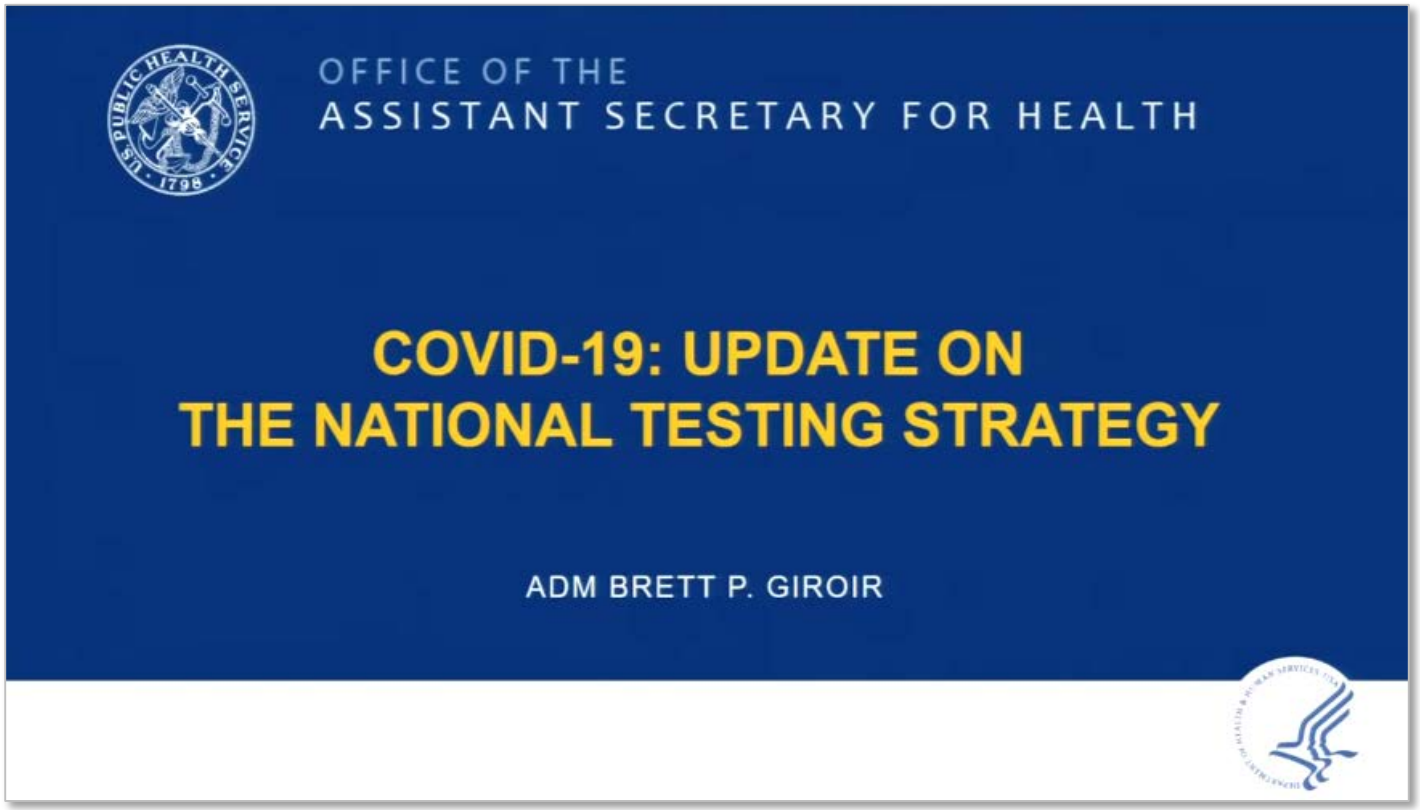
Clinical Laboratory COVID-19 Response Call

Monday, January 11th, 2021 at 3:00 PM ET

- **Welcome**
  - Jasmine Chaitram, CDC Division of Laboratory Systems (DLS)
- **OneLab Network Overview**
  - Senia Wilkins, CDC Division of Laboratory Systems (DLS)
- **Preliminary Data from BinaxNOW Antigen Testing**
  - Jessica Prince Guerra, CDC Laboratory and Testing Task Force
- **Vaccine Effect on Serology Testing**
  - Natalie Thornburg, CDC Laboratory and Testing Task Force
- **Surveillance Testing for non-CLIA Pop-up Labs**
  - Amy Zale, Centers for Medicare & Medicaid Services (CMS)
- **FDA Update**
  - Tim Stenzel, U.S. Food and Drug Administration (FDA)

