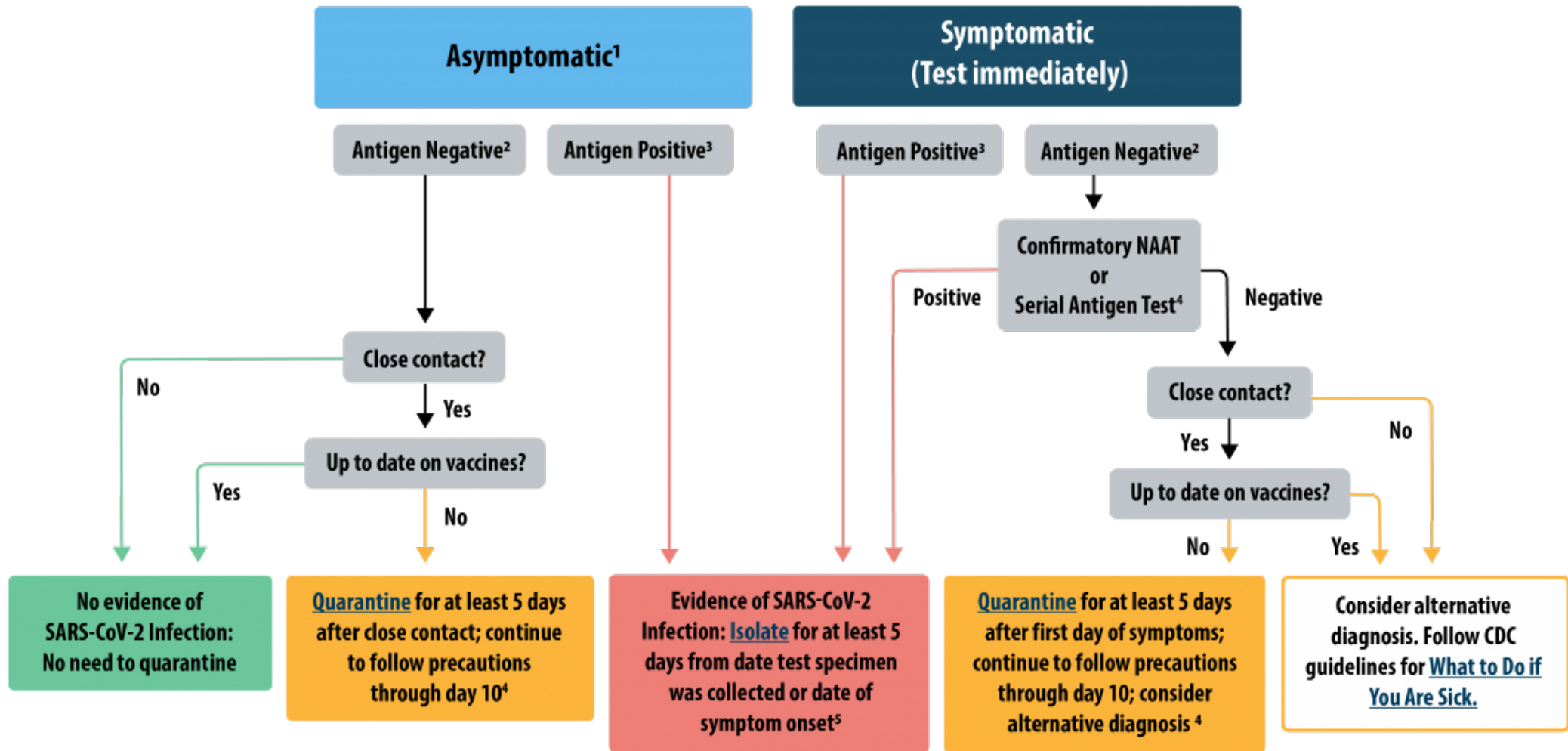


Slide decks may contain presentation material from panelists who are not affiliated with CDC. Presentation content from external panelists may not necessarily reflect CDC's official position on the topic(s) covered.



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

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>

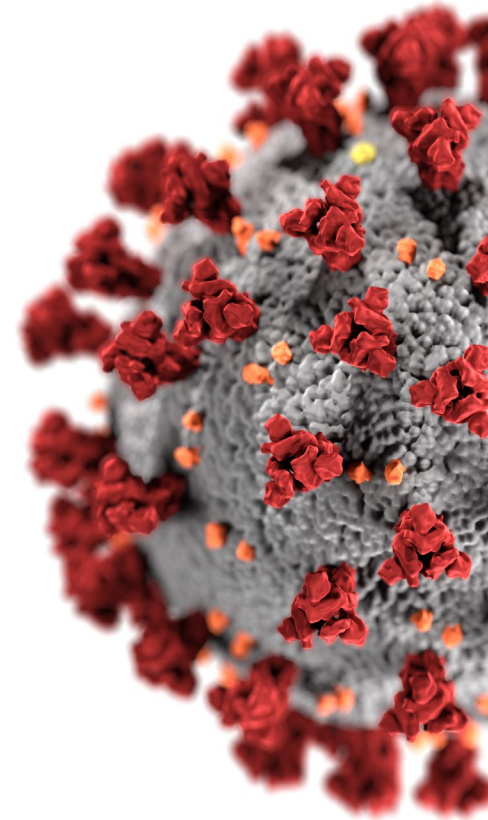
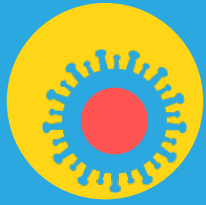


Table 1. Reporting Requirements by Entity and Type of Testing

	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

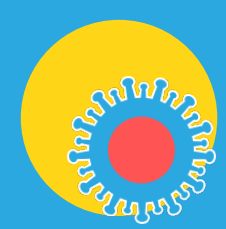
COVID-19 Home Studies



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

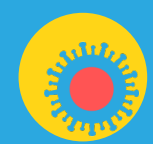
Apurv Soni MD, PhD on behalf of RADx Tech Clinical Studies Core team





