, and audio recordings on this page

The next call will be on **Monday, April 18** 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
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.
Antigen Testing Guidance Update

Reynolds (Ren) Salerno
CDC Division of Laboratory Systems (DLS)
Antigen Testing in Healthcare Settings and Testing Sites

Who the guidance is for:
- Healthcare professionals who order antigen tests, perform antigen testing, receive or report test results
- Not intended to be used as self-testing guidance for the general public

As of March 21, 2022:
- There are currently 48 antigen diagnostic test products with FDA emergency use authorization, 17 of which are authorized for home use
- ~6.5M antigen tests have been reported in healthcare settings nationwide in 2022

Testing guidance webpage views:
- As of 3/21, the antigen testing webpage has been viewed 643,146 times in 2022
- In 2021, the page received 2,856,204 views

Interim Guidance for Antigen Testing for SARS-CoV-2
Updates to Antigen Testing Guidance Webpage

• Removed:
  – General guidance for congregate settings
  – General guidance for processing and handling SARS-CoV-2 clinical specimens

• Updated:
  – Information on when to consider confirmatory testing in symptomatic and asymptomatic individuals
  – Antigen testing algorithm figure
Updated Testing Algorithm For Healthcare Professionals

**Asymptomatic**

- **Antigen Negative**
  - Close contact?
    - No
    - Up to date on vaccines?
      - Yes
        - No evidence of SARS-CoV-2 infection: No need to quarantine
      - No
        - Quarantine for at least 5 days after close contact; continue to follow precautions through day 10
  - Yes

- **Antigen Positive**
  - Close contact?
    - No
      - Yes
        - Evidence of SARS-CoV-2 infection: Isolate for at least 5 days from date test specimen was collected or date of symptom onset
    - Yes
      - Up to date on vaccines?
        - No
          - Quarantine for at least 5 days after first day of symptoms; continue to follow precautions through day 10; consider alternative diagnosis
        - Yes
          - Consider alternative diagnosis. Follow CDC guidelines for What to Do if You Are Sick.

**Symptomatic (Test immediately)**

- **Antigen Positive**
  - Confirmatory NAAT or Serial Antigen Test
    - Positive
      - Close contact?
        - No
          - Yes
            - Up to date on vaccines?
              - No
                - Quarantine for at least 5 days after first day of symptoms; continue to follow precautions through day 10; consider alternative diagnosis
              - Yes
                - Consider alternative diagnosis. Follow CDC guidelines for What to Do if You Are Sick.
    - Negative

- **Antigen Negative**
HHS Reporting Requirements Update

Jason Hall
CDC Data, Analytics, and Visualization Task Force
HHS Reporting Requirements

What is changing with the updated guidance?

• Report only positive test results from any rapid waived tests. This includes rapid NAAT and antigen testing conducted for screening testing at schools, correctional facilities, employee testing programs, long-term care facilities, and rapid testing performed in pharmacies, medical provider offices, and drive-through and pop-up testing sites.

• Facilities are no longer required to report antibody test results, positive or negative.

• Check with your local or state health department for additional reporting requirements.

<table>
<thead>
<tr>
<th>Testing Type</th>
<th>Is Reporting Required Under this Guidance?</th>
<th>Examples</th>
</tr>
</thead>
</table>
| **NAAT-testing conducted in a facility certified under CLIA to perform moderate or high-complexity tests** | Required Required | • Laboratory-based Nucleic Acid Amplification Test (NAAT) testing, including RT-PCR, TMA, LAMP, and SDA tests  
  • See https://www.cdc.gov/coronavirus/2019-ncov/lab/naats.html for more information |
| **All other testing (except antibody)**                                      | Required Optional*                          | • Testing conducted in a setting operating under a CLIA certificate of waiver such as rapid tests used in many settings (e.g., screening testing at schools, correctional facilities, employee testing programs, long-term care facilities, and point-of-care testing performed in pharmacies, medical provider offices, and drive-through and pop-up testing sites).  
  • Non-NAAT (e.g., high throughput antigen) testing conducted in a facility certified under CLIA to perform moderate or high-complexity tests |
| **Antibody testing**                                                        | Optional* Optional*                         | • Tests used to determine previous infection with SARS-CoV-2 in any setting                                                             |
Key findings for SARS-CoV-2 testing using Rapid Antigen Tests from RADx Clinical Studies Core

