

Clinical Laboratory COVID-19 Response Call

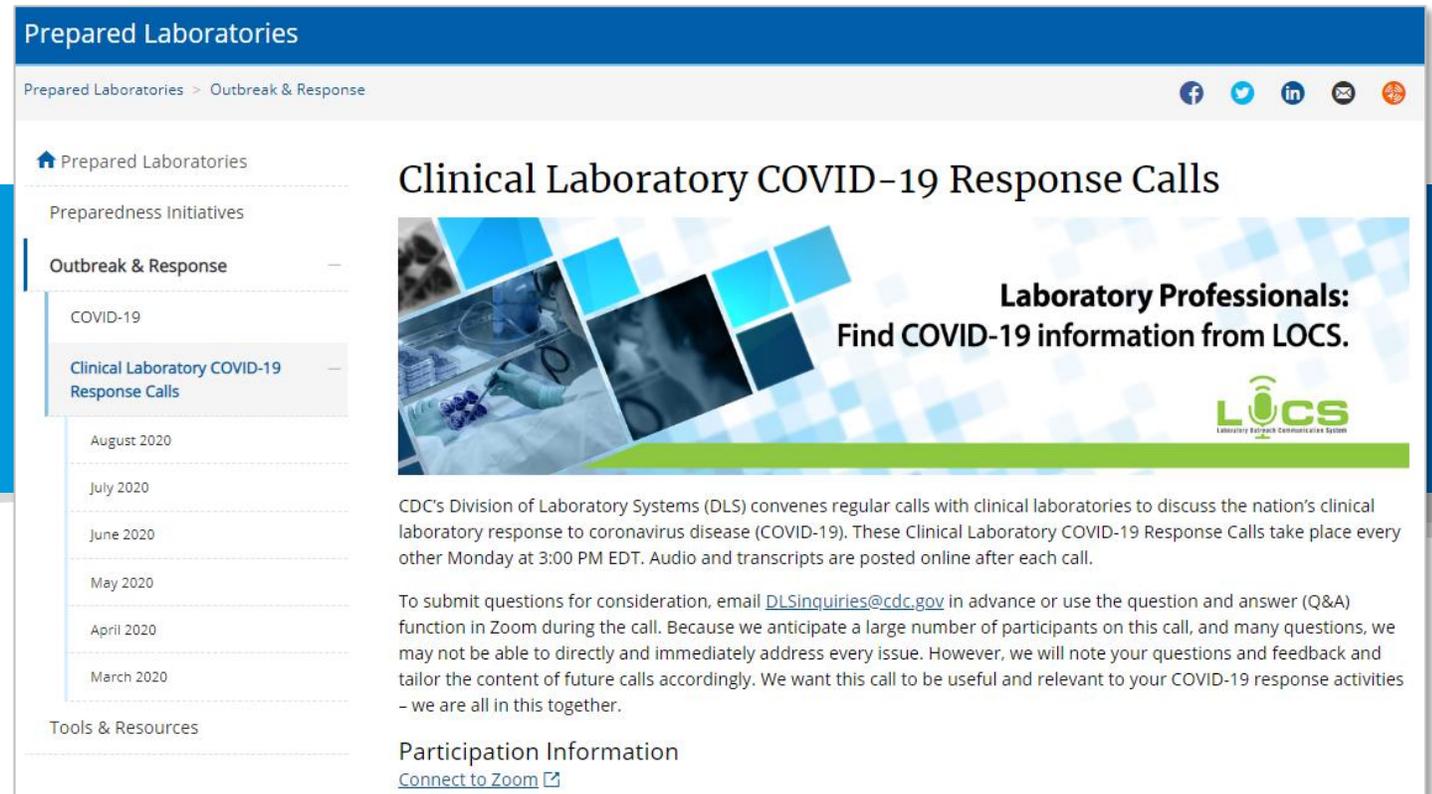
Monday, May 17, 2021 at 3:00 PM EDT

- **Welcome**
 - Jasmine Chaitram, CDC Division of Laboratory Systems (DLS)
- **Interim Guidance for Antigen Testing for SARS-CoV-2**
 - Muktha Natrajan, CDC Division of Laboratory Systems (DLS)
- **Biosafety Guidance Update**
 - Aufra C. Araujo, CDC Division of Laboratory Systems (DLS)
- **SARS-CoV-2 Variants Update**
 - Steve Oberste, CDC Laboratory and Testing Task Force for the COVID-19 Response
- **How the Federal Government is Addressing Laboratory Supply Issues**
 - Steven Santos, HHS Testing and Diagnostics Workgroup
 - Matthew Hubbard, HHS Testing and Diagnostics Workgroup
- **FDA Update**
 - Tim Stenzel, U.S. Food and Drug Administration (FDA)

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 CDC Preparedness Portal



The screenshot displays the 'Prepared Laboratories' section of the CDC website. The main heading is 'Clinical Laboratory COVID-19 Response Calls'. Below this, there is a promotional banner for 'Laboratory Professionals: Find COVID-19 information from LOCS.' with the LOCS logo. The text explains 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 also provides instructions on how to submit questions for consideration via email or a Zoom Q&A session. A 'Participation Information' section includes a link to 'Connect to Zoom'.

Prepared Laboratories

Prepared Laboratories > Outbreak & Response

Prepared Laboratories

Preparedness Initiatives

Outbreak & Response

COVID-19

Clinical Laboratory COVID-19 Response Calls

August 2020

July 2020

June 2020

May 2020

April 2020

March 2020

Tools & Resources

Clinical Laboratory COVID-19 Response Calls

**Laboratory Professionals:
Find COVID-19 information from LOCS.**

CDC's Division of Laboratory Systems (DLS) convenes regular calls with clinical laboratories to discuss the nation's clinical laboratory response to coronavirus disease (COVID-19). These Clinical Laboratory COVID-19 Response Calls take place every other Monday at 3:00 PM EDT. Audio and transcripts are posted online after each call.