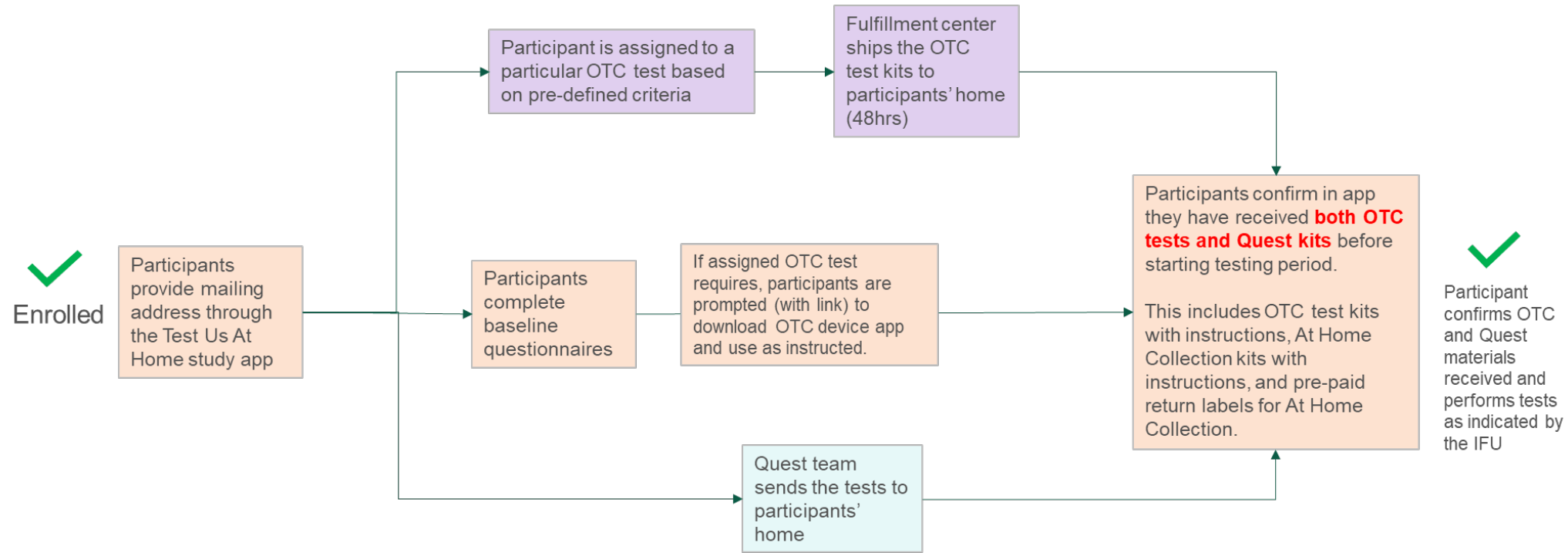
Agenda

- 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



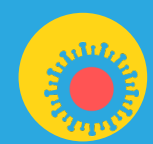
Testing Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
OTC Device	✓		✓		✓		✓		✓		✓		✓		✓
Molecular Comparator	✓		✓		✓		✓		✓		✓		✓		

