

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

CDC Preparedness Portal

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

Find CLCR call information, transcripts, and audio recordings on this page



The screenshot shows the CDC Preparedness Portal website. At the top left is the CDC logo and the text "Centers for Disease Control and Prevention" with the tagline "CDC 24/7: Saving Lives. Protecting People™". A search bar is located at the top right. The main heading is "Prepared Laboratories". Below this, there is a breadcrumb trail: "Prepared Laboratories > Outbreak & Response". A sidebar on the left contains a navigation menu with the following items: "Prepared Laboratories", "Preparedness Initiatives", "Outbreak & Response" (which is expanded to show "COVID-19" and "Clinical Laboratory COVID-19 Response Calls"), and a list of months from February 2022 down to September 2021. The main content area features a large banner for "Clinical Laboratory COVID-19 Response Calls" with a CDC logo and a background image of a virus particle. Below the banner, there is a paragraph explaining that the CDC's Division of Laboratory Systems (DLS) convenes regular calls with clinical laboratories to discuss the nation's clinical laboratory response to COVID-19. It states that these calls take place every other Monday at 3:00 PM Eastern time and that audio and transcripts are posted online after each call. A final paragraph provides instructions on how to submit questions for consideration, either by email at DLInquiries@cdc.gov or using the Q&A function in Zoom during the call. It notes that due to the large number of participants, not all questions can be addressed directly, but feedback will be noted and used to tailor future calls.

Next Scheduled CLCR Call

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?

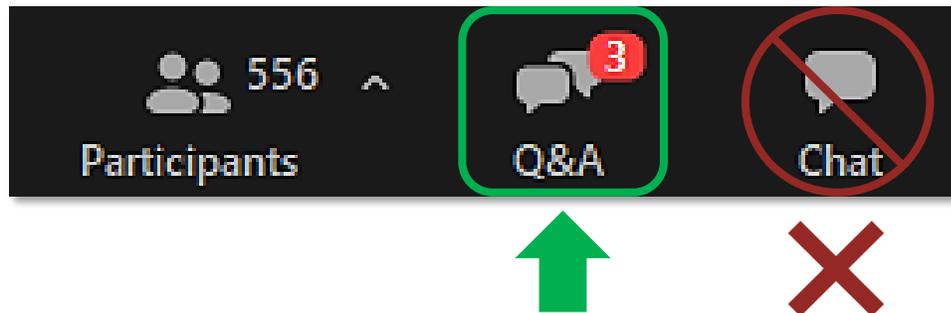
Contact LabTrainingNeeds@cdc.gov



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

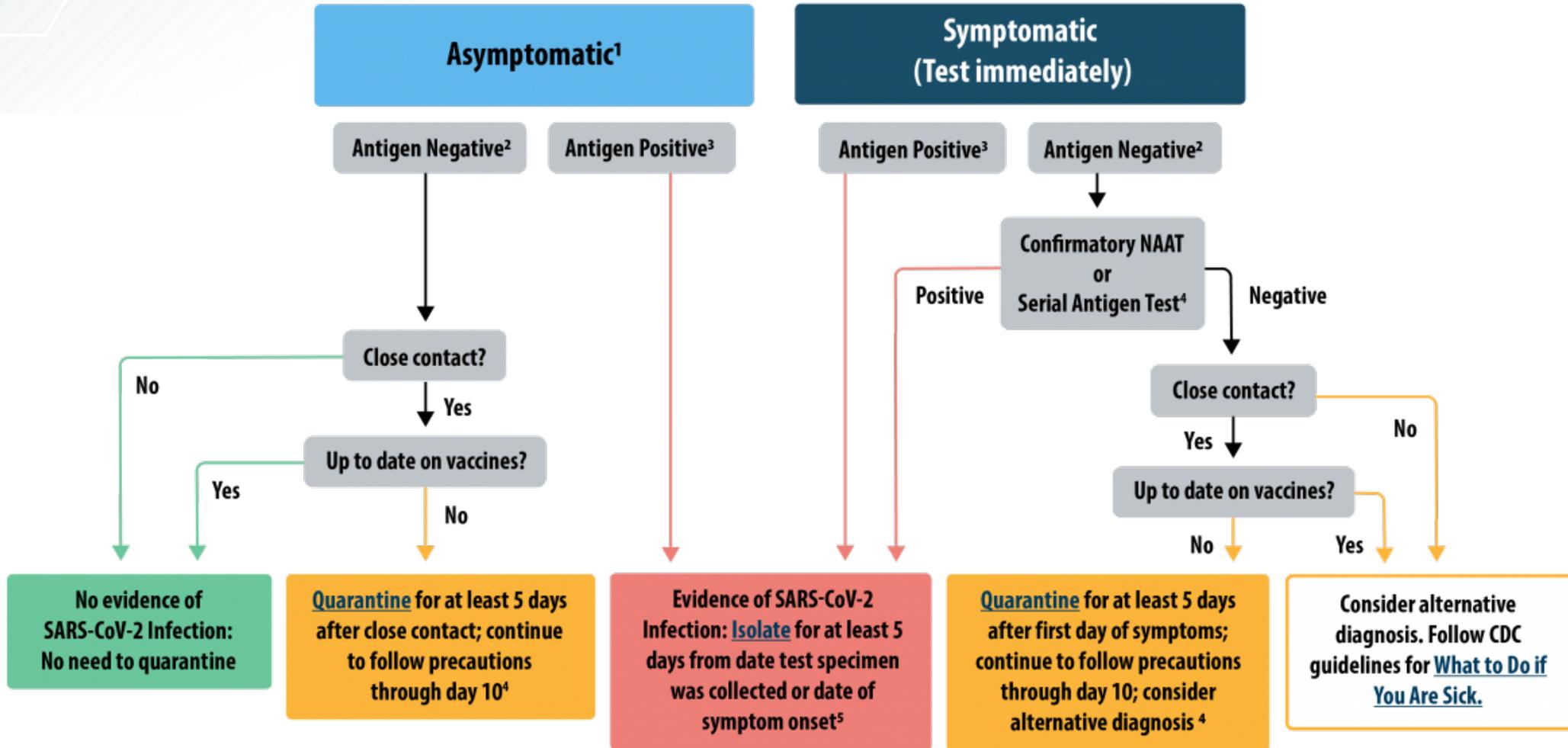
[Interim Guidance for Antigen Testing for SARS-CoV-2](#)

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

The screenshot displays the CDC COVID-19 webpage. At the top, the CDC logo and tagline 'CDC 24/7: Saving Lives. Protecting People™' are visible. A search bar contains 'Search COVID-19'. The main navigation bar includes 'HOME', 'COVID-19', 'Your Health', 'Vaccines', and 'Cas'. A red box highlights the title 'Guidance for Antigen Testing for SARS-CoV-2 for Healthcare Providers Testing Individuals in the Community'. Below this, another red box highlights the subtitle 'Interim Guidance for Antigen Testing for SARS-CoV-2', with an arrow pointing to the main title. The page is dated 'Updated Jan. 20, 2022' and includes a 'Print' option. A 'Key Points' section lists several bullet points regarding the guidance's intent for healthcare providers, its purpose for clinical and public health use, its applicability to all age groups, and its incorporation of CDC's vaccine recommendations. At the bottom, an 'On This Page' section lists links for 'General Guidance' (with a sub-link 'Using Antigen Tests for SARS-CoV-2 in Congregate Living Settings') and 'Regulatory Requirements for Using Antigen'.

Updated Testing Algorithm For Healthcare Professionals



HHS Reporting Requirements Update

Jason Hall

CDC Data, Analytics, and Visualization Task Force



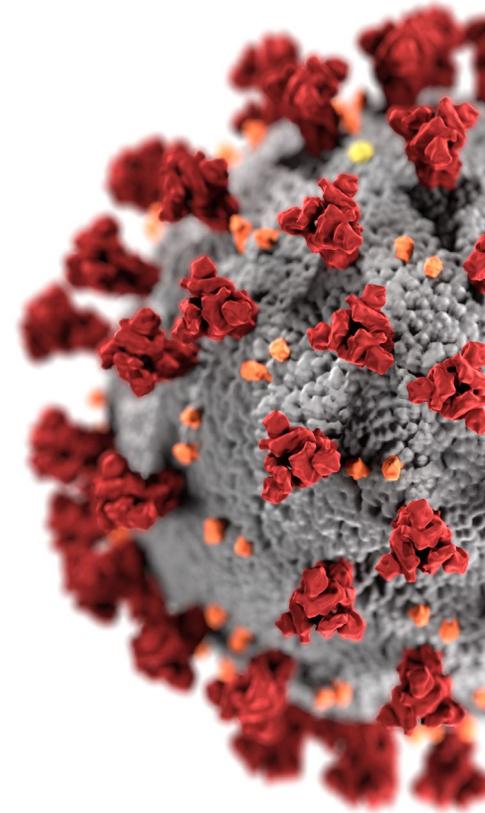
U.S. Department of
Health and Human Services
Centers for Disease
Control and Prevention

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.