To submit questions for consideration, email DLInquiries@cdc.gov in advance or use the question and answer (Q&A) function in Zoom during the call. Because we anticipate a large number of participants on this call, and many questions, we may not be able to directly and immediately address every issue. However, we will note your questions and feedback and tailor the content of future calls accordingly. We want this call to be useful and relevant to your COVID-19 response activities – we are all in this together.

Participation Information
[Connect to Zoom](#)

Schedule for Clinical Laboratory COVID-19 Response Calls

The next call will be on **Monday, June 14** from
3:00 PM to 4:00 PM EDT



We Want to Hear from You!

Training and Workforce Development

Questions about education and training?

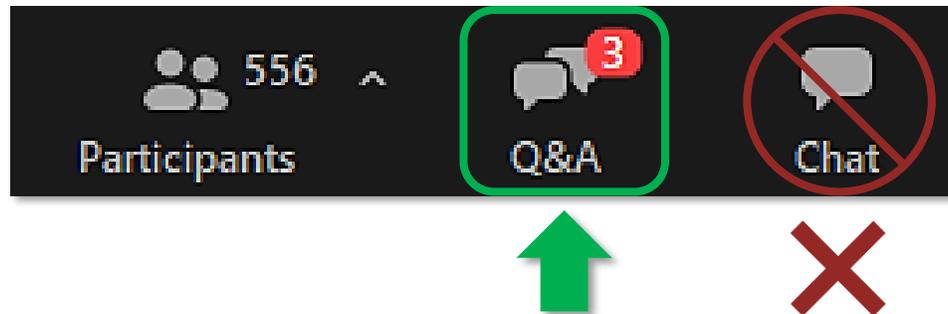
Contact LabTrainingNeeds@cdc.gov



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.

Interim Guidance for Antigen Testing for SARS-CoV-2

Update as of May 13, 2021

<https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html>

LT Muktha Natrajan, PhD, MPH
Reynolds Salerno, PhD, Director of DLS
CDC Division of Laboratory Systems (DLS)

The findings and conclusions in this report are those of the author(s) and do not necessarily represent the official position of the Centers for Disease Control and Prevention (CDC).



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

Purpose of Guidance

Support effective clinical and public health use of antigen tests

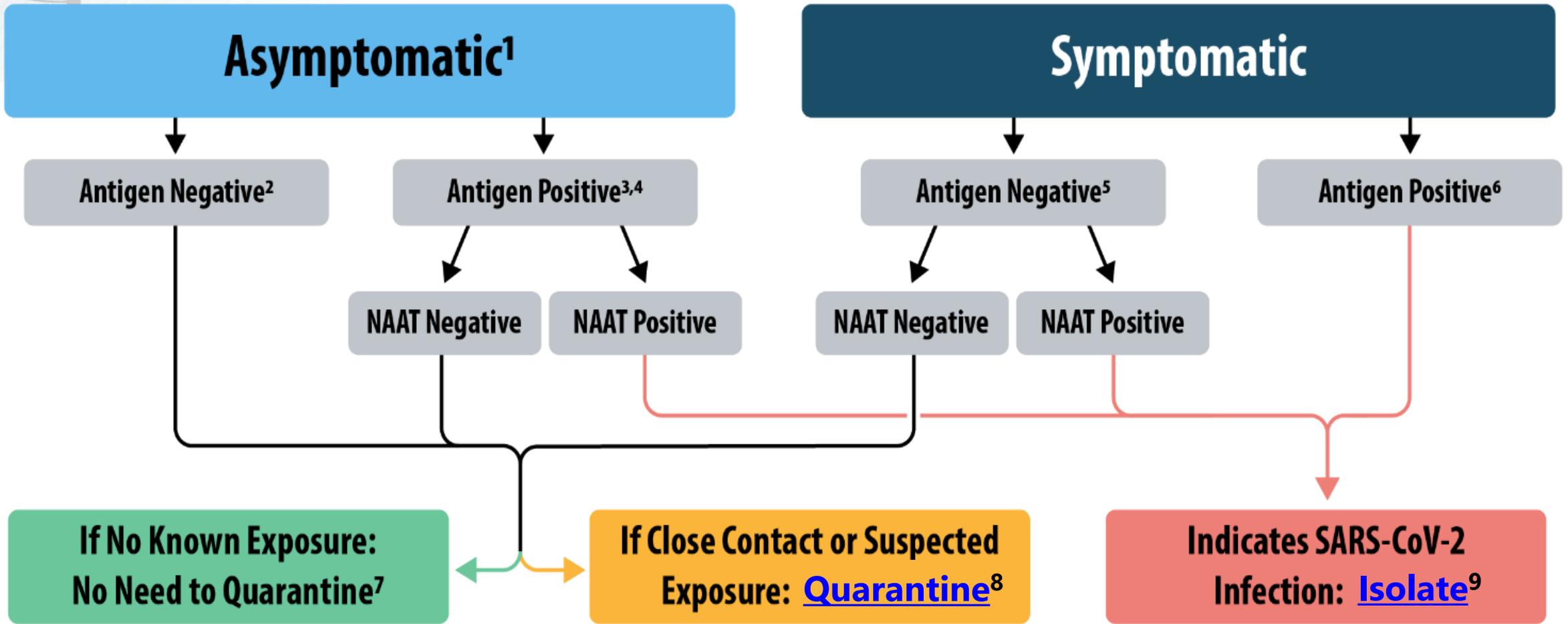
Factors that affect Test Accuracy and Pre-test Probability

Test Strategy	Diagnostic	Screening / Serial	Surveillance
Test Processing	Storage / Handling of Components	Timing and Batching of Specimens	Specimen Integrity and Performance Conditions
Clinical Context	COVID-19 Symptoms	COVID-19 Vaccination	Recent SARS-CoV-2 Infection
Community Factors	COVID-19 Exposure	Community Prevalence	Living Setting