Study Team

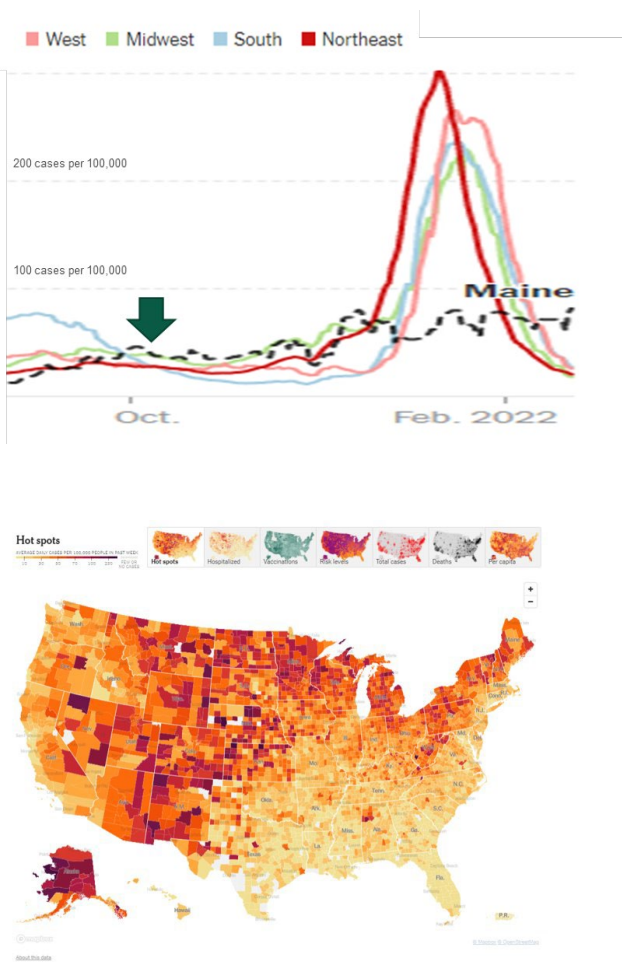
Quest Team

Participants' Experience

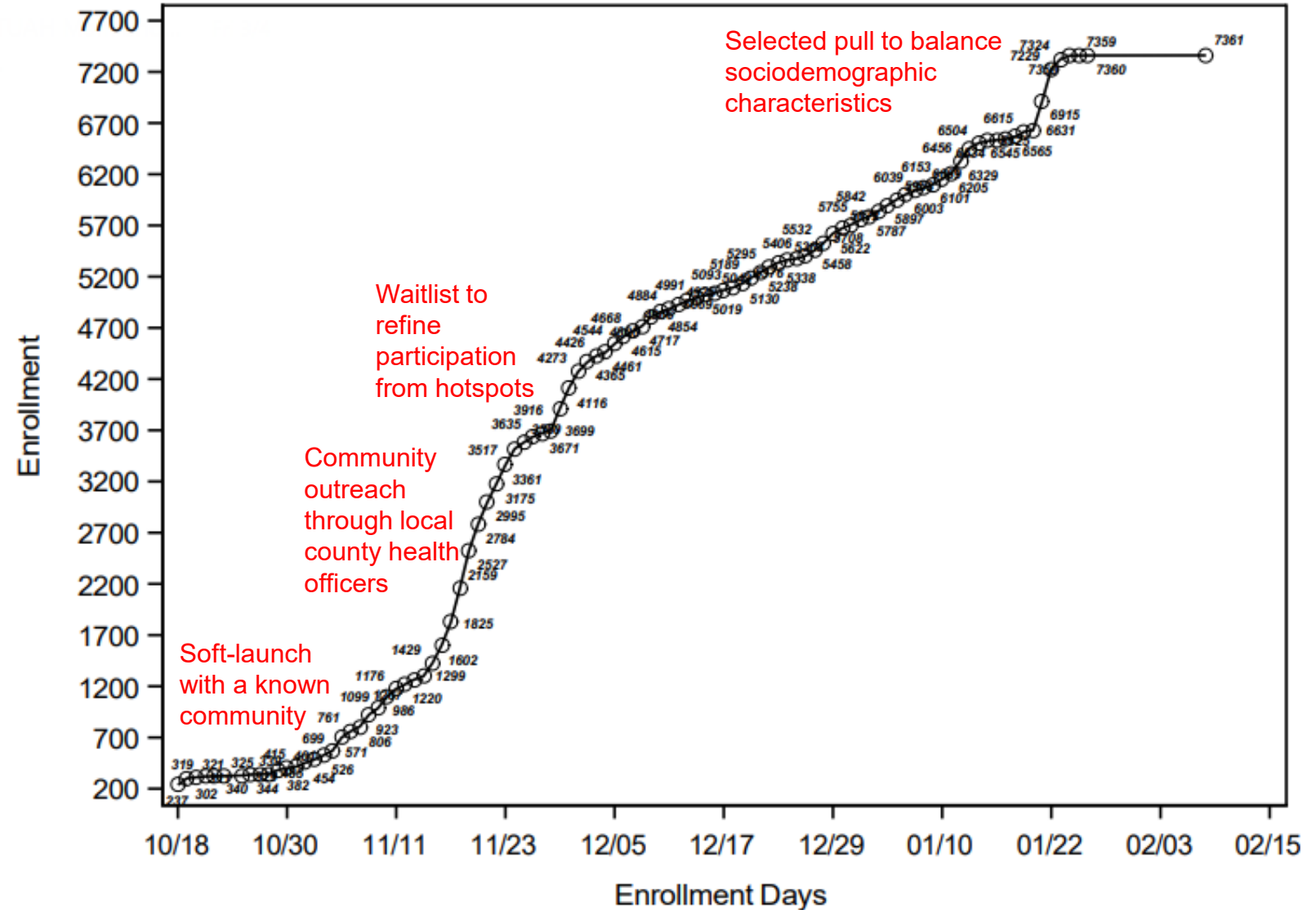
Study App Team

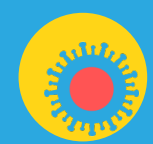


Test Us At Home Study Overview



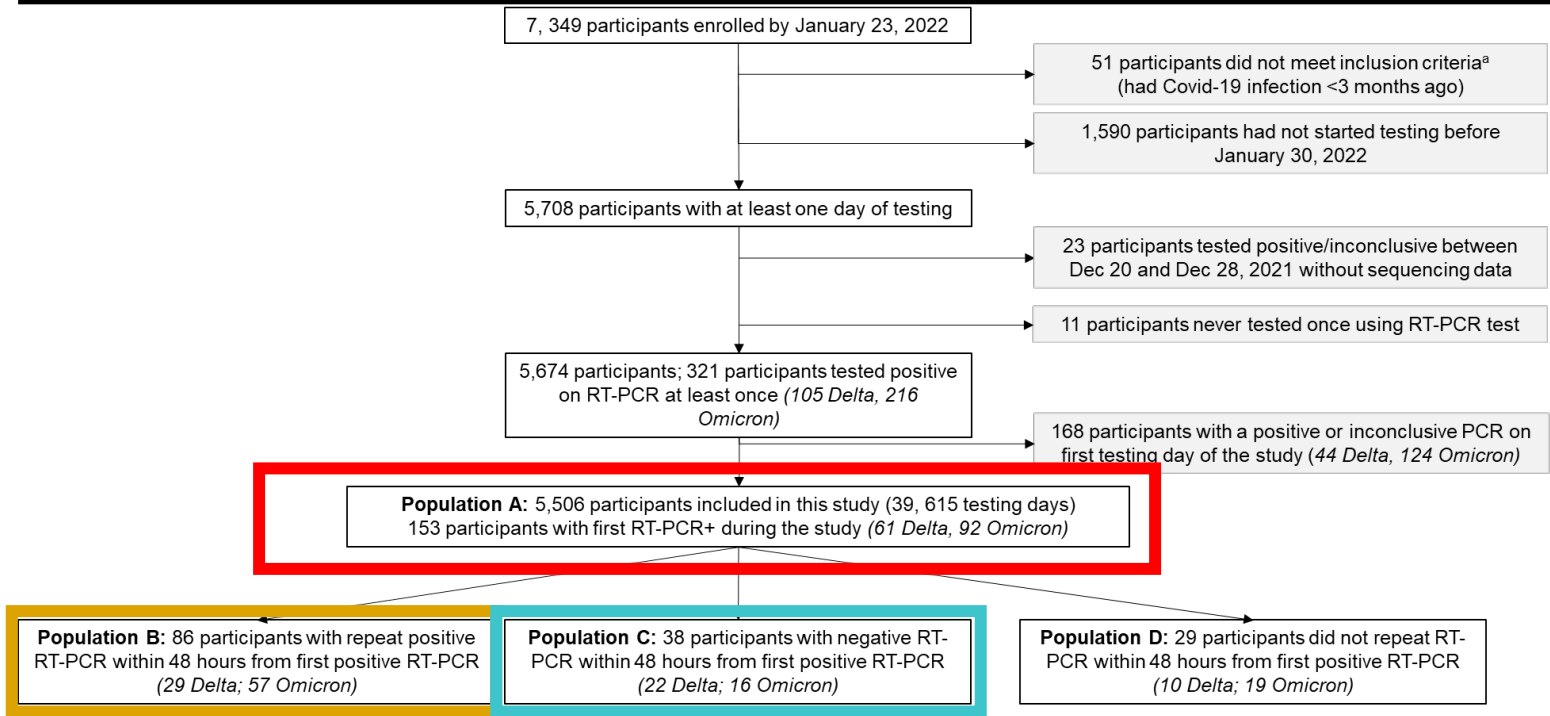
Cumulative Participant Enrollment by Days