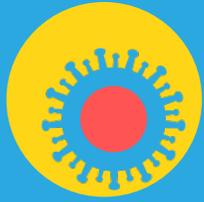
<https://www.cdc.gov/coronavirus/2019-ncov/downloads/lab/hhs-laboratory-reporting-guidance-508.pdf>



HHS Reporting Requirements

Table 1. Reporting Requirements by Entity and Type of Testing

	Is Reporting Required Under this Guidance?		Examples
	Positive Results	Negative & Inconclusive Results	
NAAT-testing conducted in a facility certified under CLIA to perform moderate or high-complexity tests	Required	Required	<ul style="list-style-type: none"> 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*	<ul style="list-style-type: none"> 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*	<ul style="list-style-type: none"> 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

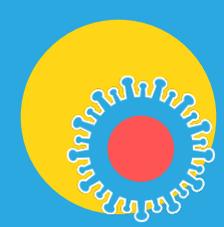
COVID-19 Home Studies



March 21, 2022: Clinical Laboratory Covid-19 Response Call

Apurv Soni MD, PhD on behalf of RADx Tech Clinical Studies Core team





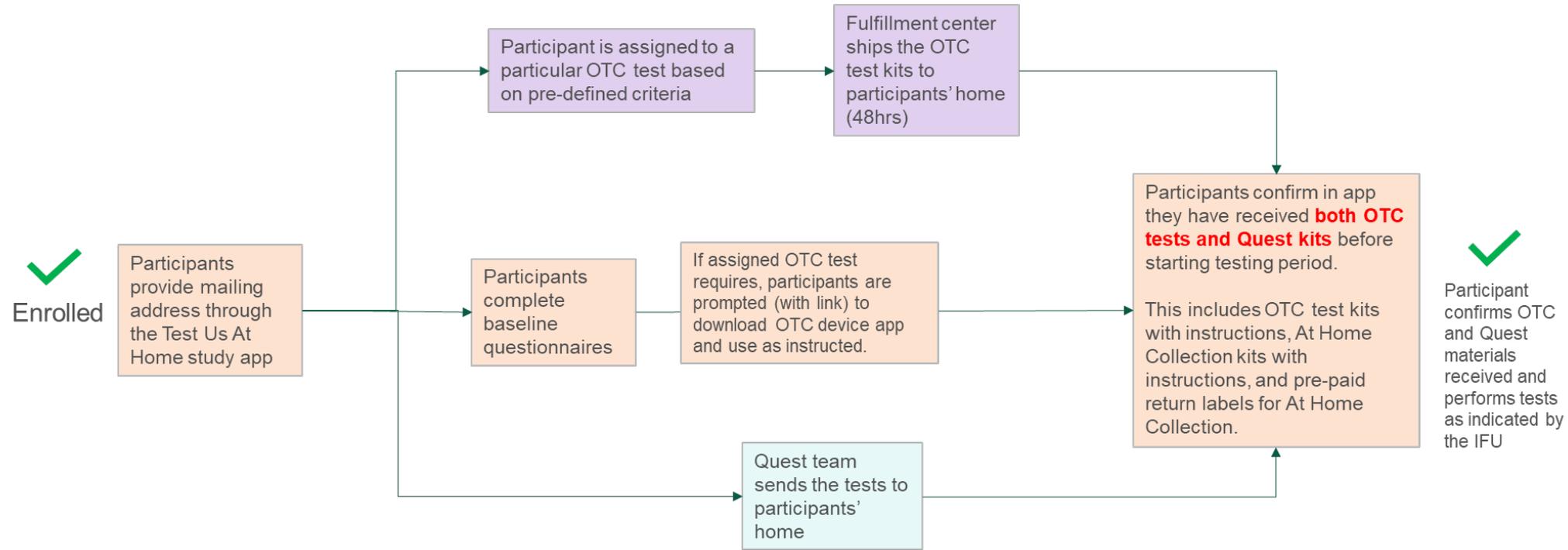
Agenda

- 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



Testing Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
OTC Device	✓		✓		✓		✓		✓		✓		✓		✓
Molecular Comparator	✓		✓		✓		✓		✓		✓		✓		