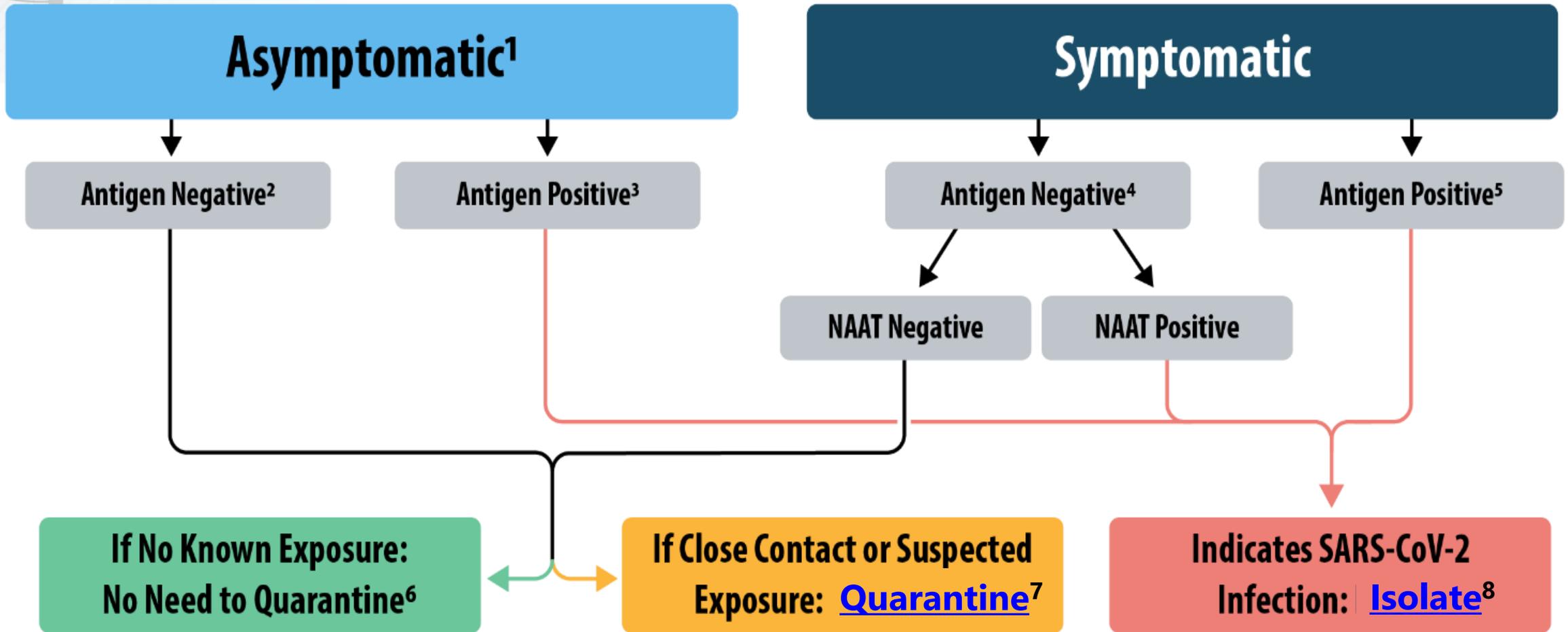
Summary of Recent Changes

- Updated guidance based on new published studies on antigen test performance.
- Clarification about which Nucleic Acid Amplification Tests (NAATs) should be used for confirmatory testing.
- Considerations for people who have had previous SARS-CoV-2 infections and those who have been fully vaccinated.
- Two new antigen testing algorithms, one for congregate living settings, and one for community settings.
- Updates to testing suggestions for fully vaccinated, asymptomatic people.

Congregate Settings Antigen Testing Algorithm



Community Settings Antigen Testing Algorithm



Thank you!

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

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The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of Centers for Disease Control and Prevention.

Biosafety Guidance Update

Aufra C. Araujo, PhD
CDC Division of Laboratory Systems (DLS)



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

Biosafety Guidance Update

<https://www.cdc.gov/coronavirus/2019-nCoV/lab/lab-biosafety-guidelines.html>

CDC Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

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COVID-19

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More Resources

- CDC in Action +
- Global COVID-19 +
- Laboratories** -
- Resources for Labs -

Guidance for Reporting SARS-CoV-2 Sequencing Results

Test for Flu & COVID-19

FAQ: Multiplex Assay for Flu and COVID-19 & Supplies

Research Use Only CDC Multiplex Assay Primers and Probes

Test for COVID-19 Only

Research Use Only 2019-Novel

Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19)

Updated May 11, 2021 [Print](#)

Summary of Recent Changes

Updates as of May 11, 2021

- Added information on *PPE* to the “General Guidance” section
- Added *Biological Risk Assessment: General Considerations for Laboratories* resource to the “General Guidance” section
- Added *Core Infection Prevention and Control Practices for Safe Healthcare Delivery* resources to the “General Guidance” section
- Added *OSHA Bloodborne Pathogens Standard* resource to the “General Guidance” section

