Clinical Laboratory COVID-19 Response Call

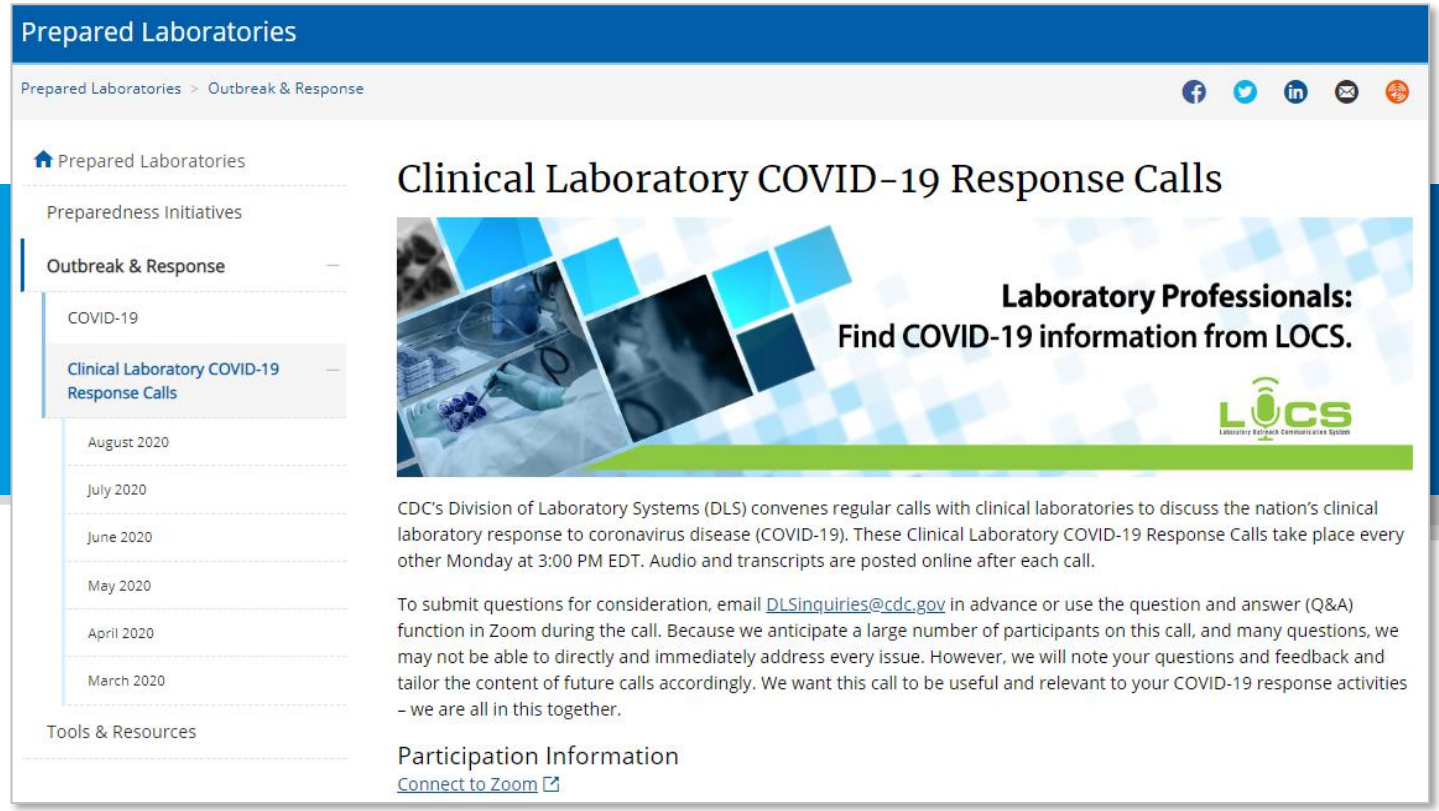
Monday, May 17, 2021 at 3:00 PM EDT

- **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



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)