Study Team

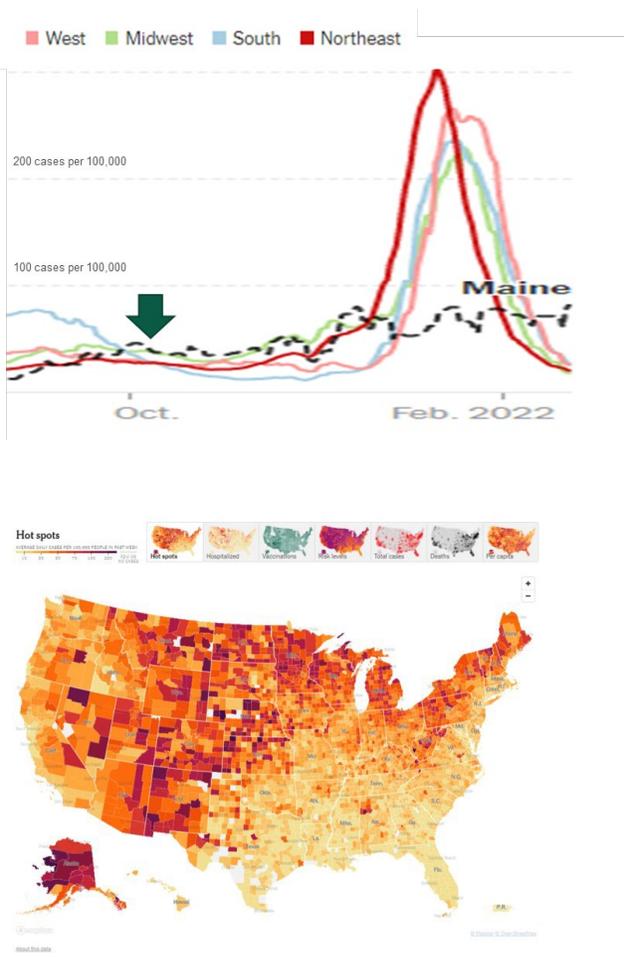
Quest Team

Participants' Experience

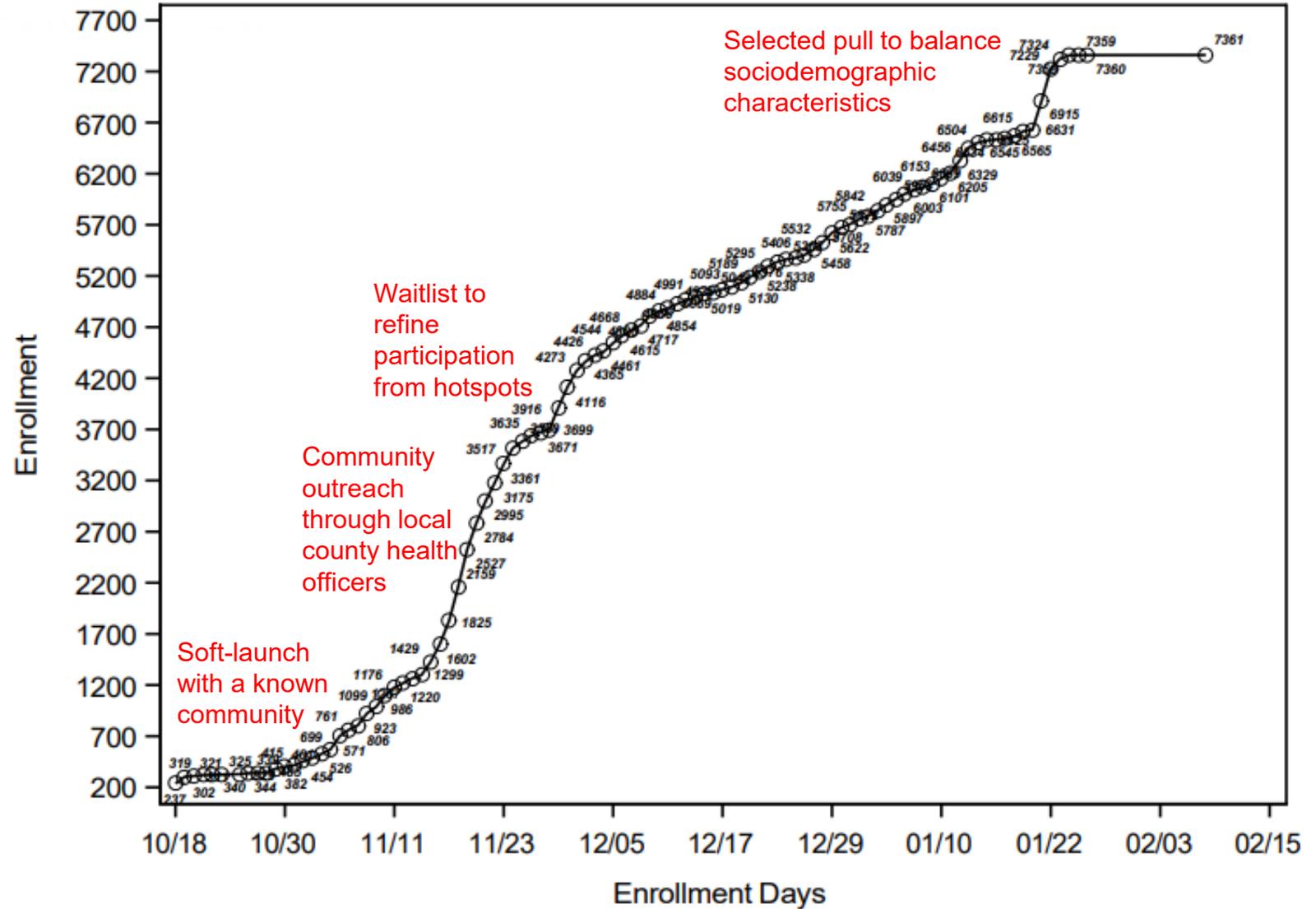
Study App Team

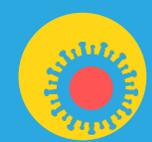


Test Us At Home Study Overview



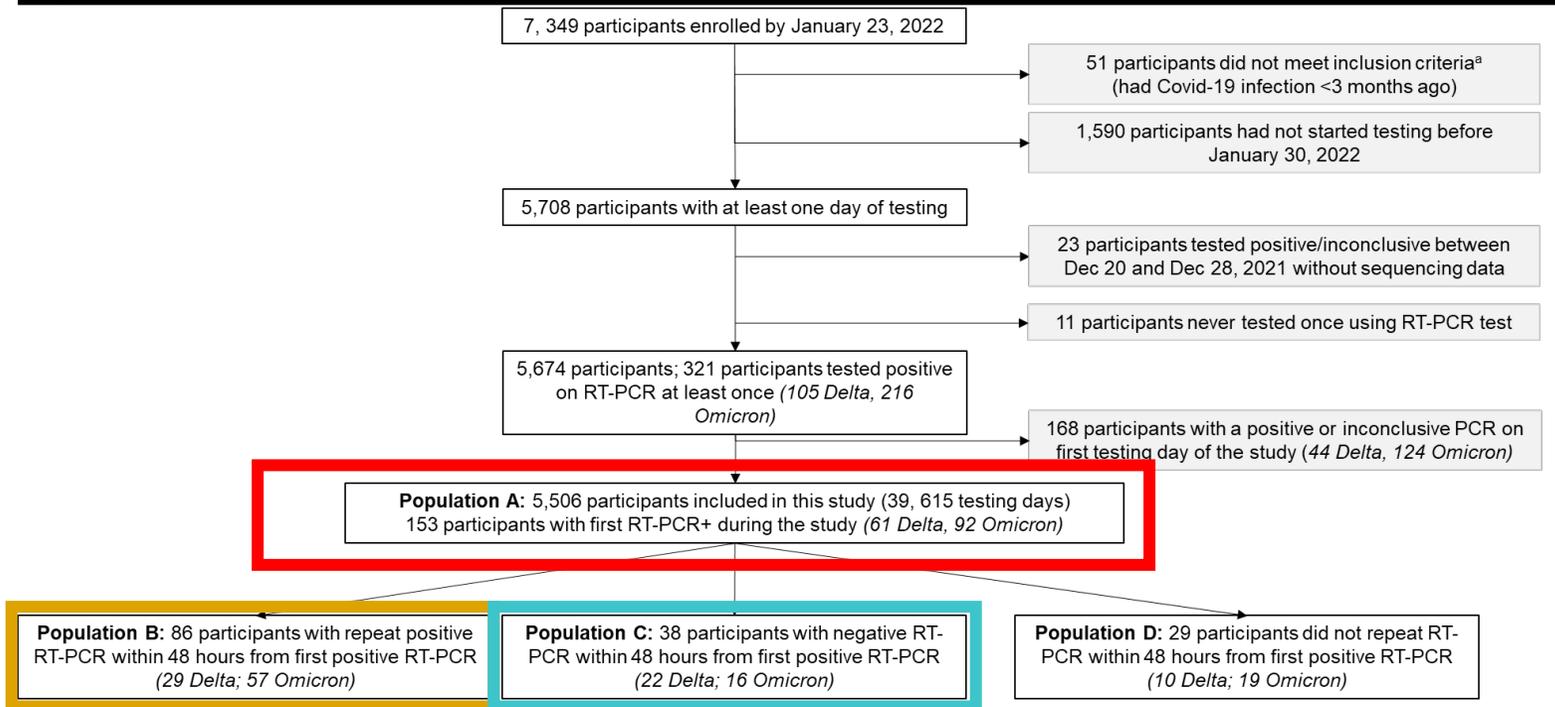
Cumulative Participant Enrollment by Days