CDC Update on Activities for SARS-CoV-2 Variant Surveillance

M. Steven Oberste, Ph.D.

Surveillance and Emerging Variants Team

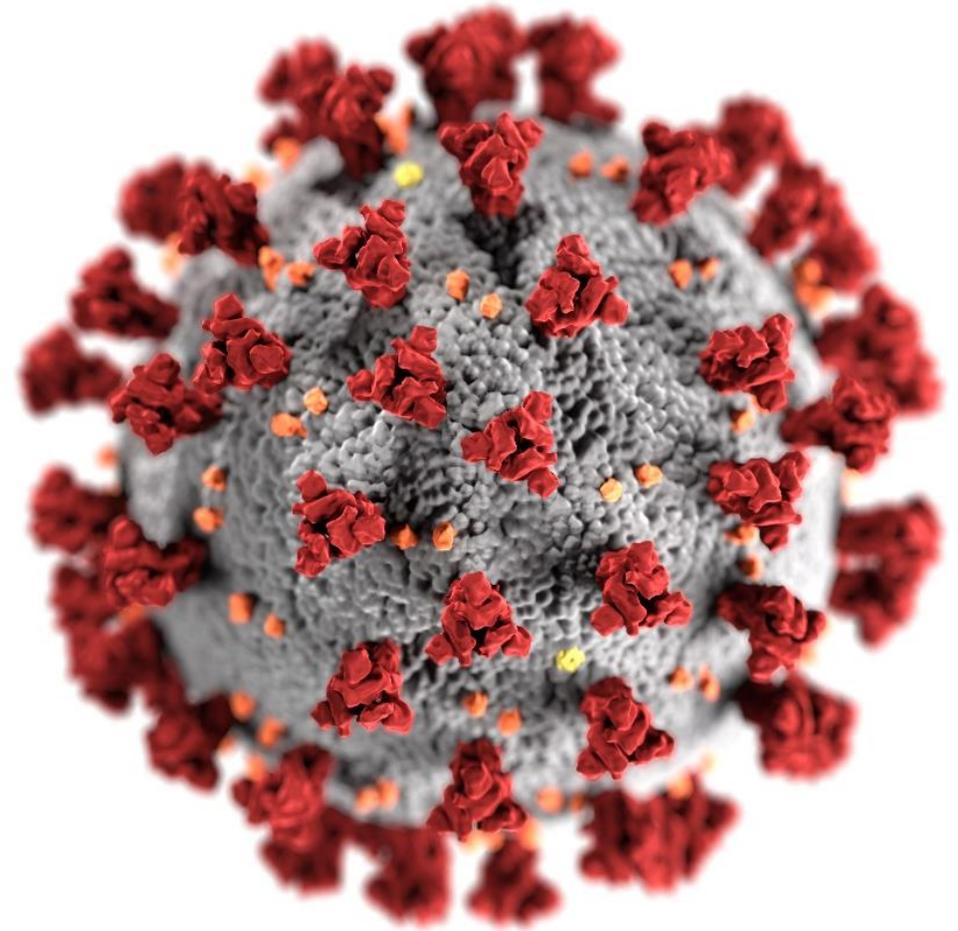
Laboratory and Testing Task Force

CDC COVID-19 Emergency Response

Acting Deputy Director, Division of Viral Disease

NCIRD, CDC

May 17, 2021



cdc.gov/coronavirus

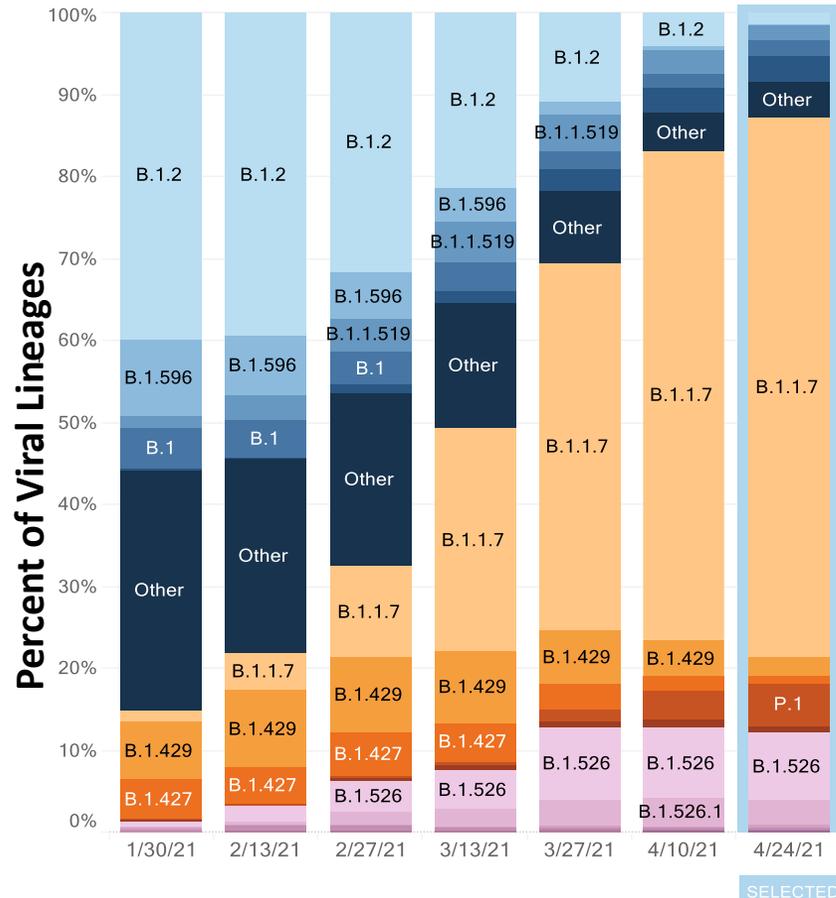
B.1.617 Lineages – Variants of Interest

Name (Pango lineage)	Spike Protein Substitutions	Name (Nextstrain)	First Detected	Attributes
B.1.617	L452R, E484Q, D614G	20A	India February 2021	<ul style="list-style-type: none"> • Potential reduction in neutralization by some EUA monoclonal antibody treatments • Slightly reduced neutralization by post-vaccination sera
B.1.617.1	(T95I), G142D, E154K, L452R, E484Q, D614G, P681R, Q1071H	20A/S:154K	India December 2020	<ul style="list-style-type: none"> • Potential reduction in neutralization by some EUA monoclonal antibody treatments • Potential reduction in neutralization by post-vaccination sera
B.1.617.2	T19R, (G142D), Δ156, Δ157, R158G, L452R, T478K, D614G, P681R, D950N	20A/S:478K	India December 2020	<ul style="list-style-type: none"> • Potential reduction in neutralization by some EUA monoclonal antibody treatments • Potential reduction in neutralization by post-vaccination sera
B.1.617.3	T19R, G142D, L452R, E484Q, D614G, P681R, D950N	20A	India October 2020	<ul style="list-style-type: none"> • Potential reduction in neutralization by some EUA monoclonal antibody treatments • Potential reduction in neutralization by post-vaccination sera