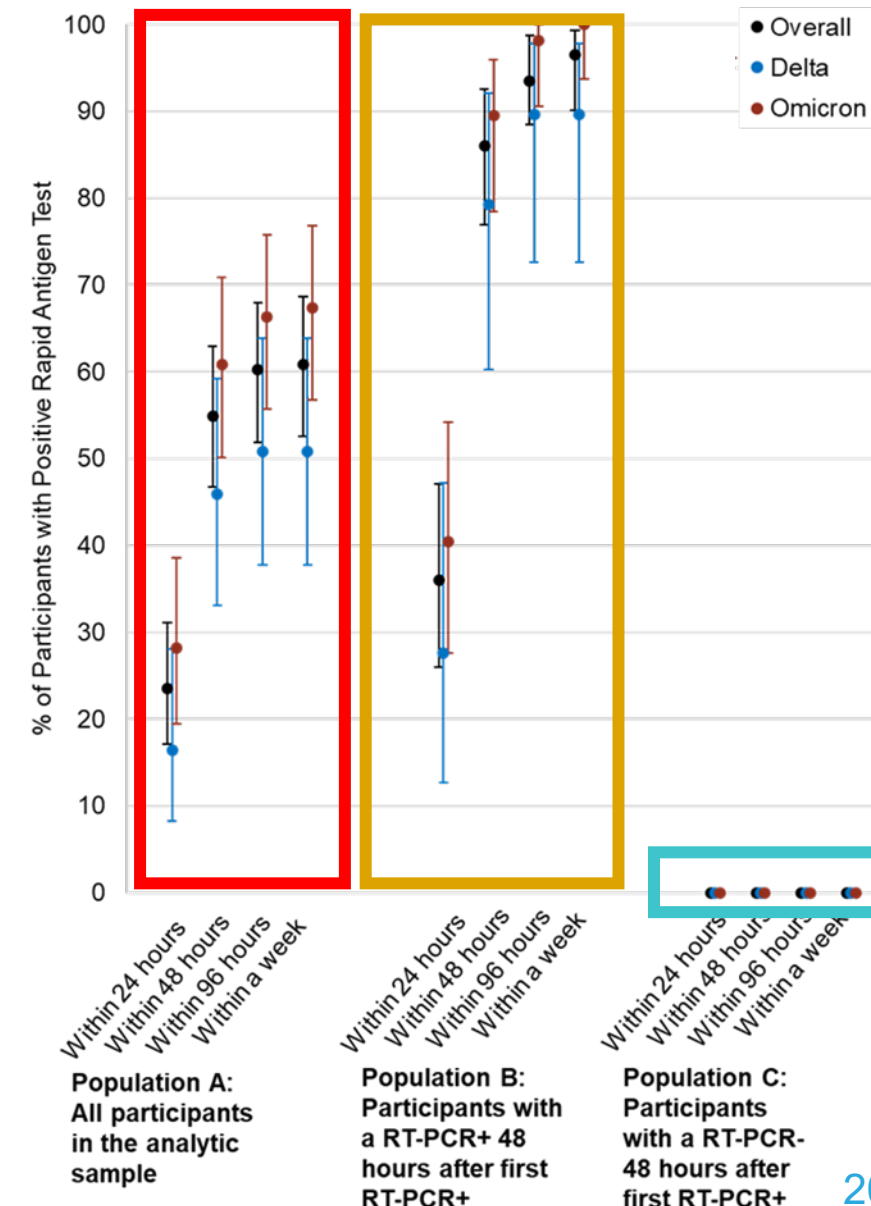


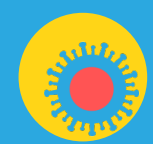
Delta vs. Omicron

Figure 1: Test Us At Home Participant CONSORT Diagram



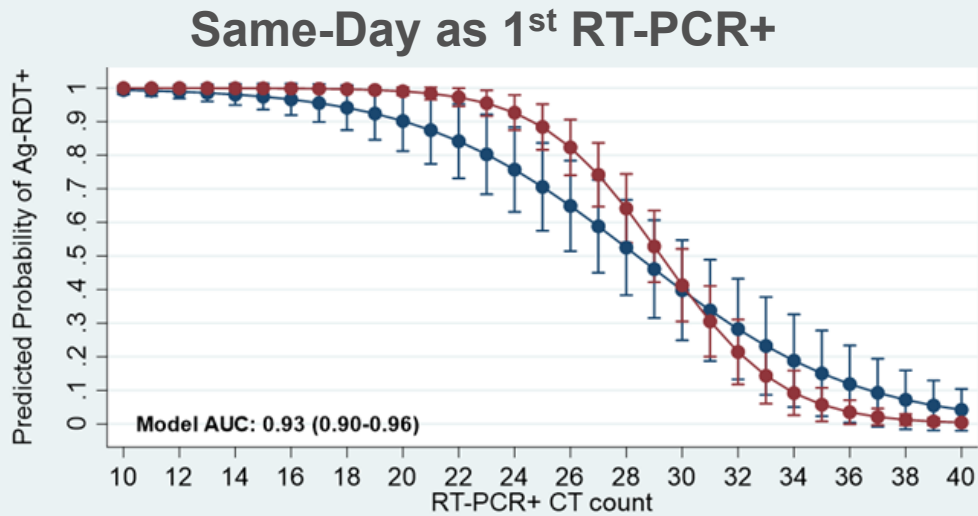
a: 51 participants self-reported meeting the eligibility criteria of no SARS-CoV2 infection within the previous three months at the time of enrollment but self-reported prior infection history within the previous three months of SARS-CoV-2 on a separate questionnaire prior to beginning their testing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



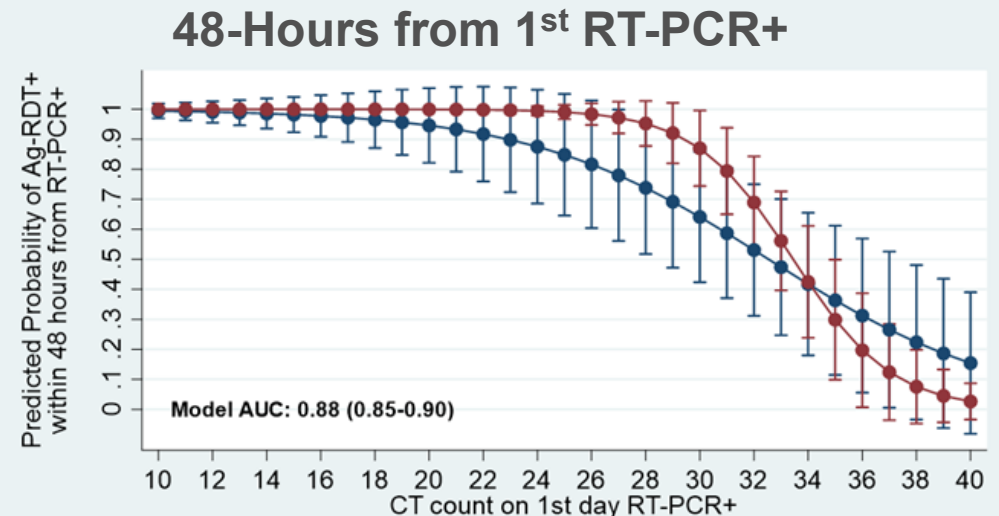


Delta vs. Omicron

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



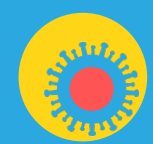
participants from Population A where index RT-PCR was available (n = 100)
 Predicted probabilities calculated using inverse logit transformation
 95% CI calculated using the Delta method

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)

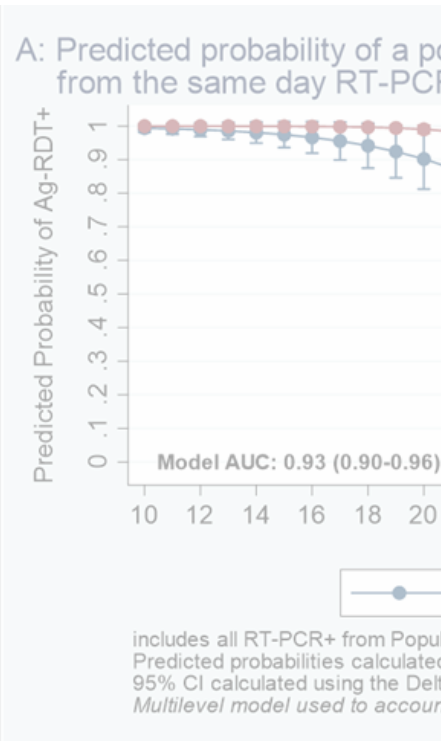
a) same-day Ag-RDT+ on coordinator read from a participant-uploaded picture