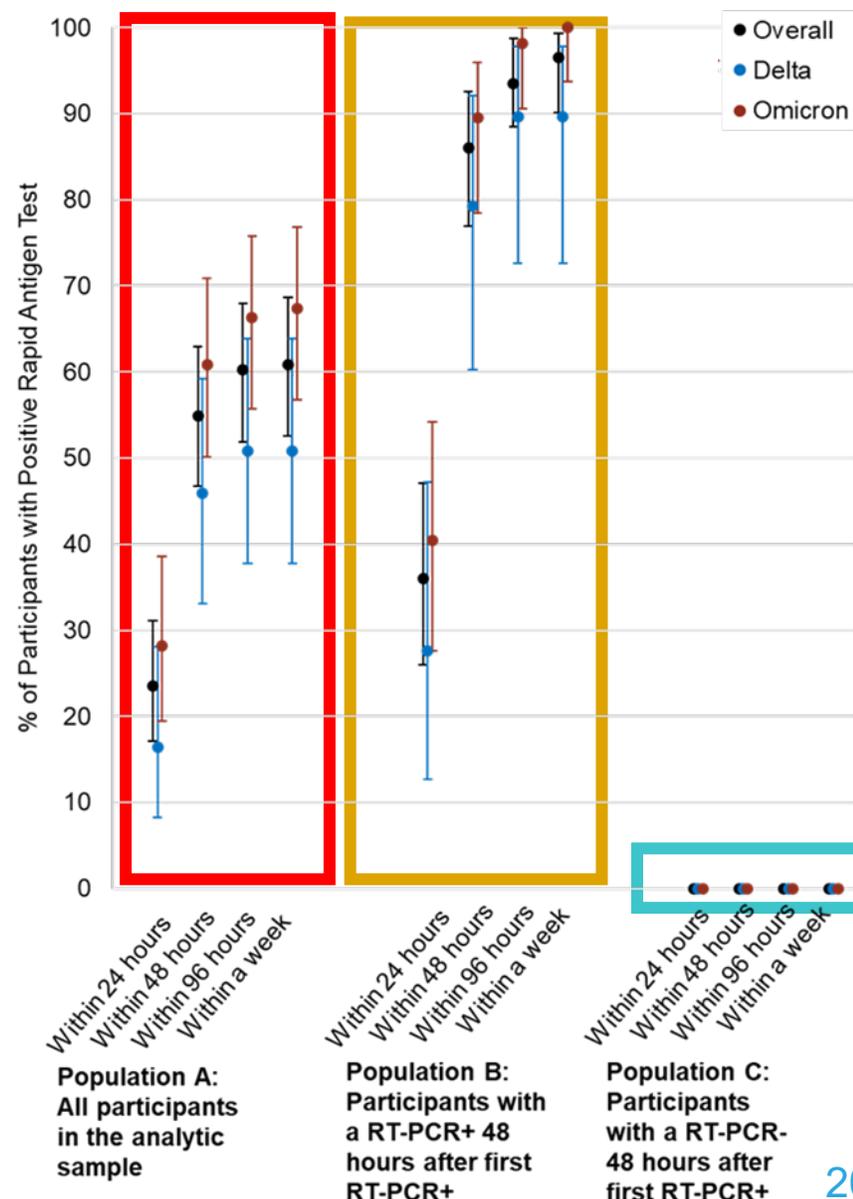


Delta vs. Omicron

Figure 1: Test Us At Home Participant CONSORT Diagram



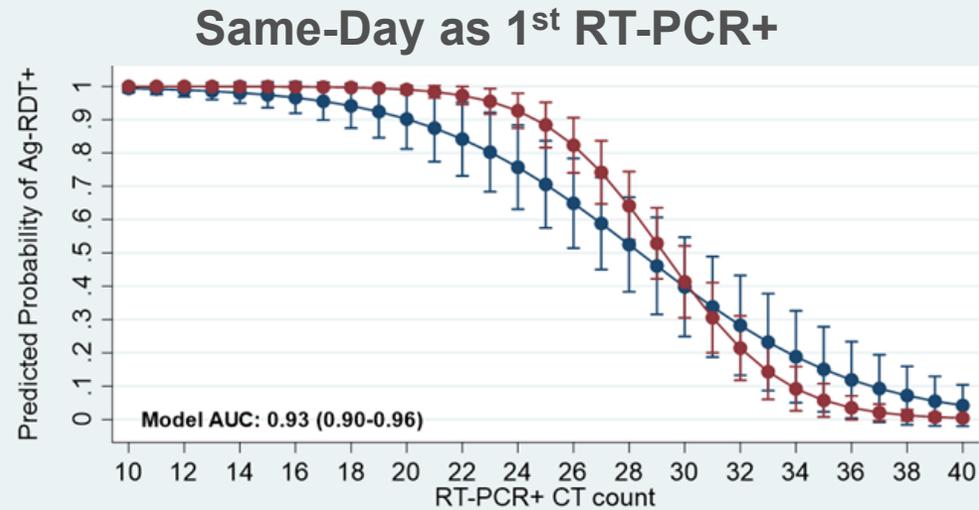
a: 51 participants self-reported meeting the eligibility criteria of no SARS-CoV2 infection within the previous three months at the time of enrollment but self-reported prior infection history within the previous three months of SARS-CoV-2 on a separate questionnaire prior to beginning their testing period



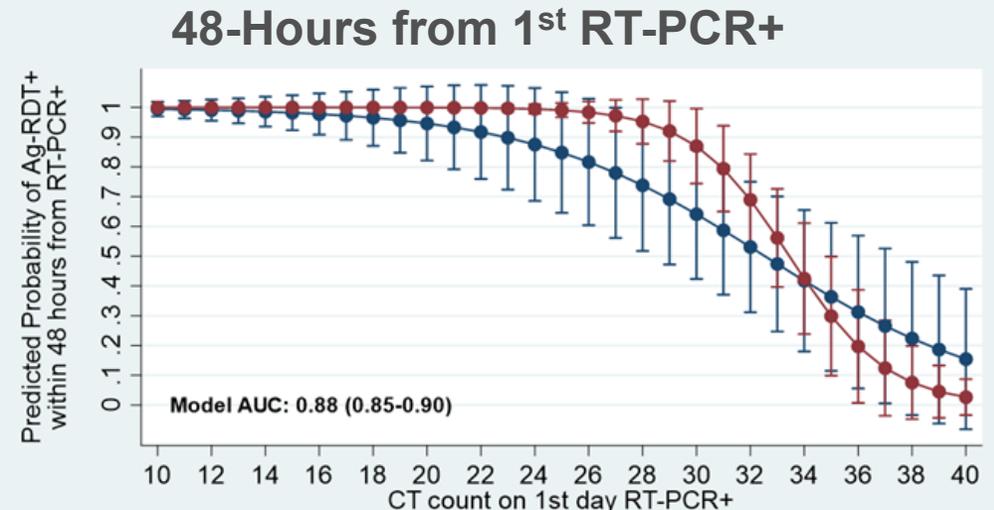


Delta vs. Omicron

Soni et al; <https://doi.org/10.1101/2022.02.27.22271090>



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



participants from Population A where index RT-PCR was available (n = 100)
 Predicted probabilities calculated using inverse logit transformation
 95% CI calculated using the Delta method

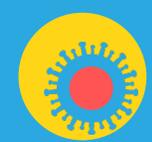
Observed data	Delta		Omicron	
	RT- PCR+ (n, col%)	Ag-RDT+ (n, row%)	RT- PCR+ (n, col%)	Ag-RDT+ (n, row%)
Same-day RT-PCR+ CT values				
<15	2 (2.2)	2 (100.0)	1 (0.5)	1 (100.0)
15 < 20	22 (24.2)	19 (86.4) ^a	24 (11.2)	23 (95.8)
20 < 25	18 (19.6)	18 (100.0)	67 (31.2)	65 (97.0)
25 < 30	20 (21.7)	11 (55.0)	56 (26.0)	40 (71.4)
30 < 35	22 (23.9)	4 (18.2)	59 (27.4)	10 (17.0)
35+	7 (7.6)	2 (28.6)	8 (3.7)	1 (12.5)

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

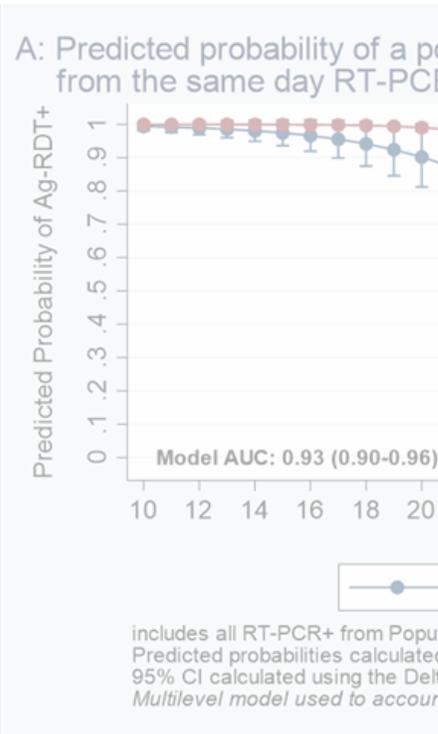
Observed data	Delta		Omicron	
	RT- PCR+ (n, col%)	Ag-RDT+ (n, row%)	RT- PCR+ (n, col%)	Ag-RDT+ (n, row%)
First RT-PCR+ CT values				
<15	1 (3.5)	1 (100.0)	0	0
15 < 20	4 (13.8)	3 (75.0) ^a	6 (8.5)	6 (100.0)
20 < 25	4 (20.0)	4 (100.0)	11 (15.5)	11 (100.0)
25 < 30	2 (6.9)	2 (100.0)	17 (23.9)	16 (94.1) ^b
30 < 35	12 (41.4)	6 (50.0)	31 (43.7)	18 (58.1)
35+	6 (20.7)	2 (33.3)	6 (8.5)	1 (16.7)