COVID-19 Testing Media Telebriefing

https://www.youtube.com/watch?v=CC4yrYtMGYo



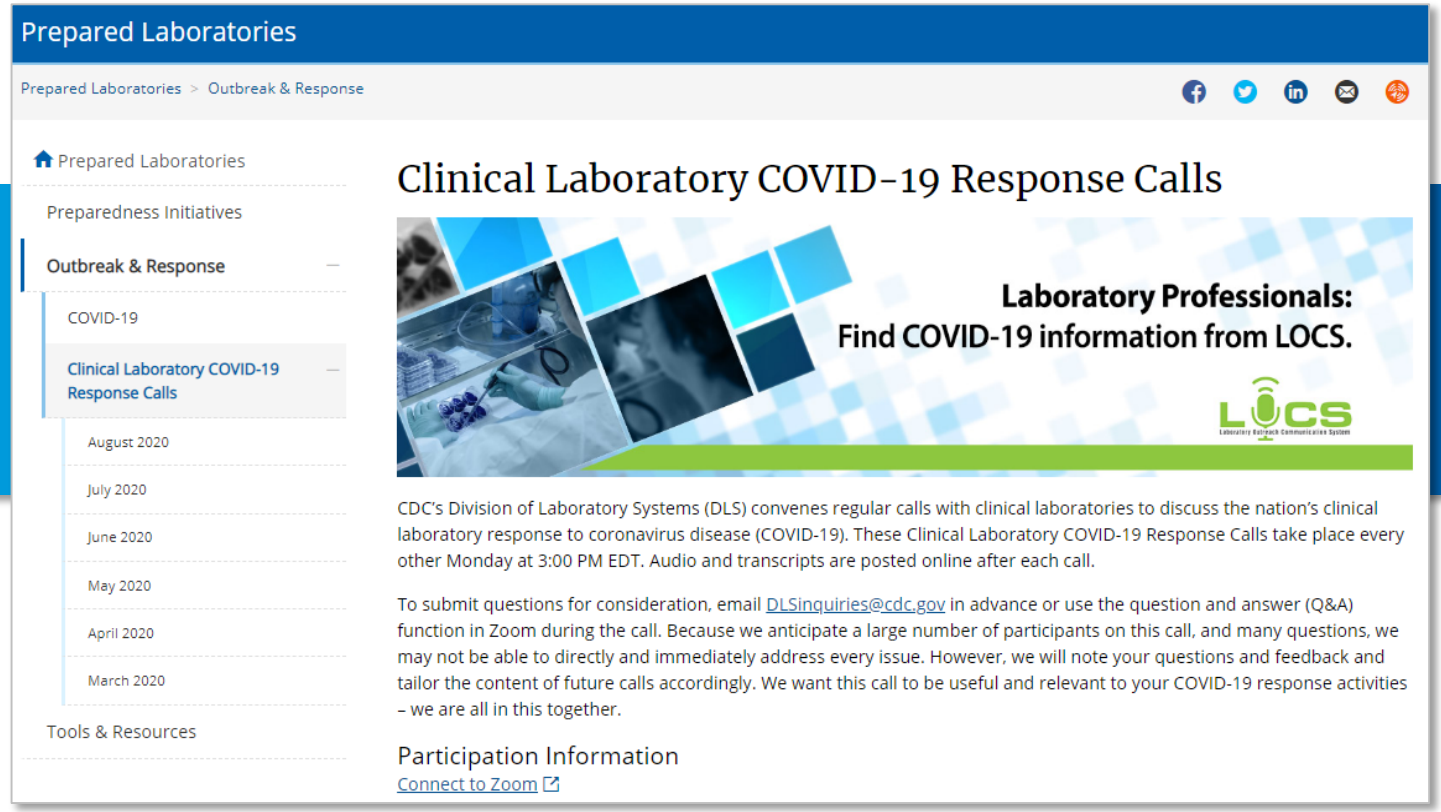
COVID-19 Resources for Laboratories

- **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, and audio recordings on the Preparedness Portal



Schedule for Clinical Laboratory COVID-19 Response Calls

The next call will be on **Monday, January 25th**

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

OneLab Network Overview

Senia Wilkins
CDC Division of Laboratory Systems (DLS)

- **Long-term Goal:** To establish a sustainable learning community of clinical laboratories, public health laboratories, and CDC to collectively support rapid, large-scale emergency responses

OneLab

A Unified Response To Training Needs

Short-term Objectives:

- OneLab collaboration network
- Needs assessment and prioritization
- Training development
- Wide-scale dissemination
- Ongoing learning community

OneLab
A Unified Response to Training Needs

OneLab

A Unified Response To Training Needs

Who Should Join?

Representatives with responsibility for education and training within clinical laboratory professional organizations (e.g., ASCLS, AACC), manufacturers, large commercial laboratories, and large hospital systems.

Join at:

www.cdc.gov/OneLab

OneLab
A Unified Response to Training Needs

THANK YOU!

Preliminary Data from BinaxNOW Antigen Testing

Jessica Prince Guerra
CDC Laboratory and Testing Task Force

Preliminary Data from BinaxNOW Antigen Testing

Confidential unpublished data – please do not disseminate or share

1/11/2021

Methods: Collaboration with Pima County, Arizona

- Community-based testing
  - Ages 10 – 95
  - Samples collected by healthcare professional
    - First: bilateral mid-turbinate nasal swabs (for antigen test)
    - Second: bilateral nasopharyngeal swabs (for PCR test)
- Paired testing with BinaxNOW and RT-PCR (either CDC Assay or Fosun assay)
- Positives from either test (n=274) have been tested by viral culture

Preliminary Results: Pima County, Arizona

- 3,419 participants aged 10 - 95 years (median = 41)
  - 2,592 (76%) asymptomatic; 827 (24%) with ≥ 1 symptom
- Race/ethnicity
  - Three-quarters self-reported race as white
  - Nearly one-third self-reported ethnicity as Hispanic or Latino
- Asymptomatic
  - 1.9% positive by antigen test; 4.7% positive by PCR
- Symptomatic
  - 13.7% positive by antigen test; 21.3% positive by PCR
- Viral culture
  - Virus recovered from 96/274 samples positive by either test