National Prevalence of SARS-CoV-2 Variants

U.S. 1/17/2021 – 04/24/2021

U.S. 4/11/2021 – 4/24/2021



	Lineage	Type	%Total	95%CI		
Most common lineages	B.1.1.7	VOC	66.0%	62.0-69.7%	Orange	Red
	B.1.526	VOI	8.2%	5.9-11.1%	Pink	Blue
	P.1	VOC	5.0%	3.3-7.5%	Brown	Red
	B.1.526.1	VOI	3.0%	2.2-4.0%	Pink	Blue
	B.1.526.2		3.0%	2.2-4.0%	Dark Blue	
	B.1.429	VOC	2.3%	1.5-3.6%	Orange	Blue
	B.1.1.519		1.9%	1.4-2.6%	Light Blue	
	B.1		1.8%	1.5-2.2%	Dark Blue	
	B.1.2		1.3%	1.1-1.7%	Light Blue	
	B.1.596		0.2%	0.1-0.3%	Light Blue	
Additional VOI/VOC lineages	B.1.427	VOC	0.9%	0.6-1.4%	Orange	Blue
	B.1.351	VOC	0.9%	0.6-1.4%	Brown	Blue
	B.1.617.2	VOI	0.5%	0.3-0.7%	Pink	
	B.1.525	VOI	0.3%	0.2-0.5%	Pink	
	B.1.617.1	VOI	0.2%	0.1-0.2%	Purple	
	P.2	VOI	0.1%	0.0-0.2%	Pink	
	B.1.617.3	† VOI	0.0%	0.0-0.1%	Purple	
	B.1.617	† VOI	0.0%	NA	Purple	
Other*	Other	4.5%	3.8-5.2%	Dark Blue		

* Other represents >200 additional lineages, which are each circulating <1% of viruses
 ** These data include Nowcast estimates, which are modeled projections that may differ from weighted estimates generated at later dates
 † Fewer than 10 observations of this variant during the selected time/location context

Weighted estimates

- ↑B.1.1.7 VOC increased to 66.0%
- ↑P.1 VOC increased to 5.0%
- ↓B.1.351 VOC decreased to 0.9%
- ↓B.1.427/429 VOC decreased to 3.2%
- ↓B.1.526/526.1 VOI decreased 8.2%/3.0%
- B.1.617 VOI lineages <1.0%
- Weighted estimates 4/11/21 - 4/24/21 fall within Nowcast prediction intervals

Specimen Collection Date, 2-weeks ending

[Variant Proportions in the U.S. | CDC](#)



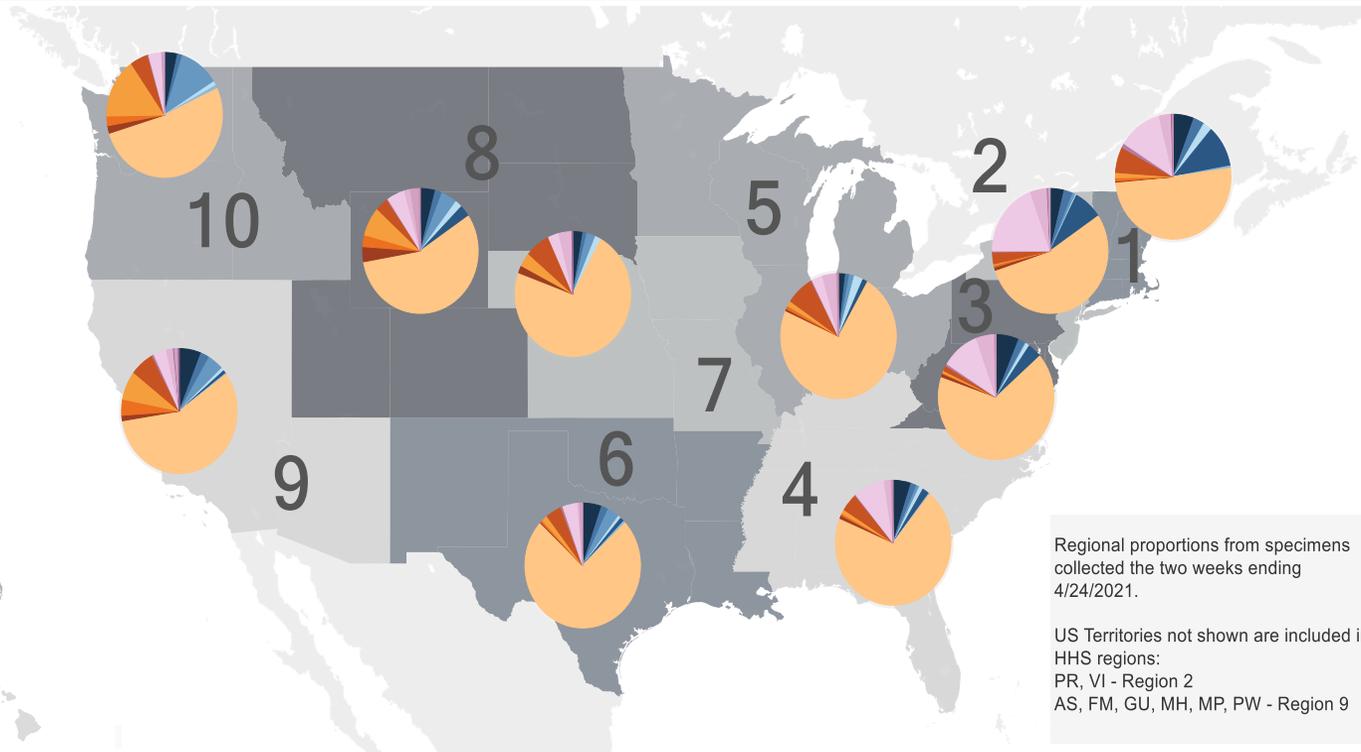
Variant of Concern - Evidence of increased transmissibility, more severe disease (hospitalizations or mortality), reduced therapeutic effectiveness, significant reduction in neutralization (convalescent or vaccinee sera), diagnostic impact, assessed to be VOC by WHO/WHO SARS-CoV-2 Virus Evolution Working Group