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

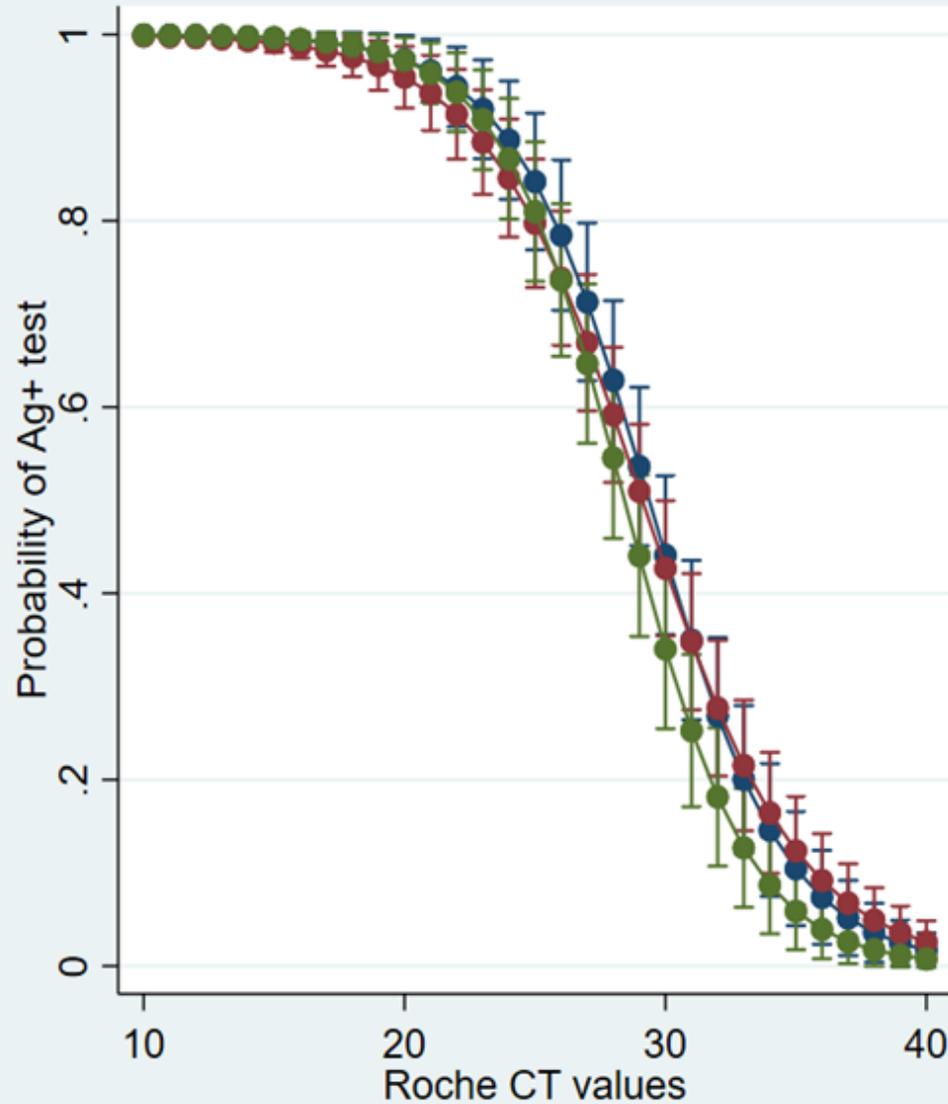
b) No subsequent test after first RT-PCR+



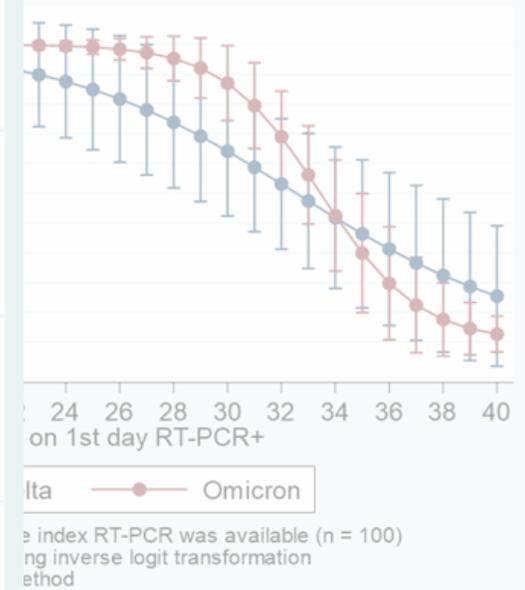
Comparison between tests overall



Soni et al; Unpublished Work



Positive antigen test within 48 hours as a function of the index CT value



Observed data	Delta
Same-day RT-PCR+ CT values	RT- PCR+ (n, col%)
<15	2 (2.2)
15 < 20	22 (24.2)
20 < 25	18 (19.6)
25 < 30	20 (21.7)
30 < 35	22 (23.9)
35+	7 (7.6)

	Omicron	
Ag-RDT+ (row%)	RT- PCR+ (n, col%)	Ag-RDT+ (n, row%)
(100.0)	0	0
(75.0) ^a	6 (8.5)	6 (100.0)
(100.0)	11 (15.5)	11 (100.0)
(100.0)	17 (23.9)	16 (94.1) ^b
(50.0)	31 (43.7)	18 (58.1)
(33.3)	6 (8.5)	1 (16.7)

a) same-day Ag-RDT+ on coordinates

Based on serial testing data from participants who were asymptomatic at time of enrollment

b) from a participant-uploaded picture



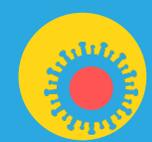
Singleton PCR+ Findings

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

Population	Population A: 1 st RT-PCR+ observed during the study			
Variant	Total	Δ	O	p-value ^a
N	153	61	92	
Testing days	1,162	471	691	
Result of RT-PCR performed within 48 hours of 1 st RT-PCR+				0.04
Positive or Indeterminant (Population B)	86 (56.2)	29 (47.5)	57 (62.0)	
Negative (Population C)	38 (24.8)	22 (36.1)	16 (17.4)	
Test not performed (Population D)	29 (19.0)	10 (16.4)	19 (20.7)	

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

Population	All			A			B			C			D		
Variant	Total	Δ ^a	O ^b	Total	Δ	O	Total	Δ	O	Total	Δ	O	Total	Δ	O
Unvaccinated (n, col%)	783 (14.1)	541 (13.0)	242 (17.6)	40 (25.8)	13 (21.3)	27 (28.7)	24 (27.9)	8 (27.6)	16 (28.1)	10 (25.6)	4 (18.2)	6 (35.3)	6 (20.0)	1 (10.0)	5 (25.0)
# Vaccine Doses (n, col%)															
1	297 (6.2)	267 (7.4)	30 (2.6)	6 (5.2)	4 (8.3)	2 (3.0)	3 (4.8)	2 (9.5)	1 (2.4)	1 (3.5)	1 (5.6)	0 (0)	2 (8.3)	1 (11.1)	1 (6.7)
2	2,717 (57.0)	2,313 (63.7)	404 (35.5)	76 (66.1)	37 (77.1)	39 (58.2)	39 (62.9)	16 (76.2)	23 (56.1)	21 (72.4)	14 (77.8)	7 (63.6)	16 (66.7)	7 (77.8)	9 (60.0)
3+	1,754 (36.8)	1,051 (29.0)	703 (61.8)	33 (28.7)	7 (14.6)	26 (38.8)	20 (32.3)	3 (14.3)	17 (41.5)	7 (24.1)	3 (16.7)	4 (36.4)	6 (25.0)	1 (11.1)	5 (33.3)