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)

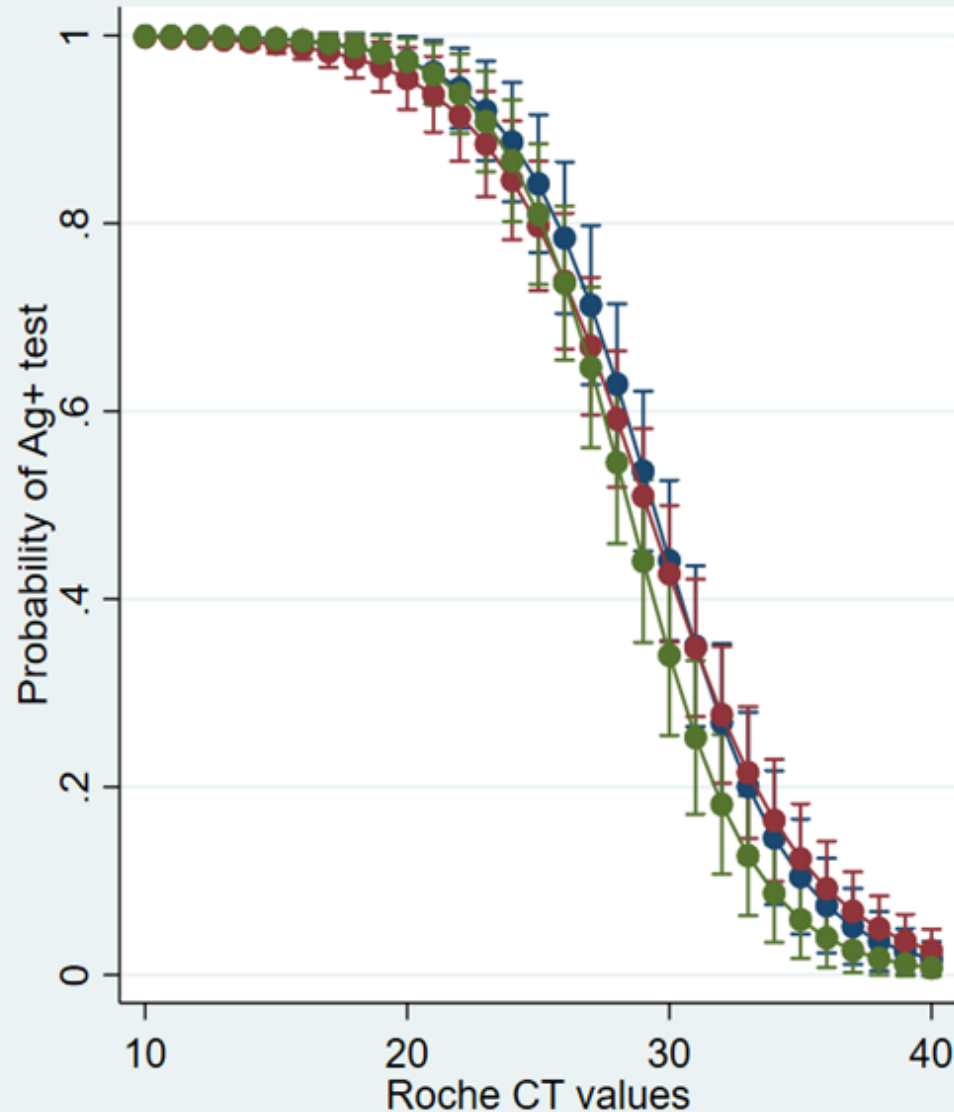
a) same-day Ag-RDT+ on coordinator read from a participant-uploaded picture
 b) No subsequent test after first RT-PCR+



Comparison between tests overall

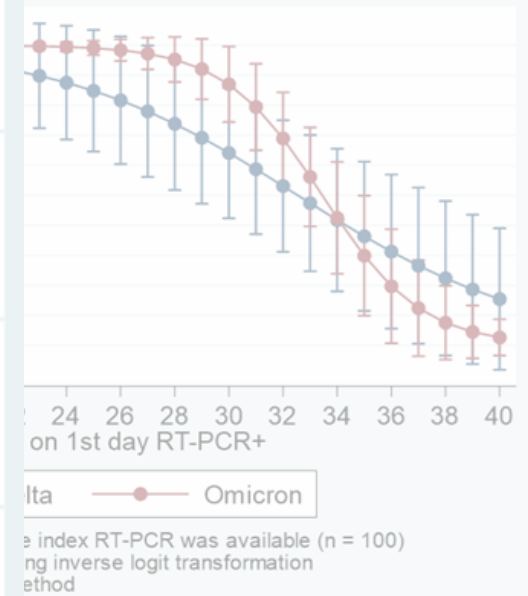


Soni et al; Unpublished Work



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

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

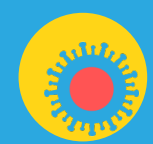


Observed data	Delta
Same-day RT-PCR+ CT values	RT- PCR+ (n, col%)
<15	2 (2.2)
15 < 20	22 (24.2)
20 < 25	18 (19.6)
25 < 30	20 (21.7)
30 < 35	22 (23.9)
35+	7 (7.6)

	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

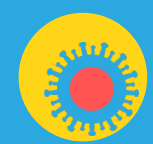
b) from a participant-uploaded picture



Singleton PCR+ Findings

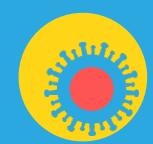
Population	Population A: 1 st RT-PCR+ observed during the study			
Variant	Total	Δ	O	p-value ^a
N	153	61	92	
Testing days	1,162	471	691	
Result of RT-PCR performed within 48 hours of 1 st RT-PCR+				0.04
Positive or Indeterminant (Population B)	86 (56.2)	29 (47.5)	57 (62.0)	
Negative (Population C)	38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