March 21, 2022: Clinical Laboratory Covid-19 Response Call
Apurv Soni MD, PhD on behalf of RADx Tech Clinical Studies Core team
1. Comparison of Antigen Test Performance with Delta and Omicron Variants
2. Timing of Rapid Antigen Test Positivity in Relation to onset of close-contact
3. Association of Mass Distribution of Tests with New Cases of SARS-CoV-2 during a subsequent Surge
4. Reporting behavior of users of Say Yes! Covid Test program
Test Us At Home Study Overview

**Brief Overview of Study**

- **Enrolled**
  - Participants provide mailing address through the Test Us At Home study app
  - Participants complete baseline questionnaires
  - If assigned OTC test requires, participants are prompted (with link) to download OTC device app and use as instructed.

- **Participant is assigned to a particular OTC test based on pre-defined criteria**
  - Fulfillment center ships the OTC test kits to participants’ home (48hrs)

- **Participants confirm in app they have received both OTC tests and Quest kits before starting testing period.**
  - This includes OTC test kits with instructions, At Home Collection kits with instructions, and pre-paid return labels for At Home Collection.

- **Participant confirms OTC and Quest materials received and performs tests as indicated by the IFU**

- **Quest team sends the tests to participants’ home**

**Testing Day**

<table>
<thead>
<tr>
<th>Testing Day</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
<th>11</th>
<th>12</th>
<th>13</th>
<th>14</th>
<th>15</th>
</tr>
</thead>
<tbody>
<tr>
<td>OTC Device</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Molecular Comparator</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

**Study Team**

**Quest Team**

**Participants’ Experience**

**Study App Team**
Test Us At Home Study Overview

- Soft-launch with a known community
- Community outreach through local county health officers
- Waitlist to refine participation from hotspots
- Selected pull to balance sociodemographic characteristics
Delta vs. Omicron

**Figure 1: Test Us At Home Participant CONSORT Diagram**

- 7,349 participants enrolled by January 23, 2022
- 51 participants did not meet inclusion criteria (had Covid-19 infection >3 months ago)
- 1,590 participants had not started testing before January 30, 2022
- 5,708 participants with at least one day of testing
- 23 participants tested positive/inconclusive between Dec 20 and Dec 28, 2021 without sequencing data
- 11 participants never tested once using RT-PCR test
- 5,674 participants; 321 participants tested positive on RT-PCR at least once (105 Delta, 215 Omicron)
- 168 participants with a positive or inconclusive PCR on first testing day of the study (44 Delta, 124 Omicron)

**Population A:** 5,500 participants included in this study (39,615 testing days)
- 153 participants with first RT-PCR+ during the study (51 Delta, 92 Omicron)

**Population B:** 86 participants with repeat positive RT-PCR within 48 hours from first positive RT-PCR (29 Delta, 57 Omicron)

**Population C:** 38 participants with negative RT-PCR within 48 hours from first positive RT-PCR (22 Delta, 16 Omicron)

**Population D:** 20 participants did not repeat RT-PCR within 48 hours from first positive RT-PCR (10 Delta, 10 Omicron)

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Soni et al; https://doi.org/10.1101/2022.02.27.22271090
Delta vs. Omicron

Same-Day as 1st RT-PCR+

48-Hours from 1st RT-PCR+

Model AUC: 0.93 (0.90-0.96)

Includes all RT-PCR+ from Population A with available CT counts (n = 306)

Predicted probabilities calculated using inverse logit transformation

95% CI calculated using the Delta method

Multilevel model used to account for repeated measures from the same participant

<table>
<thead>
<tr>
<th>Observed data</th>
<th>Delta</th>
<th>Omicron</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Same-day RT-PCR+ CT values</strong></td>
<td><strong>RT-PCR+ (n, col%)</strong></td>
<td><strong>Ag-RDT+ (n, row%)</strong></td>
</tr>
<tr>
<td>&lt;15</td>
<td>2 (2.2)</td>
<td>2 (100.0)</td>
</tr>
<tr>
<td>15 &lt; 20</td>
<td>22 (24.2)</td>
<td>19 (86.4)a</td>
</tr>
<tr>
<td>20 &lt; 25</td>
<td>18 (19.6)</td>
<td>18 (100.0)</td>
</tr>
<tr>
<td>25 &lt; 30</td>
<td>20 (21.7)</td>
<td>11 (55.0)</td>
</tr>
<tr>
<td>30 &lt; 35</td>
<td>22 (23.9)</td>
<td>4 (18.2)</td>
</tr>
<tr>
<td>35+</td>
<td>7 (7.6)</td>
<td>2 (28.6)</td>
</tr>
</tbody>
</table>