Preliminary Results: Pima County, Arizona

Symptomatic

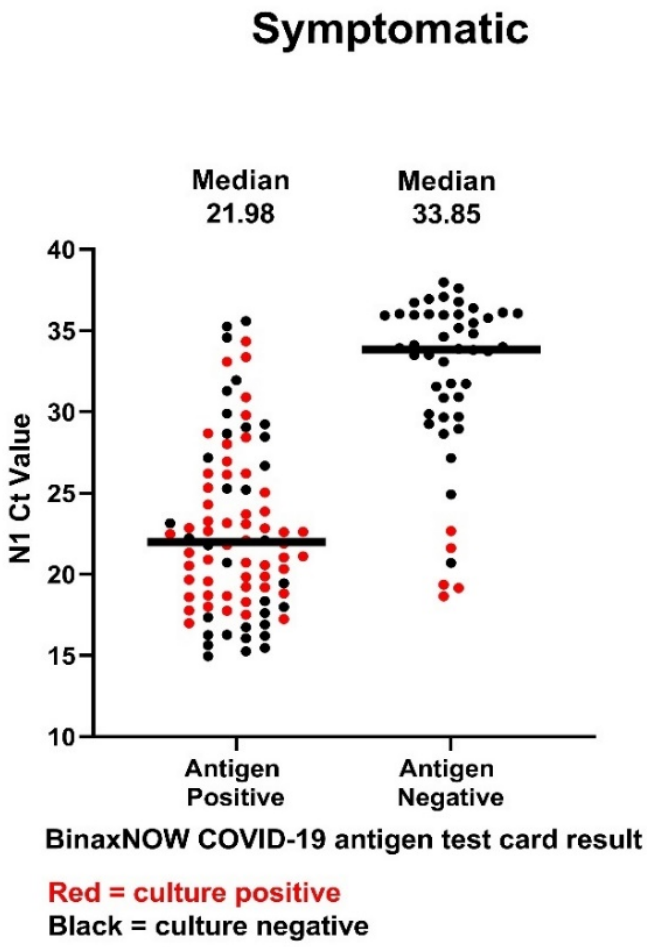
	PCR +	PCR -	
Binax +	113	0	113
Binax -	63	651	714
	176	651	827

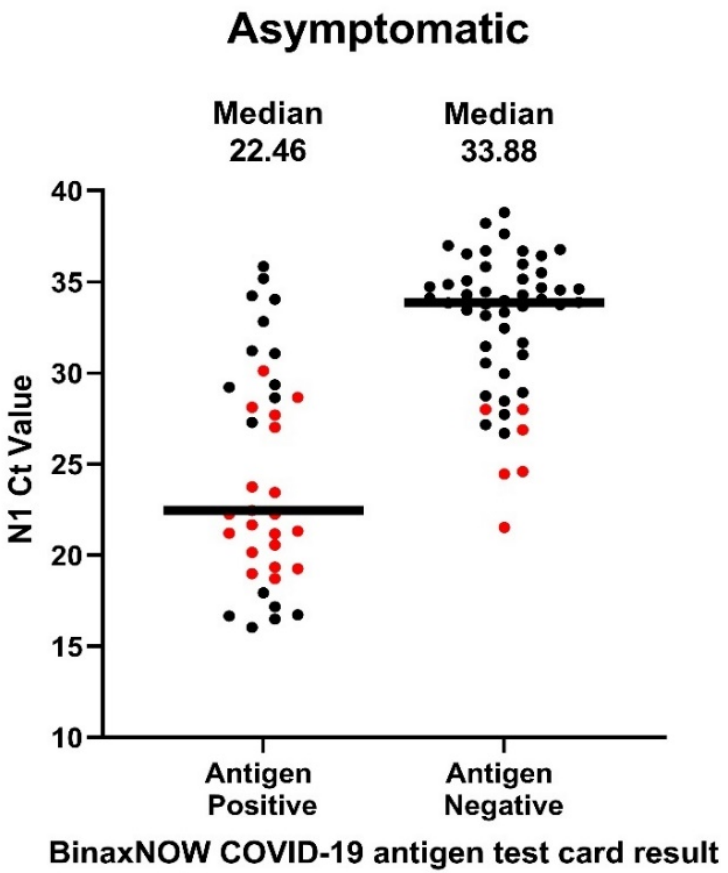
Asymptomatic

	PCR +	PCR -	
Binax +	44	4	48
Binax -	79	2465	2544
	123	2469	2854

	Symptomatic		Asymptomatic	
Sensitivity	113/176	64.2%	44/123	35.8%
Specificity	651/651	100%	2465/2469	99.8%
PPV	113/113	100%	44/48	91.7%
NPV	651/714	91.2%	2465/2544	96.9%

Preliminary Results by Viral Culture and Ct





	Total	Total Culture Tested	Virus Recovered N (%)
All positive samples	303	274	96 (35%)
Concordant positive	157	147	85 (57.8%)
False Negative by antigen test	142	124	11 (8.9%)
False Positives by antigen test	4	3	0 (0%)