Singleton PCR+ Findings

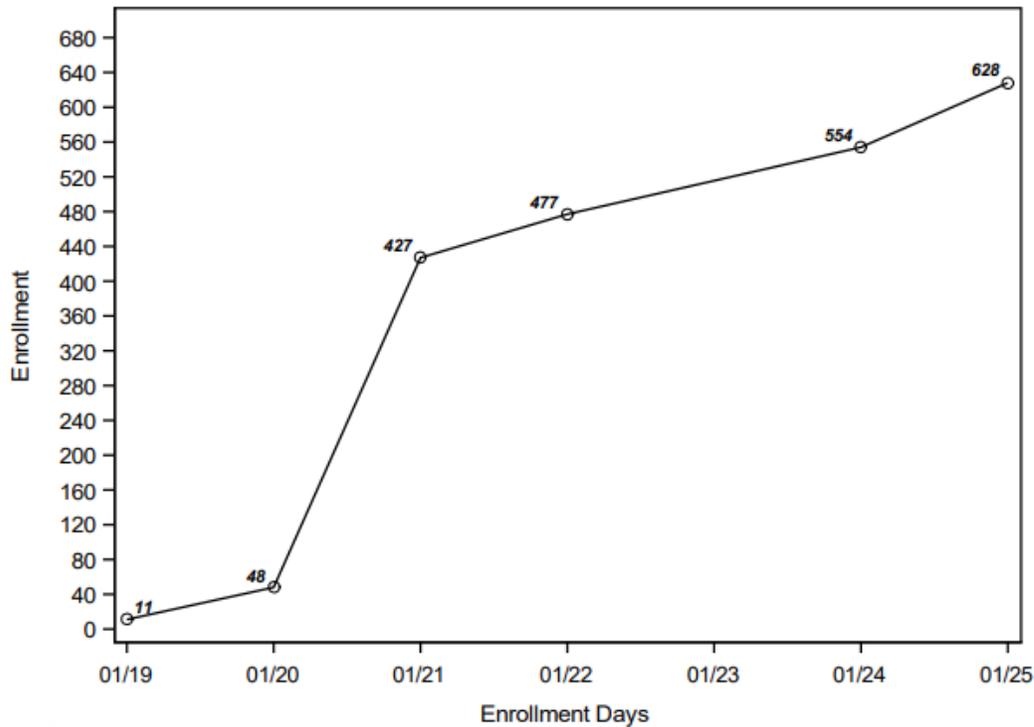
Population	B: First RT-PCR+ followed by a 2nd RT-PCR+ in 48 hours			C: First RT-PCR+ followed by RT-PCR- in 48 hours		
Variant	Total	Δ	O	Total	Δ	O
N	86	29	57	38	22	16
Testing days	670	231	439	288	170	118
Ag-RDT result in comparison to first RT-PCR+ (n, col%)						
Positive <u>same-day</u>	31 (36.1)	8 (27.6)	23 (40.4)	0 (0)	0 (0)	0 (0)
Positive w/in 48hrs	74 (86.0)	23 (79.3)	51 (89.5)	0 (0)	0 (0)	0 (0)
Positive w/in 96hrs	82 (93.5)	26 (89.7)	56 (98.2)	0 (0)	0 (0)	0 (0)
Positive w/in a week	83 (96.5)	26 (89.7)	57 (100)	0 (0)	0 (0)	0 (0)
Negative	3 (3.5)	3 (10.3)	0 (0)	38 (100)	22 (100)	16 (100)
Lowest RT-PCR+ CT count (n, col%)						
10 to <15	3 (3.5)	2 (6.9)	1 (1.8)	0 (0)	0 (0)	0 (0)
15 to <19	30 (34.9)	14 (48.3)	16 (28.1)	0 (0)	0 (0)	0 (0)
20 to <25	39 (45.4)	6 (20.7)	33 (57.9)	0 (0)	0 (0)	0 (0)
25 to <30	6 (7.0)	1 (3.5)	5 (8.8)	0 (0)	0 (0)	0 (0)
30 to <35	3 (3.5)	1 (3.5)	2 (3.5)	10 (26.3)	3 (13.6)	7 (43.8)
35+	0 (0)	0 (0)	0 (0)	6 (15.8)	4 (18.2)	2 (12.5)
Missing	5 (5.8)	5 (17.2)	0 (0)	22 (57.9)	15 (68.2)	7 (43.8)



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

Cumulative Participant Enrollment by Days



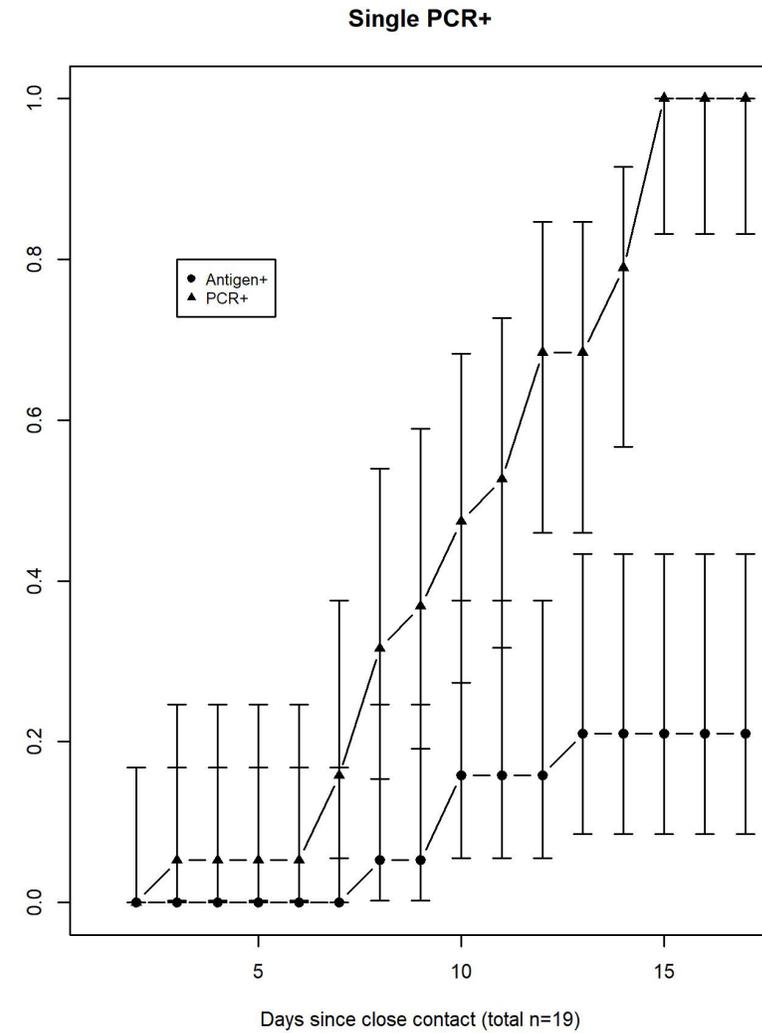
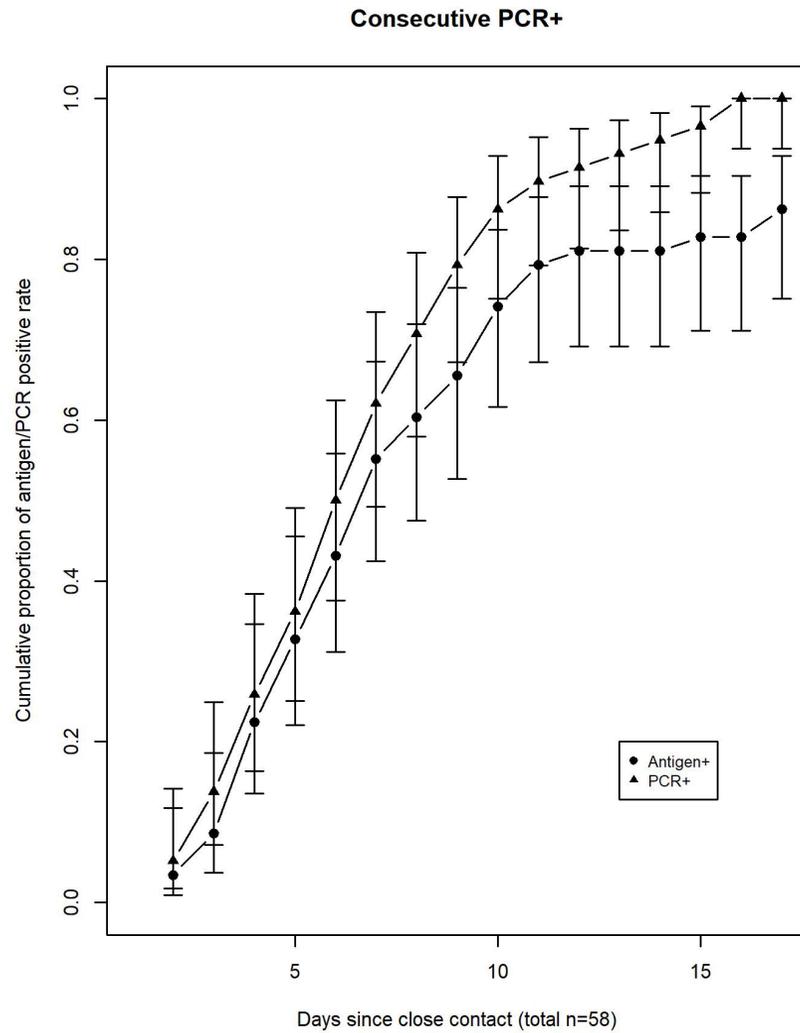
Study Day	1	2	3	4	5	6	7	8	9	10
OTC Device	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Molecular Comparator	✓	✓	✓	✓	✓	✓	✓			