Variant of Interest -Studies predict increase in transmissibility or specific genetic markers may affect virus receptor binding, neutralization, or therapeutic efficacy

Regional Prevalence of SARS-CoV-2 Variants

Two weeks ending April 24, 2021

United States: 4/11/2021 – 4/24/2021

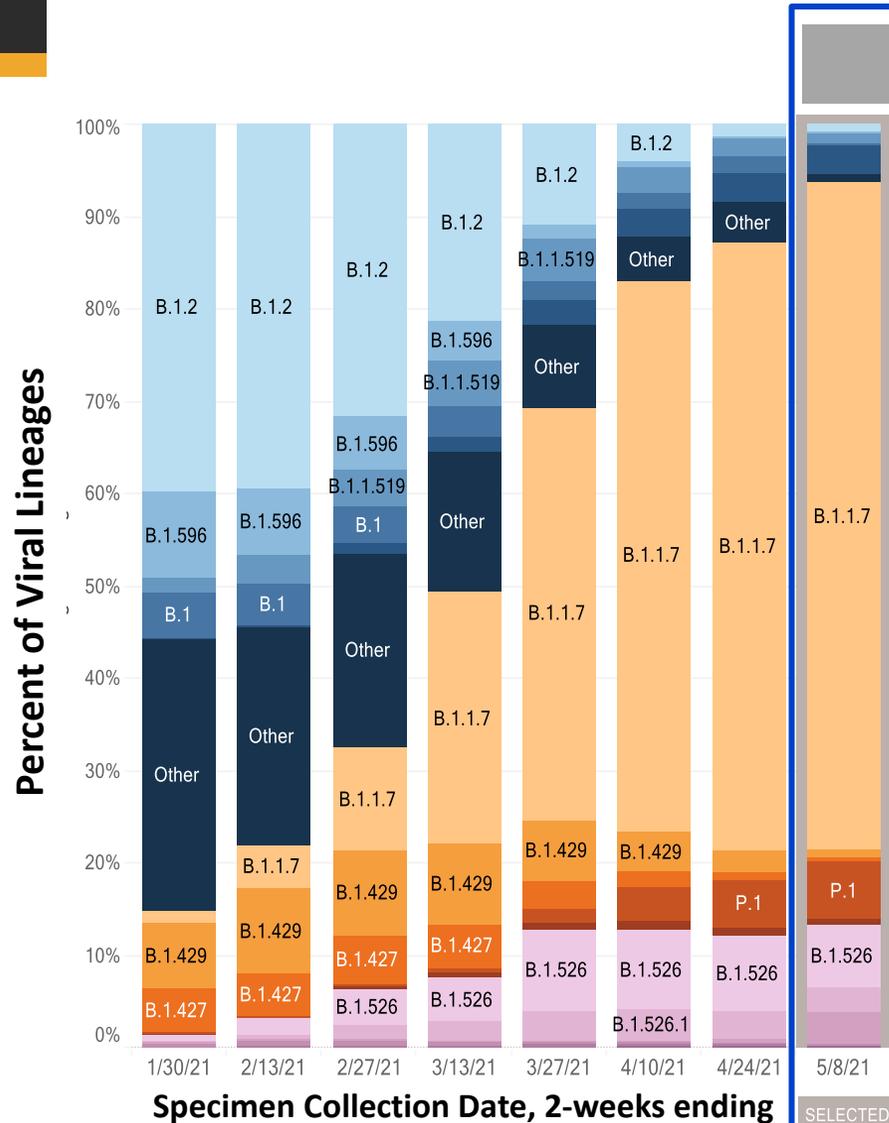


Top	B.1.2
	B.1.596
	B.1.1.519
	B.1
	B.1.526.2
VOC	B.1.1.7
	B.1.429
	B.1.427
	P.1
	B.1.351
VOI	B.1.526
	B.1.526.1
	B.1.617.2
	P.2
	B.1.525
	B.1.617.1
	B.1.617.3
	B.1.617
Other	Other

- ↑B.1.1.7 VOC >50% in all regions, as predicted by **Nowcast estimates**
 - >70% in regions 4-7
- ↑P.1 VOC increased as **predicted**
 - >3% in all regions except region 3
 - >7% in regions 5 and 7
- B.1.351 VOC ≥1% in regions 4, 7-10 remained stable as **predicted**
- ↓B.1.427/B.1.429 VOC decreased in regions 8-10 [10.5% - 18.0%]
- B.1.526/B.1.526.1 VOI remained stable as **predicted**
- B.1.617.1/B.1.617.3 VOI lineages ranged from 0%-0.3%
- B.1.617.2 VOI ranged from 0%-2.5%
 - ≥1.0% regions 8 and 9



National Nowcast Estimates of SARS-CoV-2 Lineages



NOWCAST ESTIMATES 4/25/21 - 5/8/21

	Lineage	Type	%Total	95%PI	
Most common lineages	B.1.1.7	VOC	72.4%	67.4-77.1%	Orange
	B.1.526	VOI	6.8%	4.2-9.6%	Pink
	P.1	VOC	6.2%	3.7-9.1%	Brown
	B.1.617.2	VOI	3.3%	1.4-5.7%	Purple
	B.1.526.2		3.1%	1.4-5.1%	Dark Blue
	B.1.526.1	VOI	2.8%	1.1-4.5%	Pink
	B.1.1.519		1.2%	0.3-2.3%	Blue
	B.1.2		0.7%	0.0-1.7%	Light Blue
	B.1		0.3%	0.0-1.1%	Dark Blue
	B.1.596		0.1%	0.0-0.6%	Light Blue
Additional VOI/VOC lineages	B.1.429	VOC	0.9%	0.0-2.0%	Orange
	B.1.351	VOC	0.6%	0.0-1.4%	Brown
	B.1.427	VOC	0.4%	0.0-1.1%	Orange
	B.1.525	VOI	0.2%	0.0-0.8%	Purple
	B.1.617.1	VOI	0.2%	0.0-0.6%	Purple
	P.2	VOI	0.0%	0.0-0.3%	Purple
	B.1.617.3	VOI	0.0%	0.0-0.3%	Purple
	Other*	Other	0.8%	0.0-4.0%	Dark Blue