a) Same-day Ag-RDT+ on coordinator read from a participant-uploaded picture

<table>
<thead>
<tr>
<th>Observed data</th>
<th>Delta</th>
<th>Omicron</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>First RT-PCR+ CT values</strong></td>
<td><strong>RT-PCR+ (n, col%)</strong></td>
<td><strong>Ag-RDT+ (n, row%)</strong></td>
</tr>
<tr>
<td>&lt;15</td>
<td>1 (3.5)</td>
<td>1 (100.0)</td>
</tr>
<tr>
<td>15 &lt; 20</td>
<td>4 (13.8)</td>
<td>3 (75.0)a</td>
</tr>
<tr>
<td>20 &lt; 25</td>
<td>4 (20.0)</td>
<td>4 (100.0)</td>
</tr>
<tr>
<td>25 &lt; 30</td>
<td>2 (8.9)</td>
<td>2 (100.0)</td>
</tr>
<tr>
<td>30 &lt; 35</td>
<td>12 (41.4)</td>
<td>6 (50.0)</td>
</tr>
<tr>
<td>35+</td>
<td>6 (20.7)</td>
<td>2 (33.3)</td>
</tr>
</tbody>
</table>

a) Same-day Ag-RDT+ on coordinator read from a participant-uploaded picture

b) No subsequent test after first RT-PCR+
Comparison between tests overall

Soni et al; Unpublished Work

- Probability of Ag+ test

<table>
<thead>
<tr>
<th>Observed data</th>
<th>Delta</th>
</tr>
</thead>
<tbody>
<tr>
<td>Same-day RT-PCR+ CT values</td>
<td>RT-PCR+ (n, col%)</td>
</tr>
<tr>
<td>&lt;15</td>
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<tr>
<td>20 &lt; 25</td>
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</tr>
<tr>
<td>25 &lt; 30</td>
<td>20 (21.7)</td>
</tr>
<tr>
<td>30 &lt; 35</td>
<td>22 (23.9)</td>
</tr>
<tr>
<td>35+</td>
<td>7 (7.6)</td>
</tr>
</tbody>
</table>

- Omicron

Based on serial testing data from participants who were asymptomatic at time of enrollment.
### Singleton PCR+ Findings

#### Table 1: Distribution of participant characteristics based on the variant type

<table>
<thead>
<tr>
<th>Population</th>
<th>Population A: 1st RT-PCR+ observed during the study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Variant</td>
<td>Total</td>
</tr>
<tr>
<td>N</td>
<td>153</td>
</tr>
<tr>
<td>Testing days</td>
<td>1,162</td>
</tr>
<tr>
<td>Result of RT-PCR performed within 48 hours of 1st RT-PCR+</td>
<td></td>
</tr>
<tr>
<td>Positive or Indeterminant (Population B)</td>
<td>86 (56.2)</td>
</tr>
<tr>
<td>Negative (Population C)</td>
<td>38 (24.8)</td>
</tr>
<tr>
<td>Test not performed (Population D)</td>
<td>29 (19.0)</td>
</tr>
</tbody>
</table>

#### Table 1: Distribution of participant characteristics for different populations used in this analysis

<table>
<thead>
<tr>
<th>Population</th>
<th>All</th>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
</tr>
</thead>
<tbody>
<tr>
<td>Variant</td>
<td>Total</td>
<td>Δ</td>
<td>O</td>
<td>Total</td>
<td>Δ</td>
</tr>
<tr>
<td>Unvaccinated (n, col%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td># Vaccine Doses (n, col%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>297</td>
<td>6</td>
<td>23</td>
<td>6</td>
<td>2</td>
</tr>
<tr>
<td>(6.2) (14.1) (5.2)</td>
<td>(2.6)</td>
<td>(8.3)</td>
<td>(3.0)</td>
<td>(4.8)</td>
<td>(9.5)</td>
</tr>
<tr>
<td>2</td>
<td>2,717</td>
<td>404</td>
<td>39</td>
<td>76</td>
<td>37</td>
</tr>
<tr>
<td>(57.0) (63.7) (58.2)</td>
<td>(35.5)</td>
<td>(77.1)</td>
<td>(76.2)</td>
<td>(62.9)</td>
<td>(76.2)</td>
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<tr>
<td>3+</td>
<td>1,754</td>
<td>703</td>
<td>26</td>
<td>33</td>
<td>26</td>
</tr>
<tr>
<td>(36.8) (29.0) (38.8)</td>
<td>(61.8)</td>
<td>(14.6)</td>
<td>(14.3)</td>
<td>(32.3)</td>
<td>(41.5)</td>
</tr>
</tbody>
</table>
# Singleton PCR+ Findings