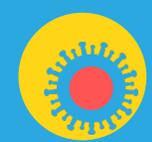
	Close Contact	Frequency	Percent
		17	3%
False		64	10%
True		547	87%
Total		628	100%

State	Frequency	Percent
	17	3%
CA	8	1%
CO	2	0%
CT	1	0%
DE	3	0%
FL	3	0%
GA	12	2%
IA	18	3%
ID	21	3%
IL	3	0%
IN	29	5%
KS	15	2%
KY	21	3%
MA	61	10%
ME	1	0%
MI	18	3%
MN	5	1%
MO	3	0%
MS	1	0%
NC	3	0%
NE	1	0%
NH	41	7%
NJ	3	0%
NM	1	0%
NY	4	1%
OR	2	0%
PA	2	0%
RI	4	1%
SC	1	0%
TN	3	0%
TX	3	0%
UT	21	3%
VA	1	0%
VT	8	1%
WA	287	46%
WI	1	0%
Total	628	100%



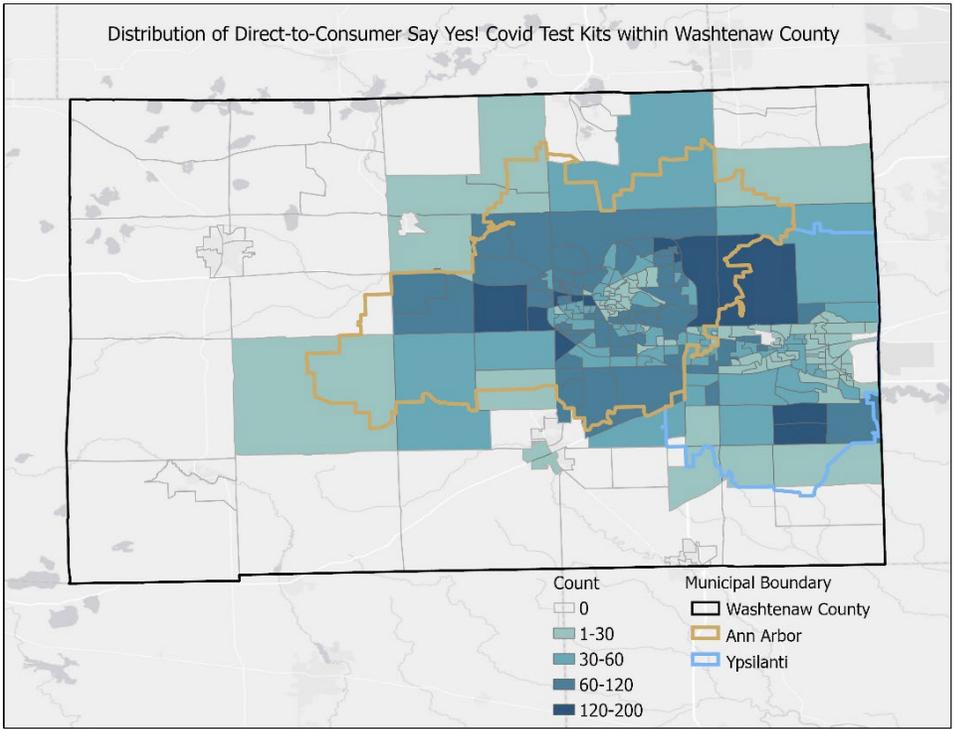
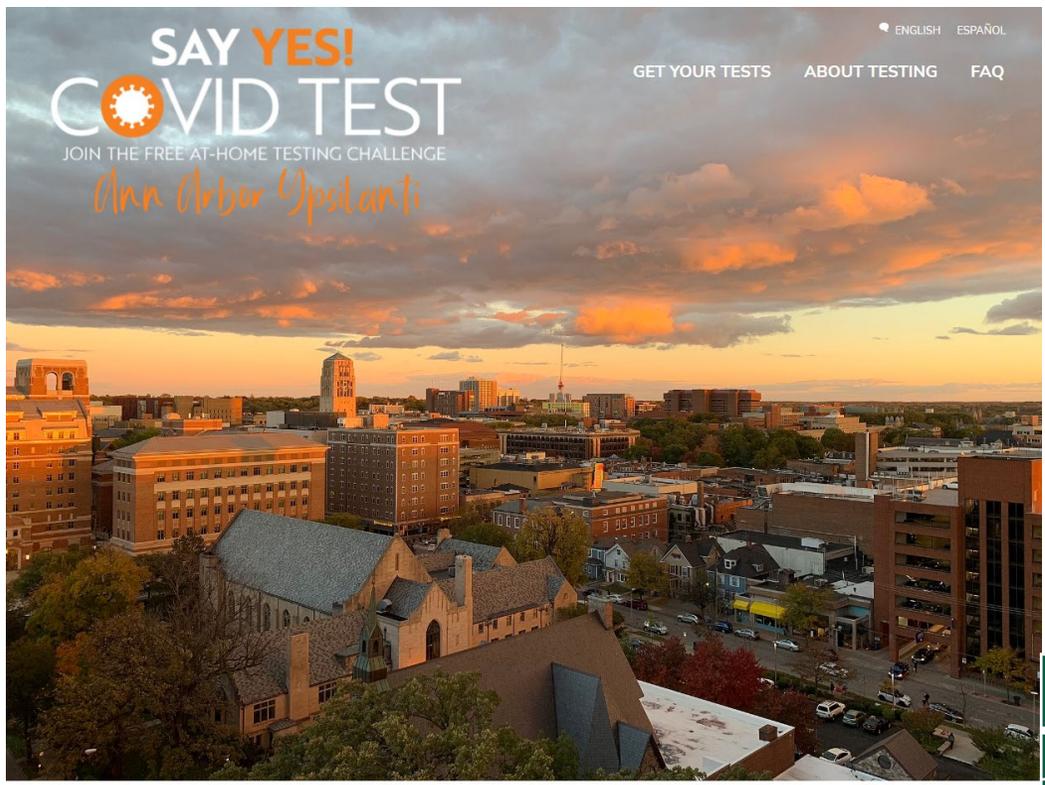
Time from First Close Contact





SYCT! Michigan

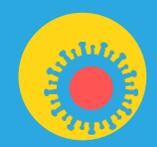
500, tests kits (25 per family) distributed June 7th – August 11th



Region	Population (2019):	Mean Cases (Mar –Jun)	Standard Deviation	Vaccination Rate: June 7 th	Vaccination Rate: Aug 11 th
Ann Arbor	120,735	25.2	20.2	72.4	75.3
Ypsilanti	20,828	27.6	21.0	54.3	59.1
Washtenaw County ^a	226,038	23.1	39.8	62.0	65.2