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

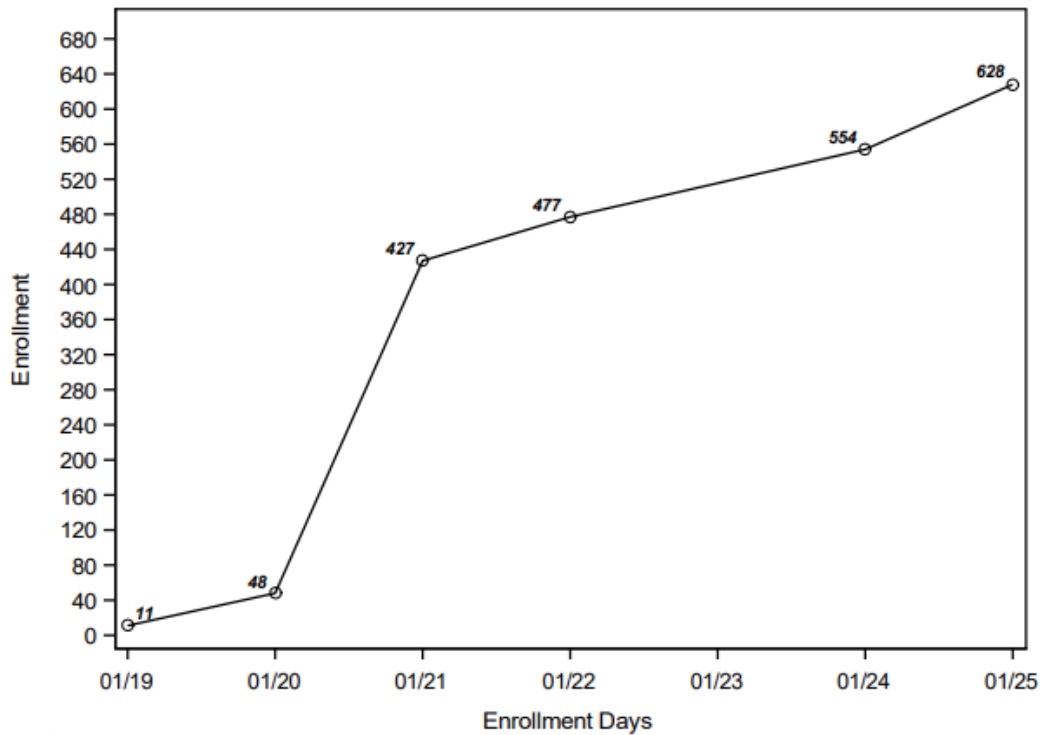
Population	B: First RT-PCR+ followed by a 2nd RT-PCR+ in 48 hours			C: First RT-PCR+ followed by RT-PCR- in 48 hours		
Variant	Total	Δ	O	Total	Δ	O
N	86	29	57	38	22	16
Testing days	670	231	439	288	170	118
Ag-RDT result in comparison to first RT-PCR+ (n, col%)						
Positive <u>same-day</u>	31 (36.1)	8 (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

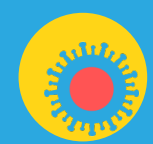
Cumulative Participant Enrollment by Days



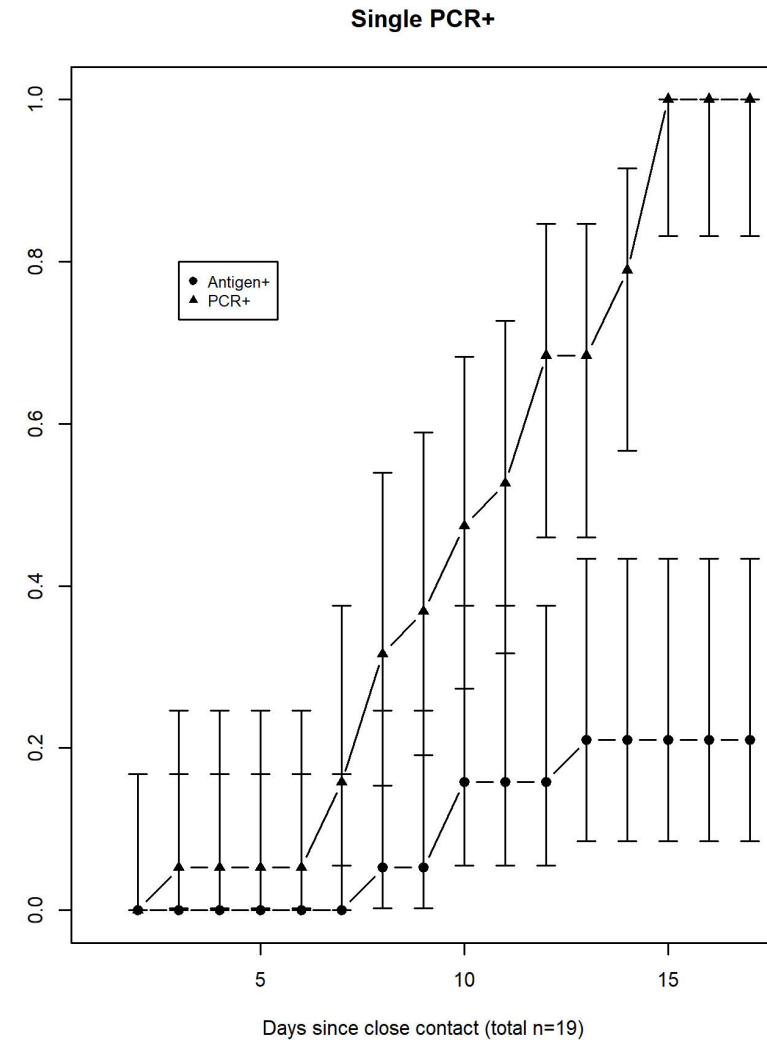
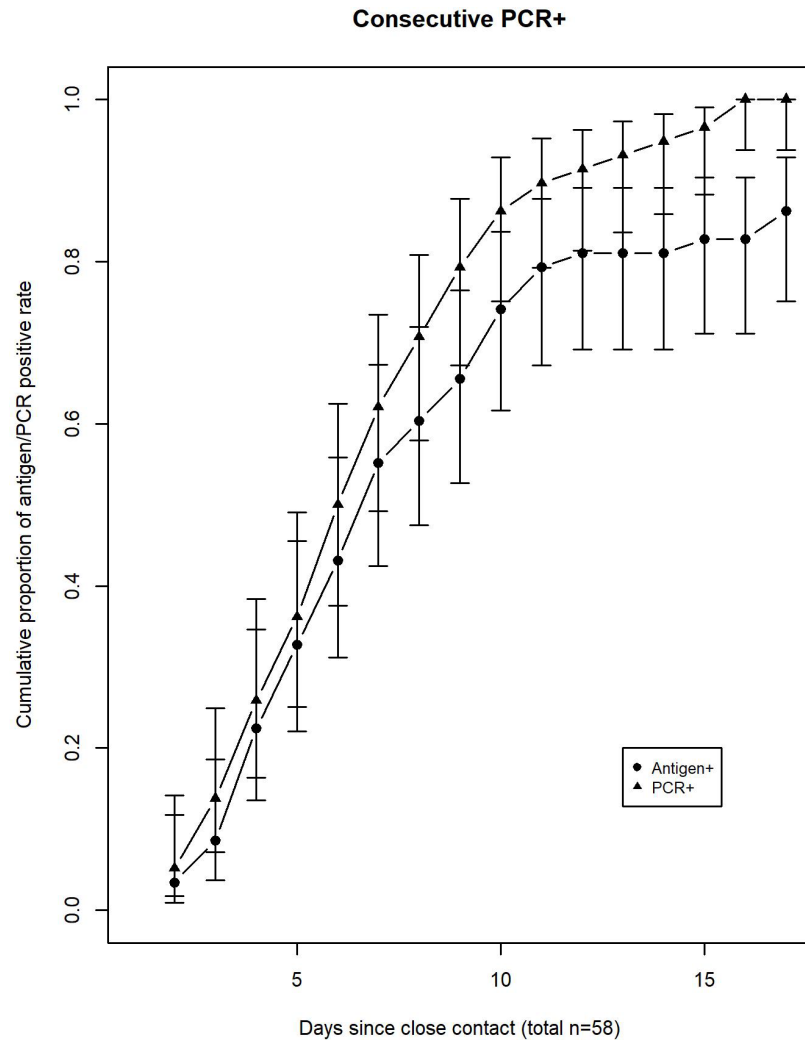
Study Day	1	2	3	4	5	6	7	8	9	10
OTC Device	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Molecular Comparator	✓	✓	✓	✓	✓	✓	✓			