<table>
<thead>
<tr>
<th>Population</th>
<th>B: First RT-PCR+ followed by a 2nd RT-PCR+ in 48 hours</th>
<th>C: First RT-PCR+ followed by RT-PCR- in 48 hours</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total</td>
<td>Δ</td>
</tr>
<tr>
<td>N Testing days</td>
<td>86</td>
<td>29</td>
</tr>
<tr>
<td>Ag-RDT result in comparison to first RT-PCR+ (n, col%)</td>
<td>670</td>
<td>231</td>
</tr>
<tr>
<td>Positive same-day</td>
<td>31</td>
<td>8</td>
</tr>
<tr>
<td>Positive w/in 48hrs</td>
<td>74</td>
<td>23</td>
</tr>
<tr>
<td>Positive w/in 96hrs</td>
<td>82</td>
<td>26</td>
</tr>
<tr>
<td>Positive w/in a week</td>
<td>83</td>
<td>26</td>
</tr>
<tr>
<td>Negative</td>
<td>3</td>
<td>3</td>
</tr>
</tbody>
</table>

Lowest RT-PCR+ CT count (n, col%) | 10 to <15 | 15 to <19 | 20 to <25 | 25 to <30 | 30 to <35 | 35+ | Missing |
<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>3</td>
<td>2</td>
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<td>0</td>
<td>0</td>
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<td>5</td>
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<tr>
<td></td>
<td>39</td>
<td>6</td>
<td>23</td>
<td>10</td>
<td>10</td>
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<td>5</td>
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<td>5</td>
<td>0</td>
<td>22</td>
<td>15</td>
<td>7</td>
<td>5</td>
</tr>
</tbody>
</table>

24
**Test Us At Home Daily**

- Objective: Characterize PPA of Rapid Antigen Tests (Abbott, BD) in relation to onset of close-contact, symptoms, RT-PCR+
- Requirement: Recruitment of asymptomatic close-contacts

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**Cumulative Participant Enrollment by Days**

<table>
<thead>
<tr>
<th>Study Day</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>OTC Device</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Molecular Comparator</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
</tbody>
</table>

**Close Contact Frequency Percent**

- False: 64 (10%)
- True: 547 (87%)
- Total: 628 (100%)

Soni et al; Unpublished Work
Time from First Close Contact

Soni et al; Unpublished Work
500, tests kits (25 per family) distributed June 7th – August 11th

Keep Testing Ypsilanti and Ann Arbor!

If you have already received a test kit, please continue testing twice per week as we continue to see increase in COVID-19 community transmission resulting from the Delta variant. The initiative has already distributed over 20,000 kits and has now concluded.

### Region Population Mean Cases Standard Deviation Vaccination Rate: June 7th Vaccination Rate: Aug 11th

<table>
<thead>
<tr>
<th></th>
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<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Ann Arbor</td>
<td>120,735</td>
<td>25.2</td>
<td>20.2</td>
<td>72.4</td>
<td>75.3</td>
</tr>
<tr>
<td>Ypsilanti</td>
<td>20,828</td>
<td>27.6</td>
<td>21.0</td>
<td>54.3</td>
<td>59.1</td>
</tr>
<tr>
<td>Washtenaw Countya</td>
<td>226,038</td>
<td>23.1</td>
<td>39.8</td>
<td>62.0</td>
<td>65.2</td>
</tr>
</tbody>
</table>
SYCT! Michigan Association with Community Transmission

<table>
<thead>
<tr>
<th>Region</th>
<th>Cases Prevented per Day (at Day 60)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ann Arbor + Ypsilanti joint</td>
<td>39.2</td>
</tr>
<tr>
<td>Ann Arbor</td>
<td>22.1</td>
</tr>
<tr>
<td>Ypsilanti</td>
<td>23.4</td>
</tr>
</tbody>
</table>

Soni et al; Unpublished Work
FDA Update

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

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

- 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/](https://open.fda.gov/apis/device/covid19serology/)
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
Thank You For Your Time!

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