Preliminary Results, Antigen Test Sensitivity in Viral Culture Positive Samples

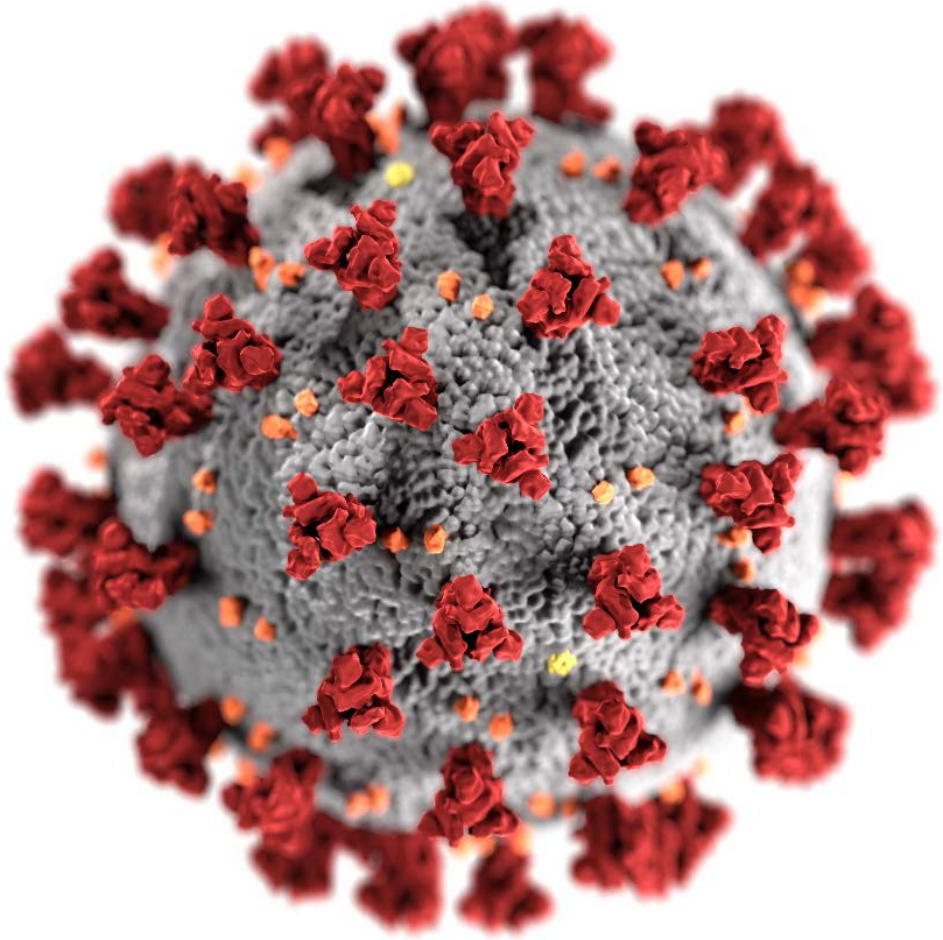
	Symptomatic	Asymptomatic
Total	68	28
Antigen Positive, rRT-PCR Positive	63	22
Antigen Negative, rRT-PCR Positive	5	6
Sensitivity	92.6%	78.6%

Summary

- Sensitivity of the BinaxNOW antigen test was lower in asymptomatic than symptomatic persons (35.8% versus 64.2%), but specificity was high.
- Sensitivity was higher among viral culture positive samples, however some antigen test-negative samples also had culturable virus.
- Symptomatic persons who receive a negative antigen test result should be tested by nucleic acid amplification test (NAAT).
- The faster turnaround time of the antigen test can limit transmission by more rapidly identifying infectious persons for isolation.