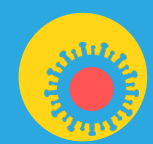
	Close Contact	Frequency	Percent
		17	3%
False		64	10%
True		547	87%
Total		628	100%

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%



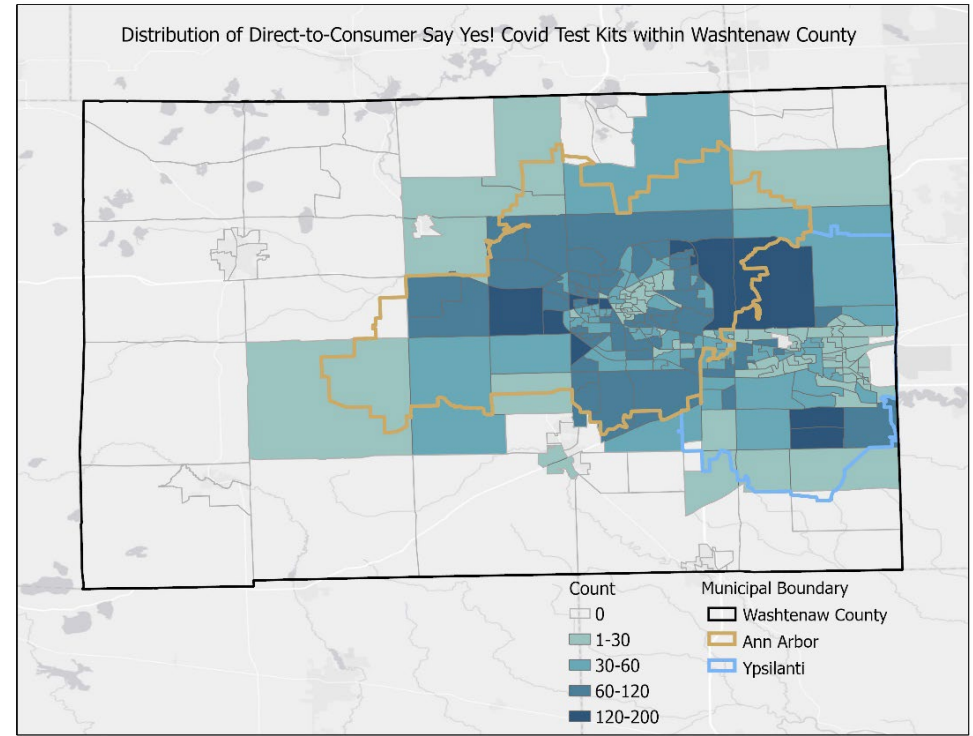
Time from First Close Contact





SYCT! Michigan

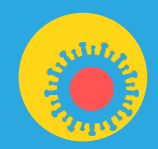
500, tests kits (25 per family) distributed June 7th – August 11th



Region	Population (2019):	Mean Cases (Mar –Jun)	Standard Deviation	Vaccination Rate: June 7 th	Vaccination Rate: Aug 11 th	Vaccination Rate: Oct 15 th
Ann Arbor	120,735	25.2	20.2	72.4	75.3	78.3
Ypsilanti	20,828	27.6	21.0	54.3	59.1	62.8
Washtenaw County ^a	226,038	23.1	39.8	62.0	65.2	67.7

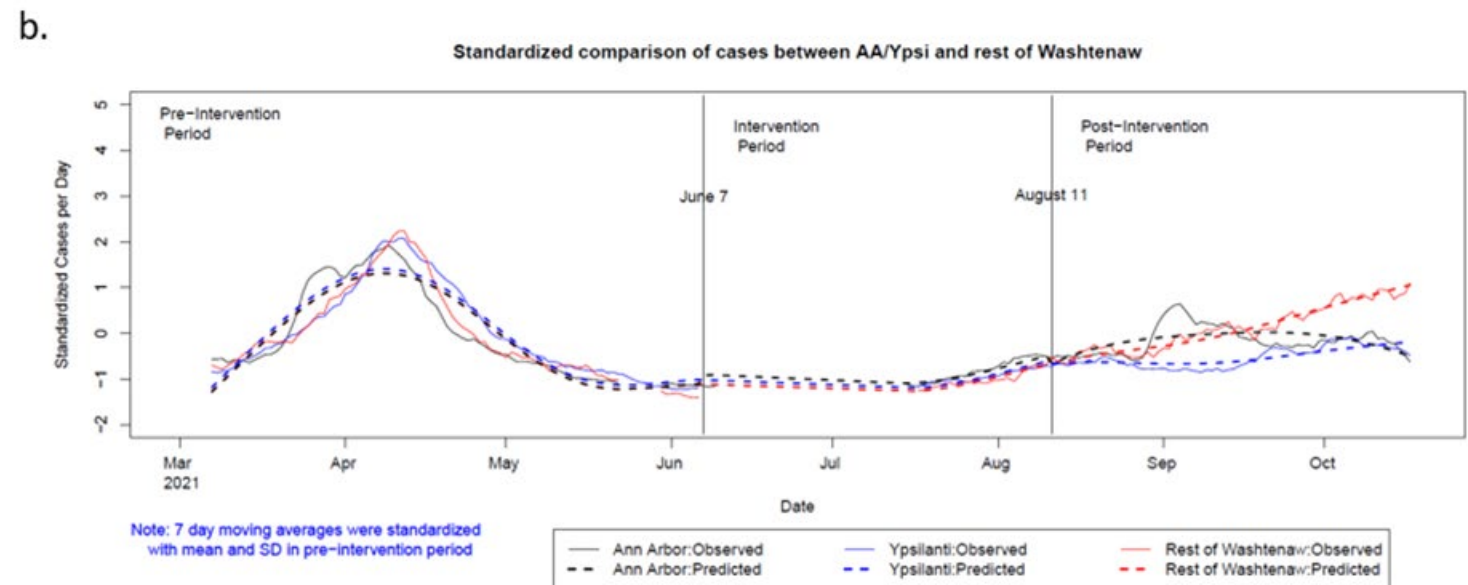
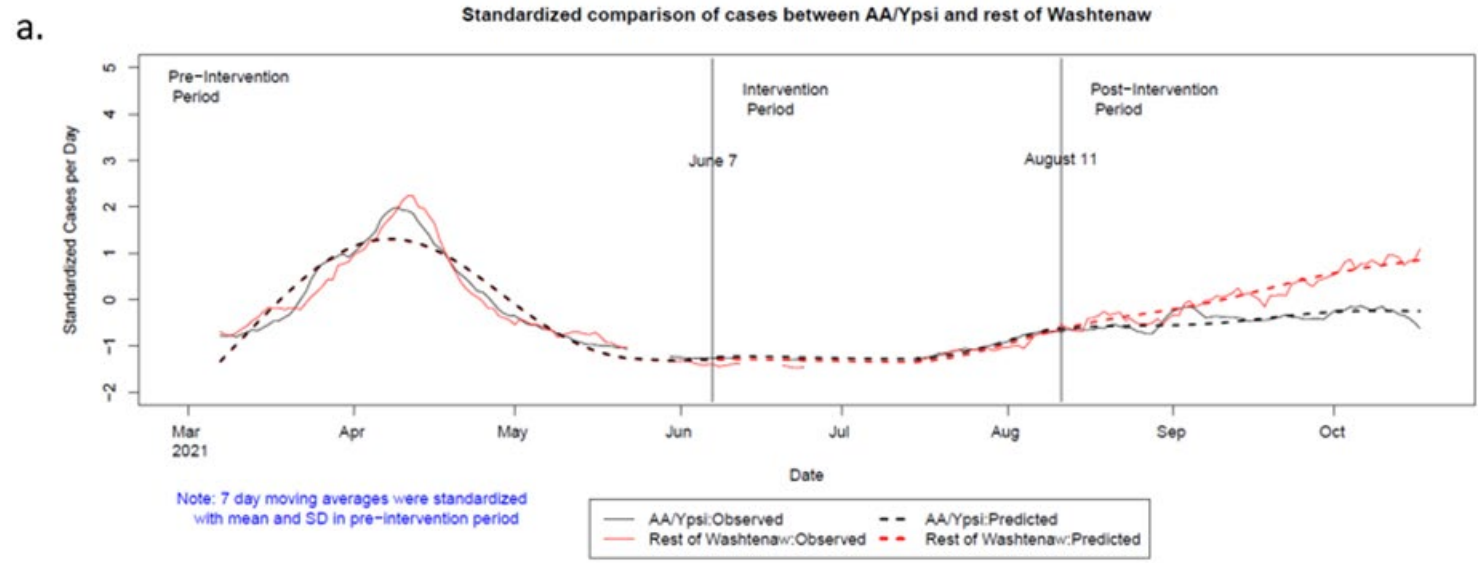
Keep Testing Ypsilanti and Ann Arbor!