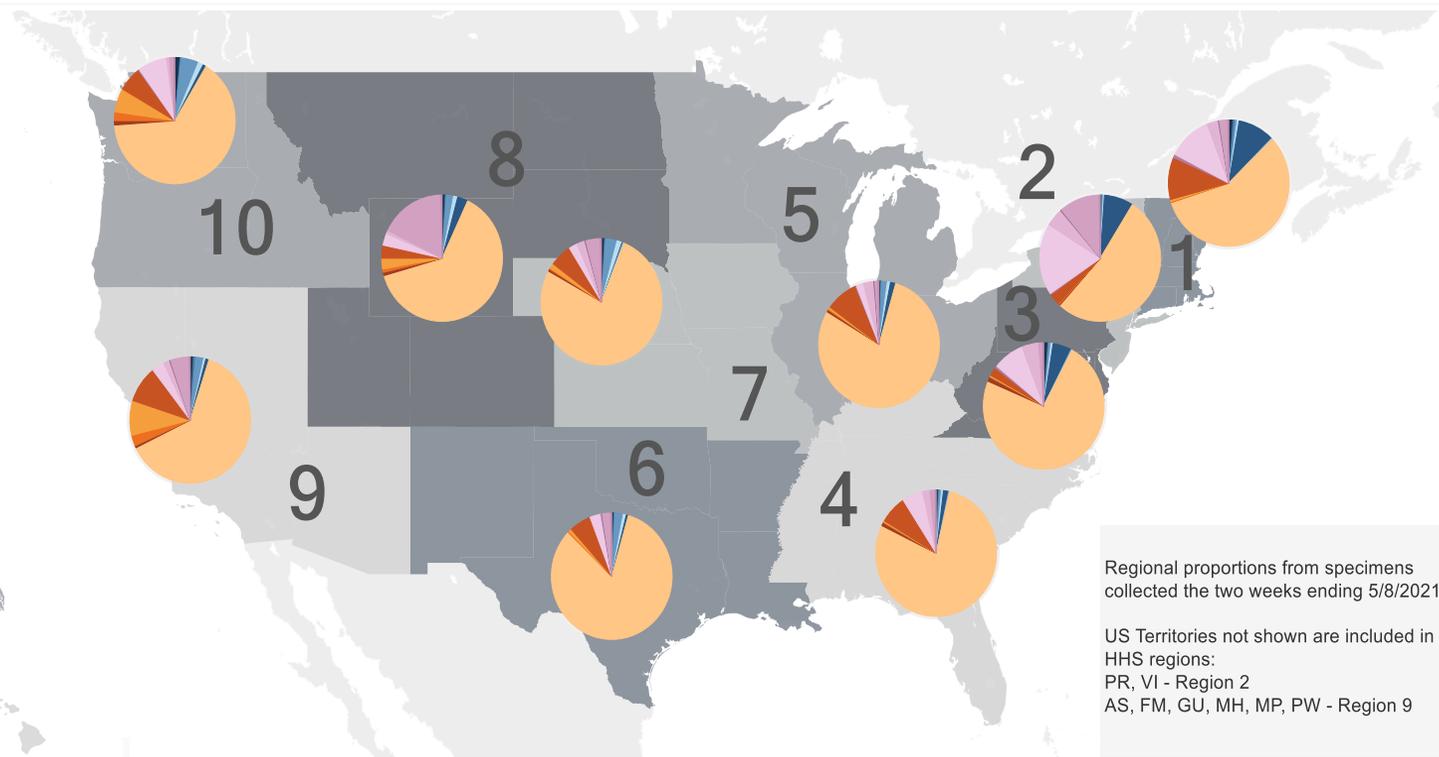
* Other represents >200 additional lineages, which are each circulating at <1% of viruses
 ** These data include Nowcast estimates, which are modeled projections that may differ from weighted estimates generated at later dates

Nowcast national estimates predict:

- ↑B.1.1.7 VOC to increase to 72.4%
- ↑P.1 VOC to increase to 6.2%
- ↓B.1.351 VOC to decrease to 0.6%
- ↓B.1.427/429 VOC to decrease to 1.3%
- ↓B.1.526 VOI to decrease to 6.8%
- B.1.526.1 VOI to remain steady at 2.8%
- ↑B.1.617.2 VOI to increase to 3.3%
- B.1.617.1/B.1.617.3 VOI to remain <1%

Regional Nowcast Estimates of SARS-CoV-2 Variants

United States: 4/25/2021 – 5/8/2021 NOWCAST



Regional proportions from specimens collected the two weeks ending 5/8/2021.

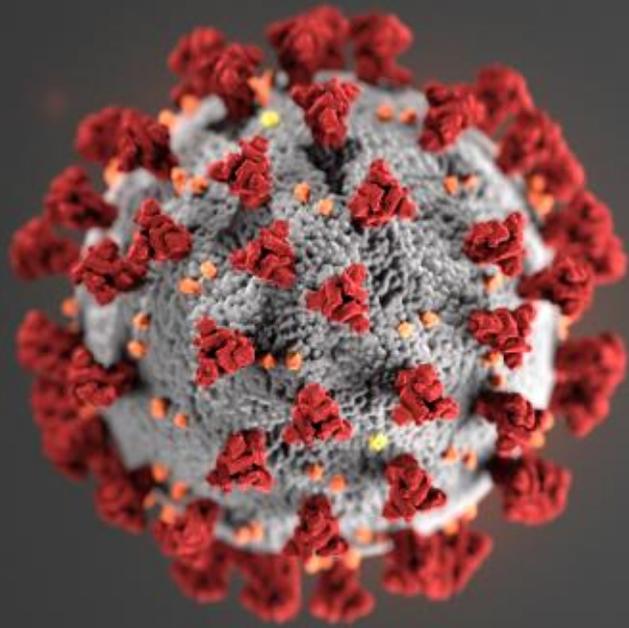
US Territories not shown are included in HHS regions:
PR, VI - Region 2
AS, FM, GU, MH, MP, PW - Region 9