Vaccine effect on serology testing

Natalie J. Thornburg, PhD
Division of Viral Diseases
January 11, 2021



cdc.gov/coronavirus

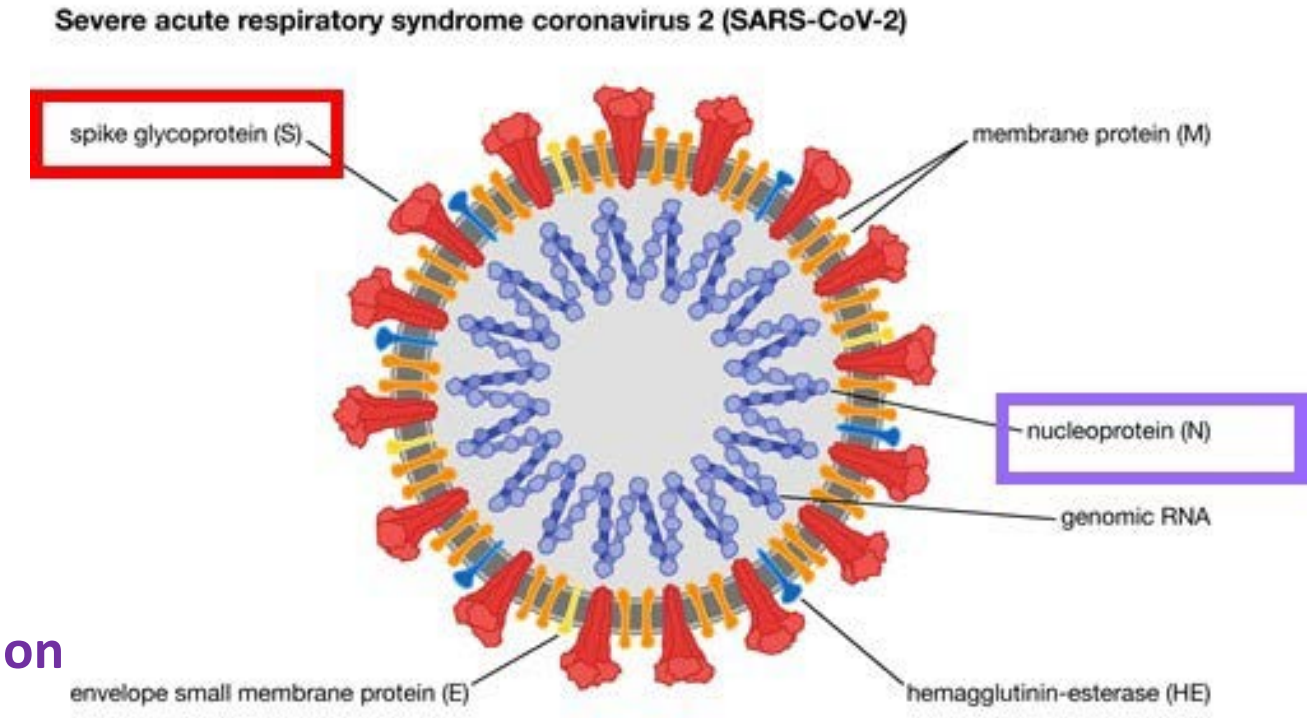
SARS-CoV-2 antibody binding assays

- 59 FDA EUA serology assays to detect SARS-CoV-2 antibodies
  - Qualitative ; semi-quantitative
  - Target spike, portions of the spike, or nucleocapsid

- CDC in collaboration with FDA, NCI and NIH – independent evaluation of tests
  - Panel of 30 pos / 80 neg
  - 85 tests evaluated

SARS-CoV-2 antibody binding assays

- Detection antigens
  - Spike (S) glycoprotein – in vaccine products
    - S ectodomain
    - S1 domain
    - Receptor binding domain (RBD)
  - Nucleocapsid (N)
  - Mulitplex – both S and N
    - Differentiation of infection vs vaccination
- Ig class
  - Total and Pan-Ig
  - IgM
  - IgG
  - IgM/IgG



IgG and IgM seroconversion occurred almost simultaneously

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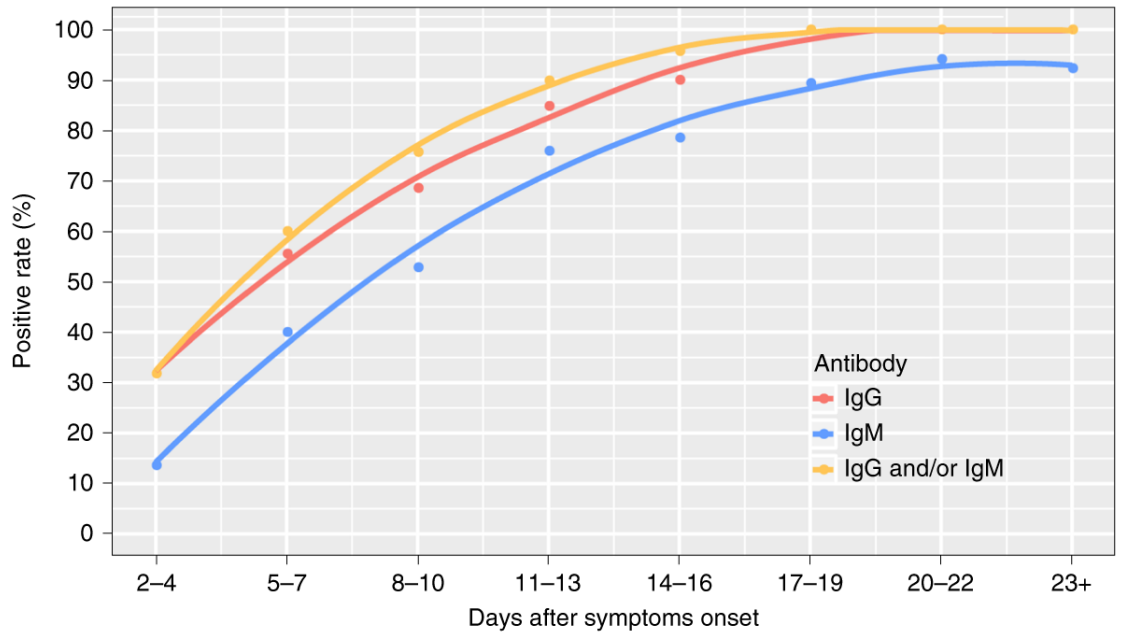