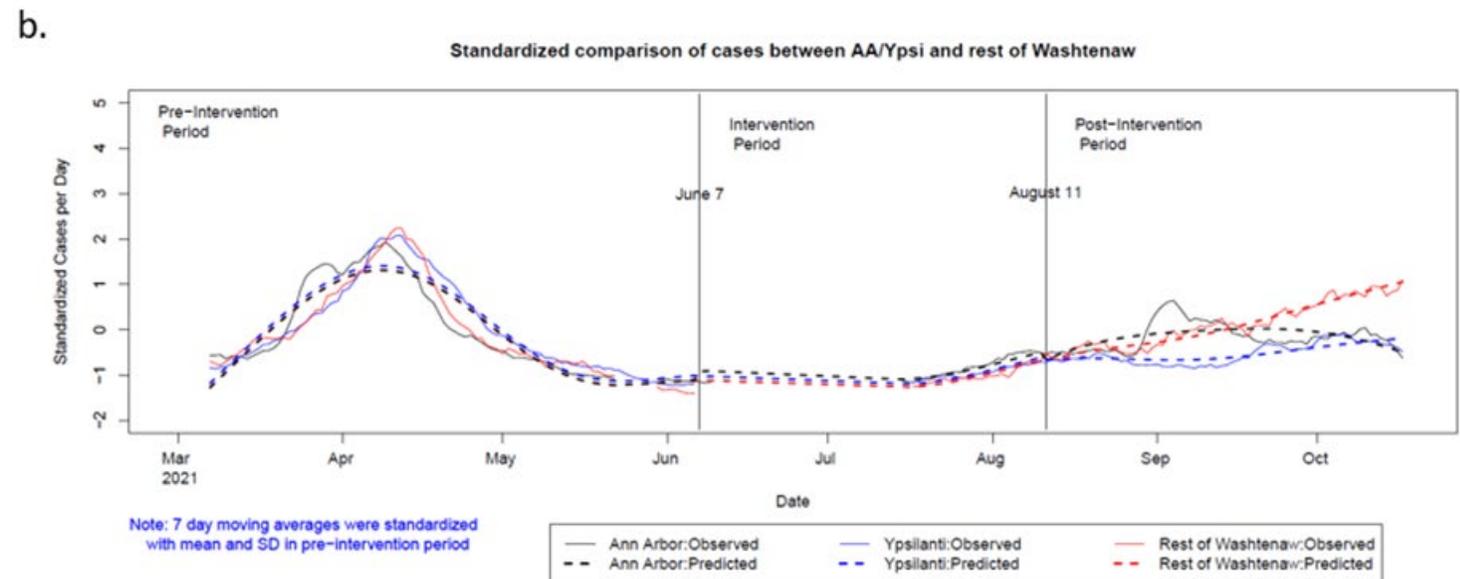
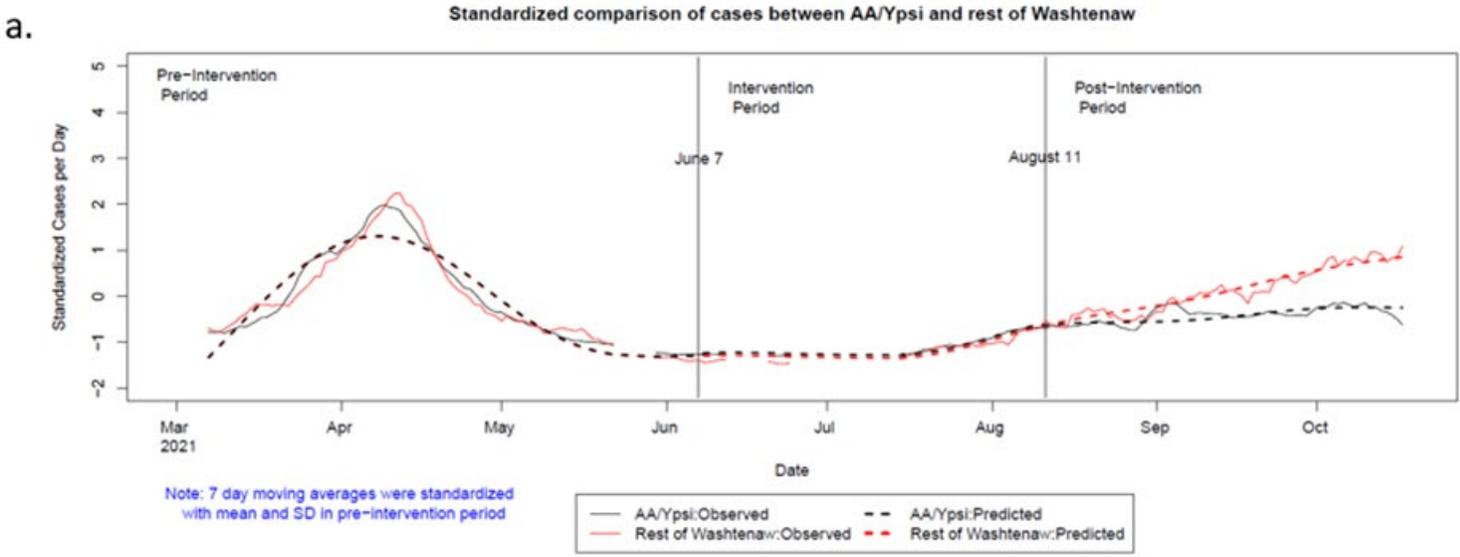
Keep Testing Ypsilanti and Ann Arbor!

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.



SYCT! Michigan Association with Community Transmission

Region	Cases Prevented per Day (at Day 60)
Ann Arbor + Ypsilanti joint	39.2
Ann Arbor	22.1
Ypsilanti	23.4



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

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**

<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 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>



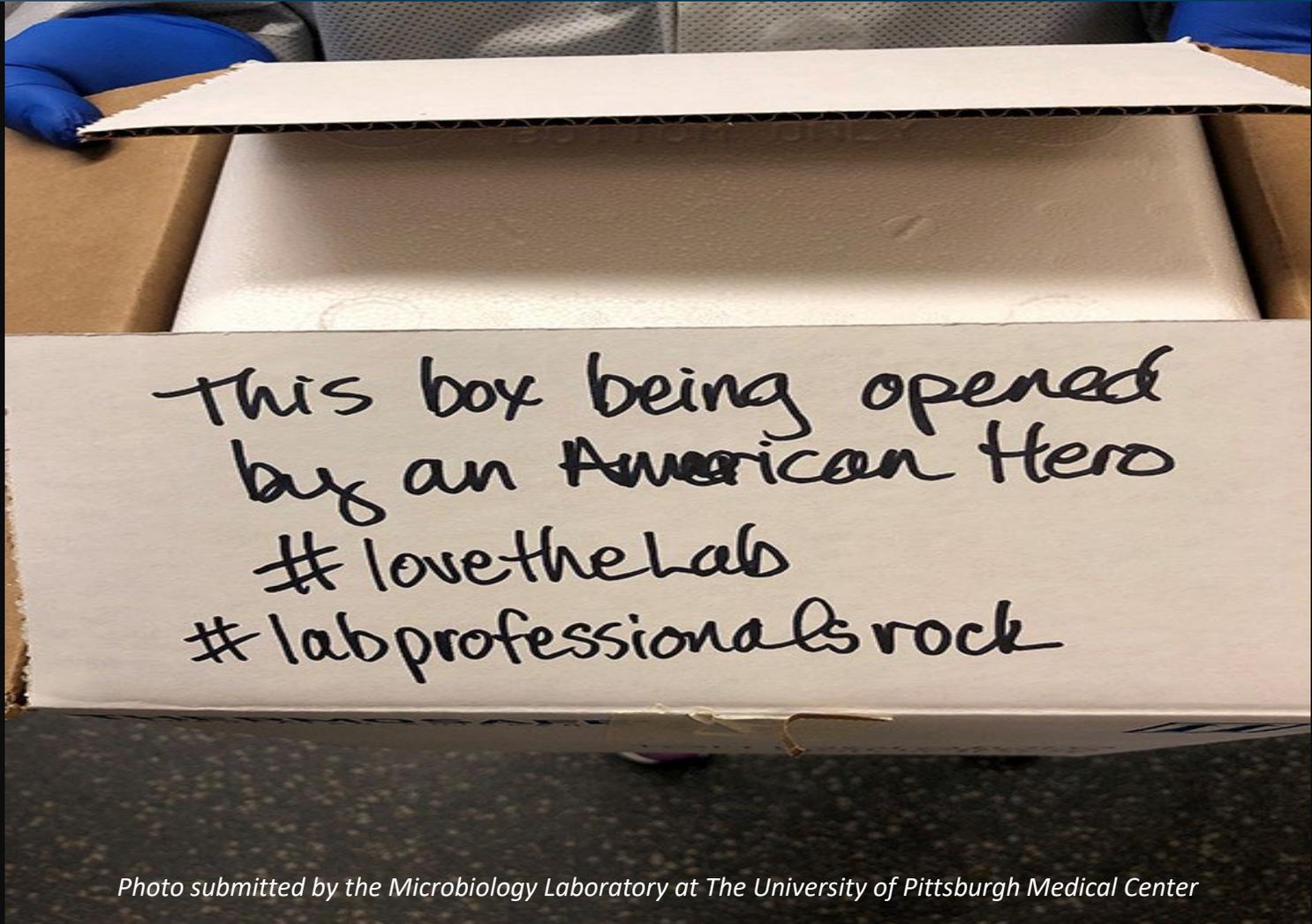
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#labprofessionalsrock

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