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

- **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/>

- **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>

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

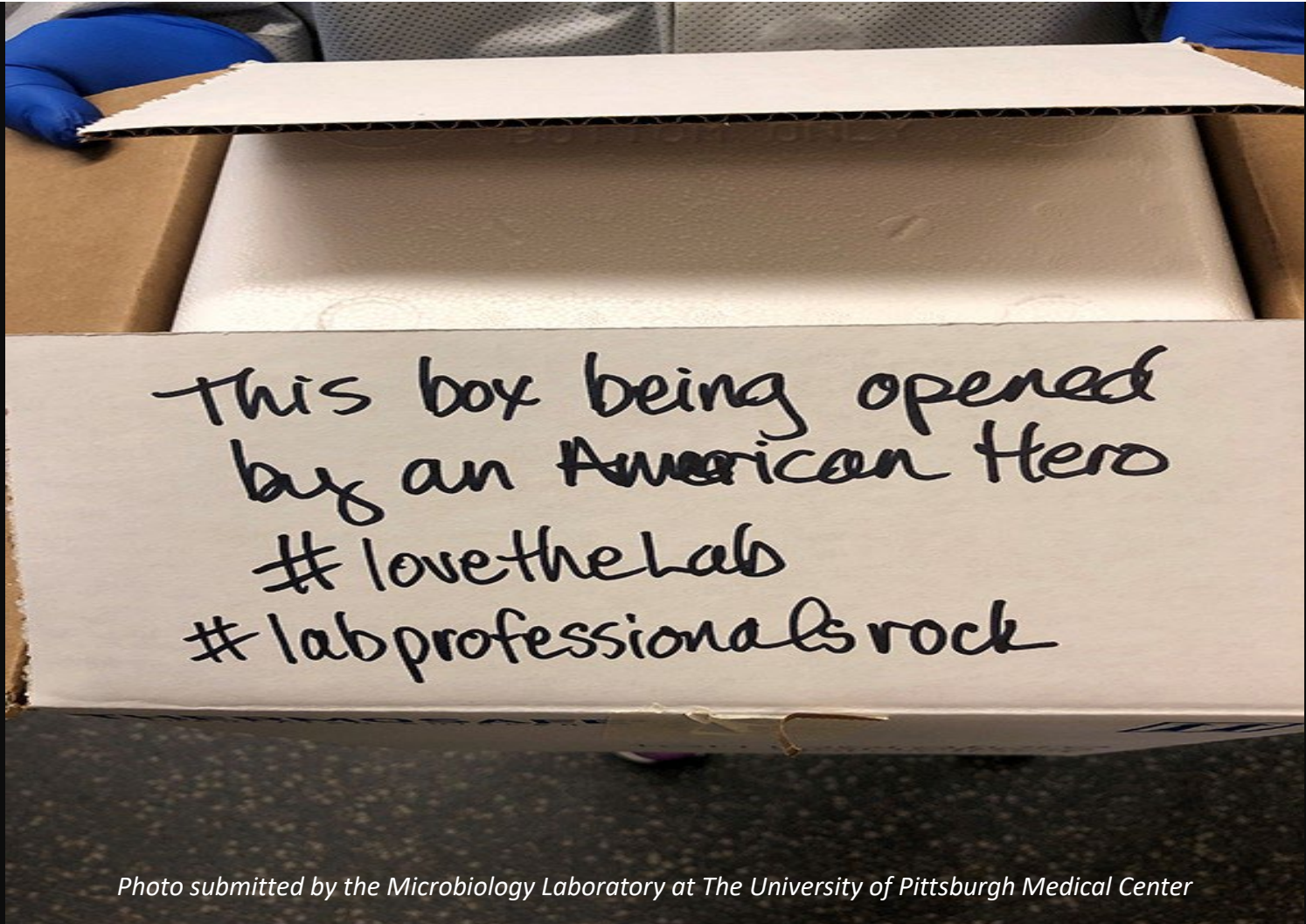


<https://twitter.com/cdcgov>

<https://www.instagram.com/cdcgov>



<https://www.linkedin.com/company/cdc>



This box being opened
by an American Hero
#lovethelab
#labprofessionalsrock

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