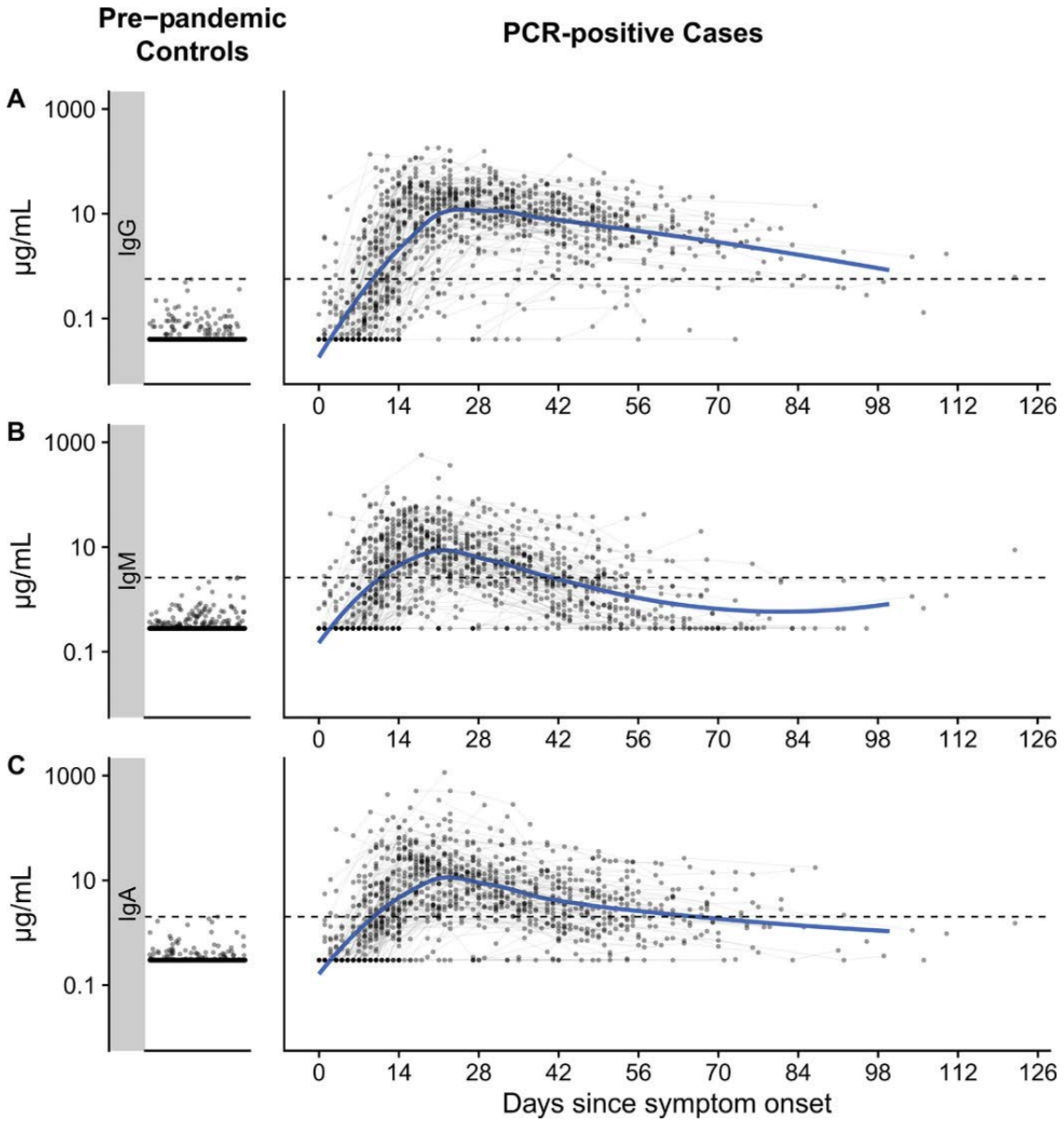
Days *	2–4 (*N* = 22)	5–7 (*N* = 45)	8–10 (*N* = 70)	11–13 (*N* = 79)	14–16 (*N* = 70)	17–19 (*N* = 47)	20–22 (*N* = 17)	23+ (*N* = 13)
IgG	7	25	48	67	63	47	17	13
IgM	3	18	37	60	55	42	16	12
IgG and/or IgM	7	27	53	71	67	47	17	13

* Number of serum samples with positive results

- Median day of seroconversion was 13 d post symptom onset for both S1-IgG and S1-IgM
- Three types of seroconversion
  - Synchronous (n=9 patients)
  - S1-IgM earlier than S1-IgG (n=7 patients)
  - S1-IgM later than S1-IgG (n=10 patients)