Top	B.1.2	
	B.1.596	
	B.1.1.519	
	B.1	
	B.1.526.2	
VOC	B.1.1.7	
	B.1.429	
	B.1.427	
	P.1	
	B.1.351	
VOI	B.1.526	
	B.1.526.1	
	B.1.617.2	
	P.2	
	B.1.525	
	B.1.617.1	
	B.1.617.3	
	B.1.617	
Other	Other	

Nowcast estimates **predict:**

- ↑B.1.1.7 VOC will increase to >60% in regions 3-10
- ↑P.1 VOC will increase in all regions
 - >10% in region 1
- ↑B.1.351 VOC to increase in regions 3, 10
- B.1.427/429 VOC will be highest in regions 9, 10
- B.1.526/B.1.526.1 VOI will be higher in regions 1-3
- ↑B.1.617.2 VOI to increase in regions 2, 7-9





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

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How the Federal Government is Addressing Laboratory Supply Issues

Steven Santos

HHS Testing and Diagnostics Workgroup

Matthew Hubbard

HHS Testing and Diagnostics Workgroup





These slides were shared during the call but are not available for public distribution.

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)

- **SARS-CoV-2 Viral Mutations: Impact on COVID-19 Tests**

<https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/sars-cov-2-viral-mutations-impact-covid-19-tests>

- **A SARS-CoV-2 Nucleocapsid Variant that Affects Antigen Test Performance**

<https://www.medrxiv.org/content/10.1101/2021.05.05.21256527v1>

- **BioFire De Novo authorized test**

https://www.accessdata.fda.gov/cdrh_docs/pdf20/DEN200031.pdf

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>



<https://twitter.com/cdcgov>



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

Thank You For Your Time!

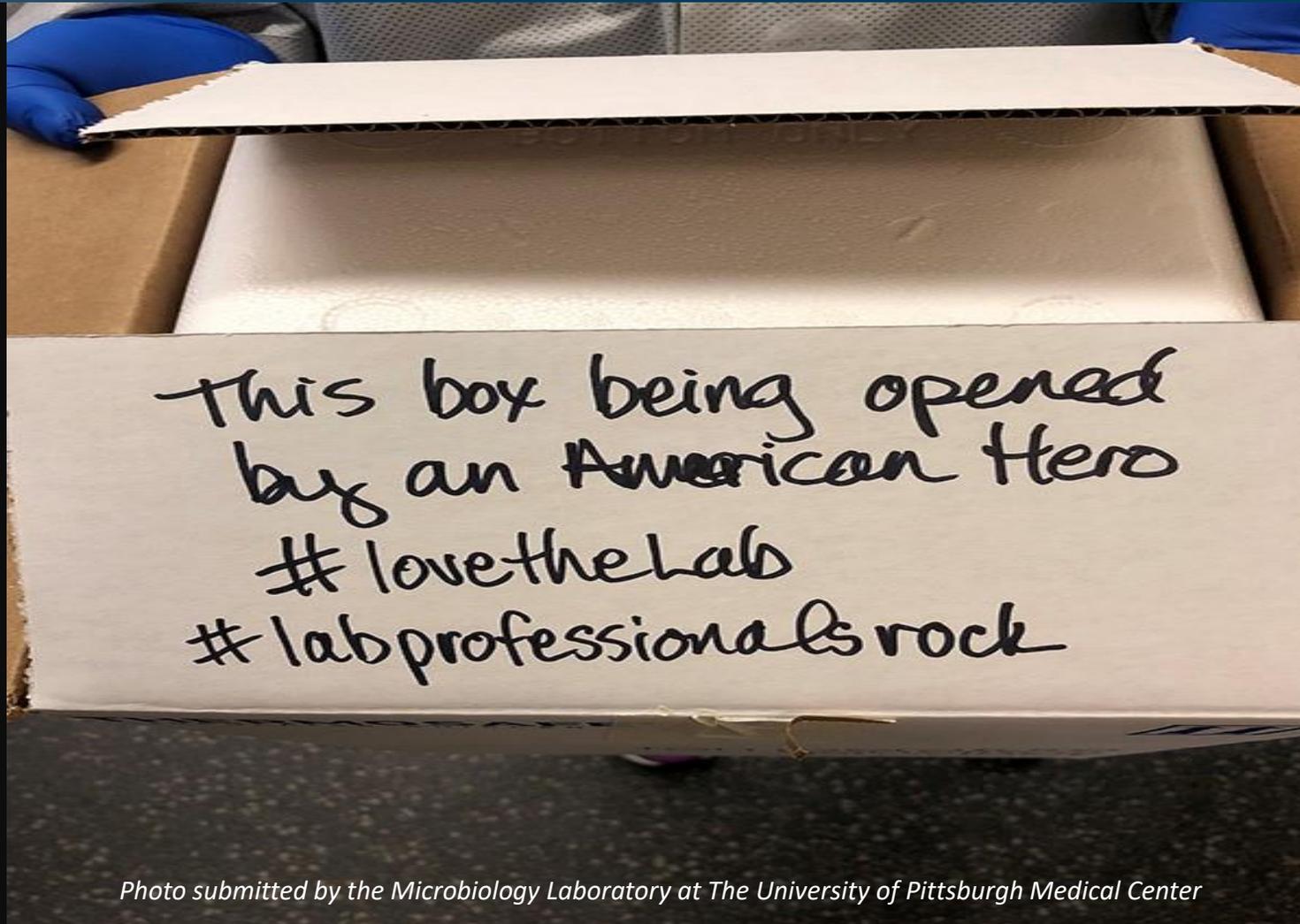


Photo submitted by the Microbiology Laboratory at The University of Pittsburgh Medical Center