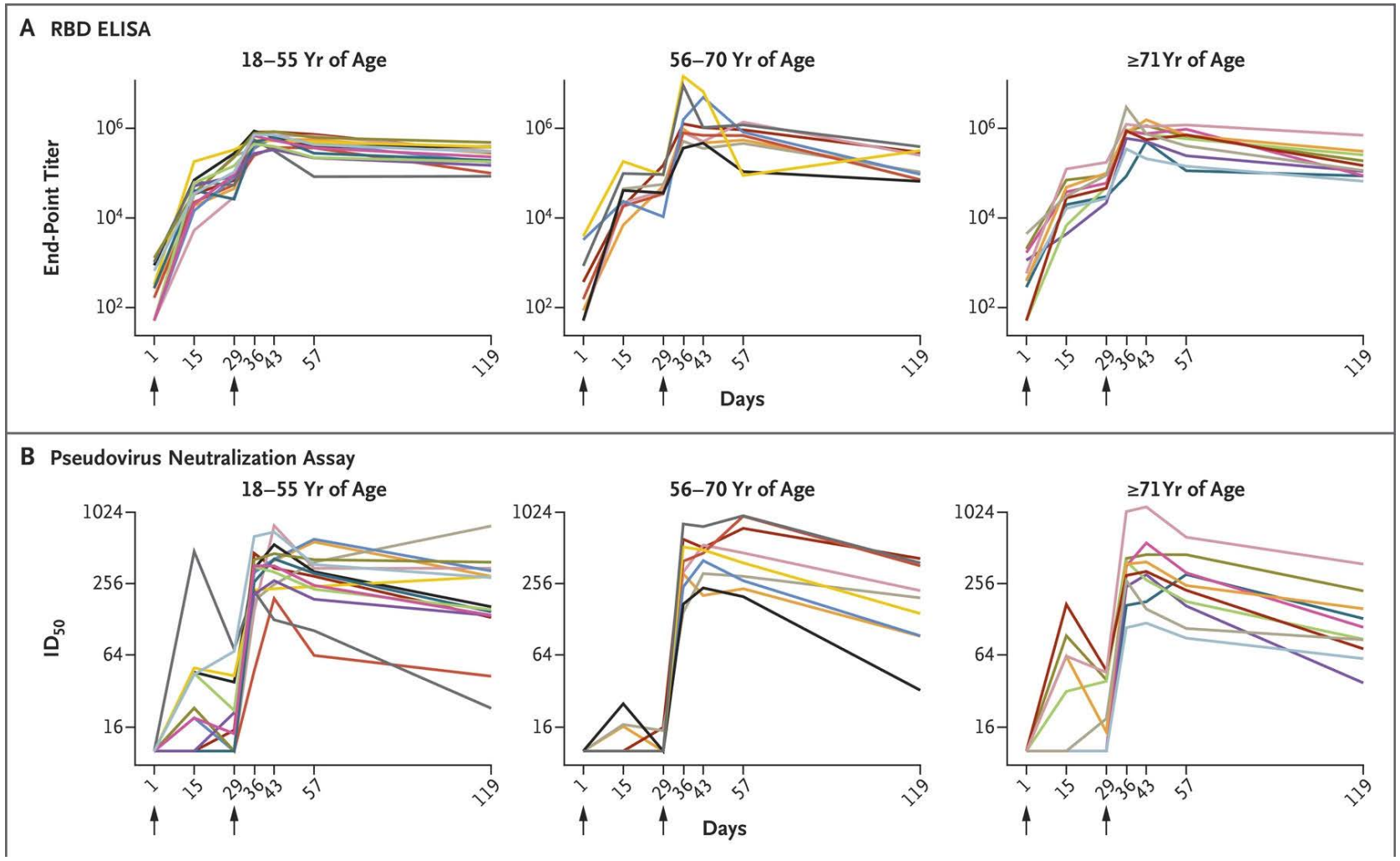
Long, et al. Antibody responses to SARS-CoV-2 in patients with COVID-19. *Nature Medicine*. 2020 Jun;26(6):845-8.

IgG persists longer than IgM and IgA



Iyer et al., 2020.

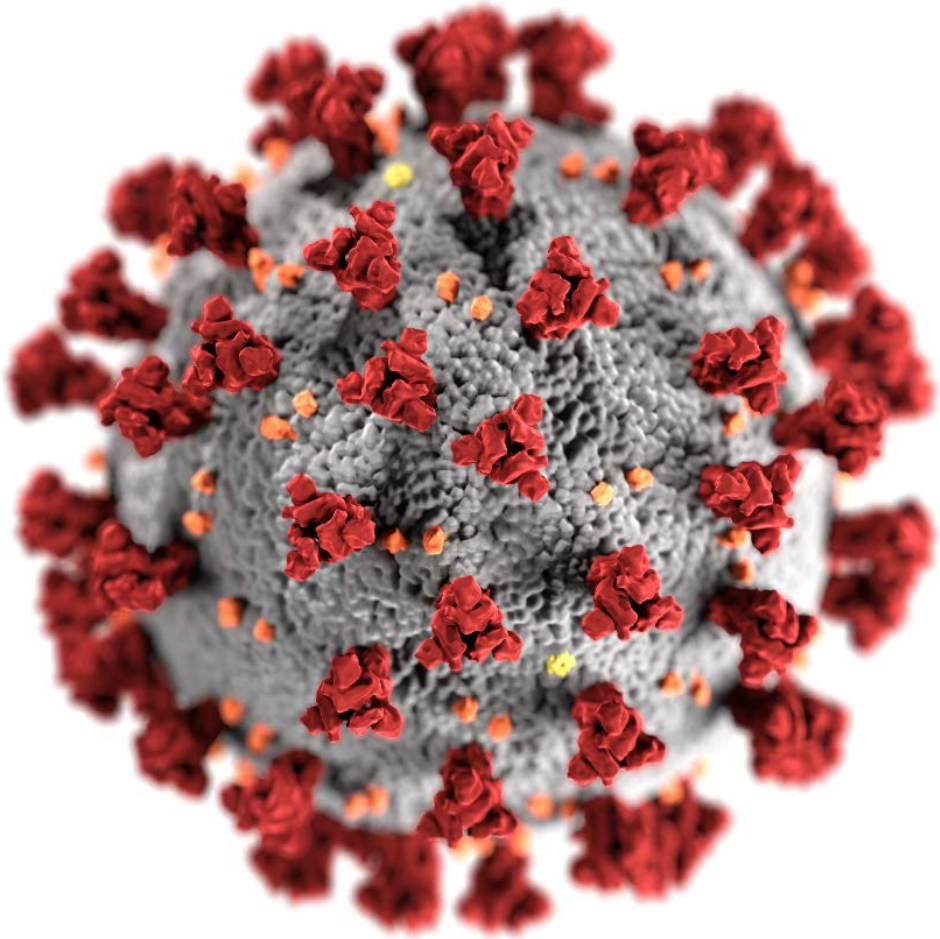
Durability of responses after SARS-CoV-2 mRNA-1273 vaccination (n = 34)



Widge et al., 2020

Summary

- Vaccine products use spike ectodomain
- FDA EUA authorized serology assays test for antibodies against spike ectodomain, a portion of the spike ectodomain, or nucleocapsid
- Spike-based tests will detect antibodies after vaccination and natural infection
- Nucleocapsid-based tests will detect antibodies only after natural infection
- Antibodies after natural infection and vaccination decrease over time, but IgG can persist



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

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.

Surveillance Testing for non-CLIA Pop-up Labs

Amy Zale
Centers for Medicare & Medicaid Services (CMS)

Centers for Medicare and Medicaid Services (CMS)

- **CLIA Laboratory Guidance During COVID-19 Memo and FAQs**

  https://www.cms.gov/medicareprovider-enrollment-and-certificationsurveycertificationgeninfopolicy-and-memos-states-and/clinical-laboratory-improvement-amendments-clia-laboratory-guidance-during-covid-19-public-health

- **FAQs Only**

  https://www.cms.gov/medicare/quality-safety-oversight-general-information/coronavirus

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**
  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/

FDA U.S. FOOD & DRUG ADMINISTRATION

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

U.S. FOOD & DRUG ADMINISTRATION

CDC Social Media

https://www.facebook.com/CDC

https://twitter.com/cdcgov

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

Thank You For Your Time!

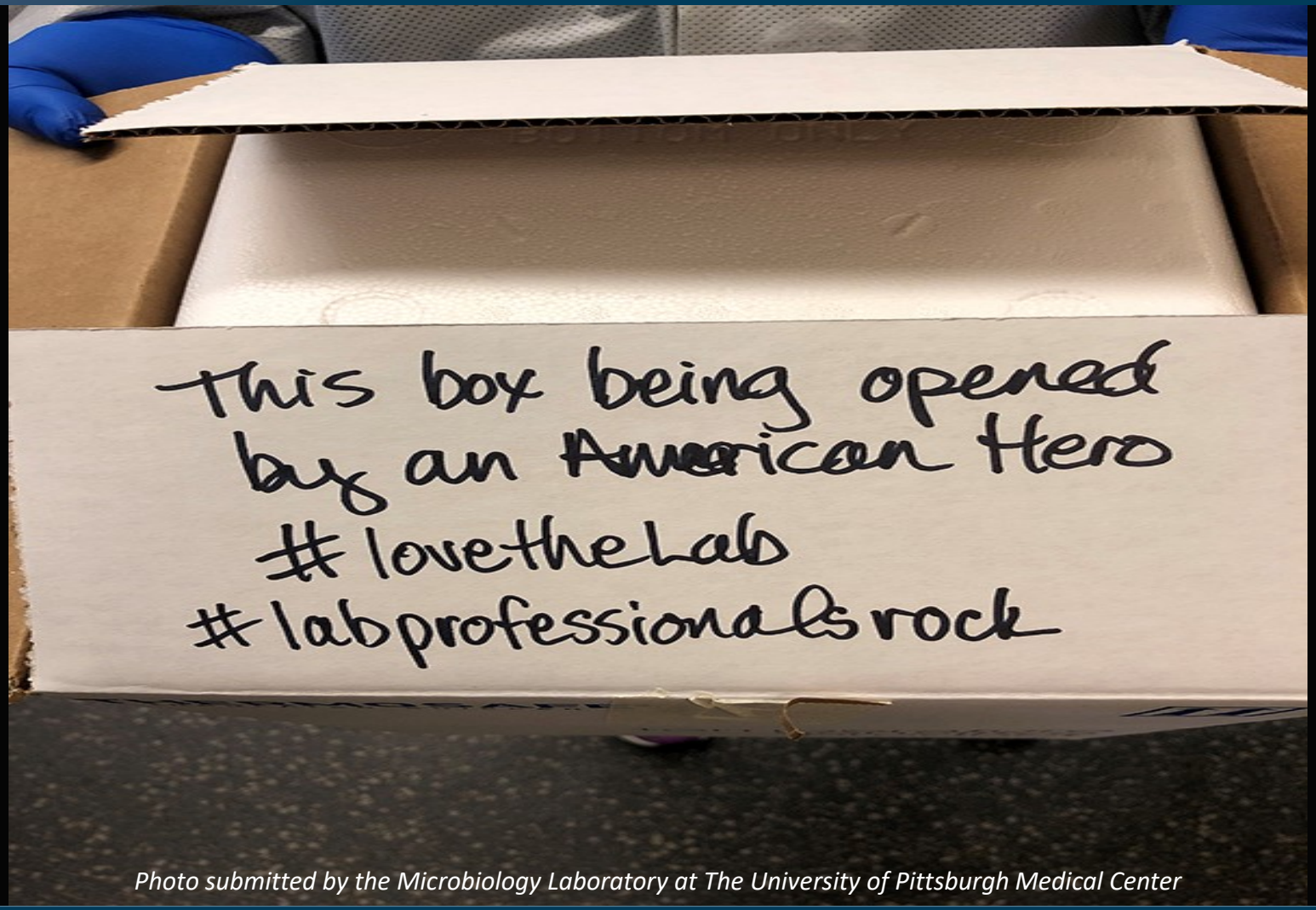


Photo submitted by the Microbiology Laboratory at The University of Pittsburgh Medical Center