Purpose of Guidance

Support effective clinical and public health use of antigen tests

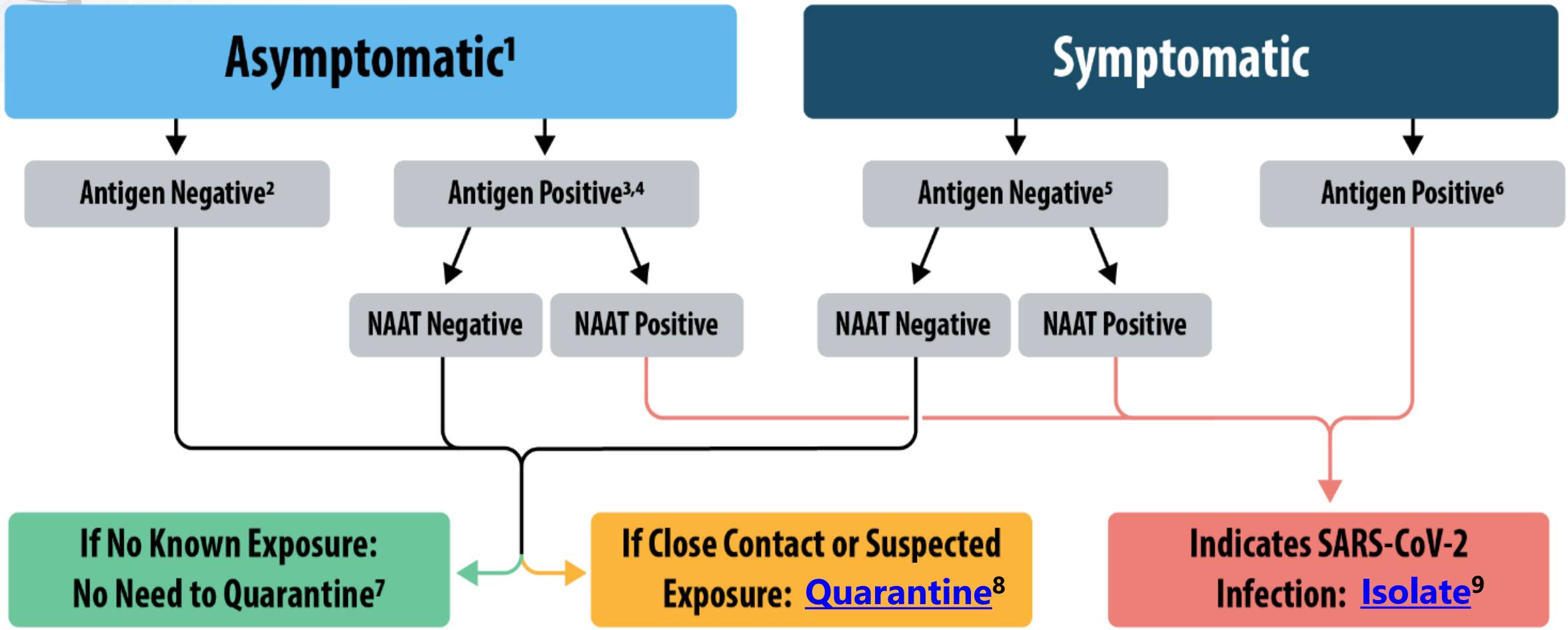
Factors that affect Test Accuracy and Pre-test Probability

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

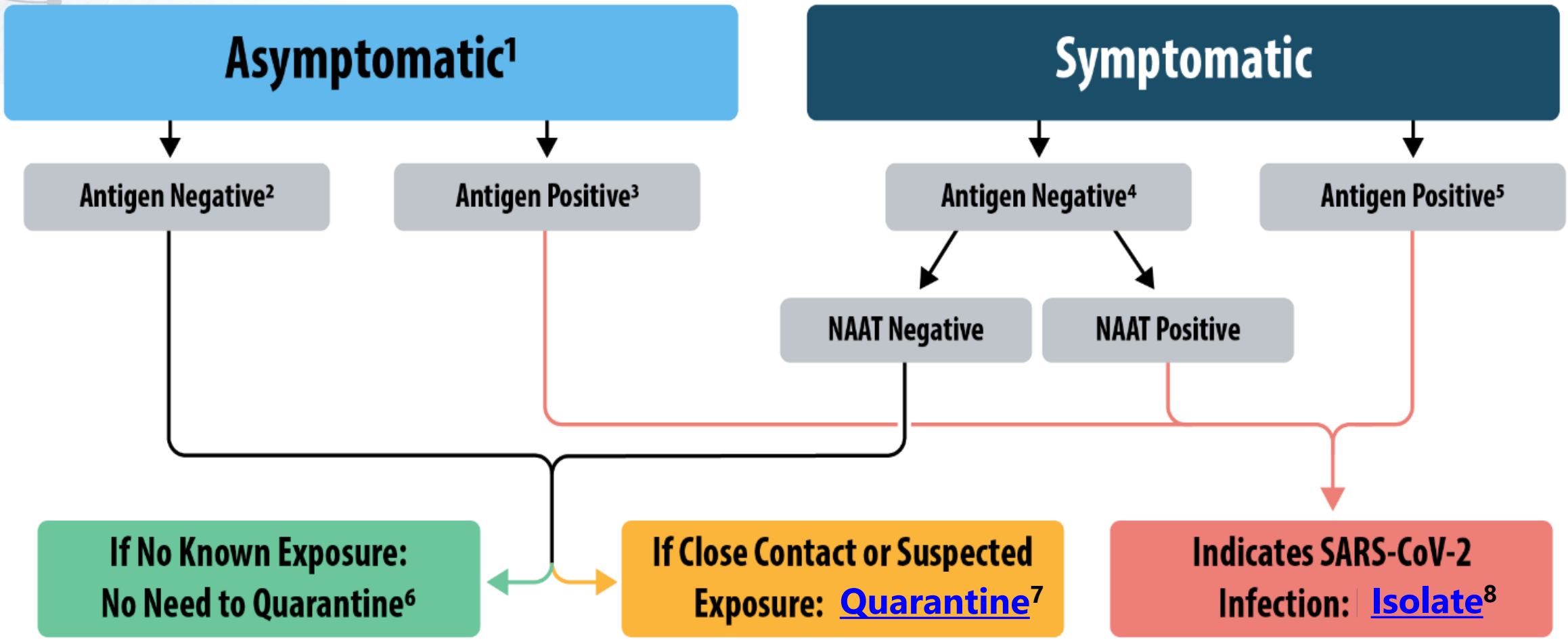
Summary of Recent Changes

- 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

Use of trade names is for identification only and does not imply endorsement by U.S. Centers for Disease Control and Prevention.

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.

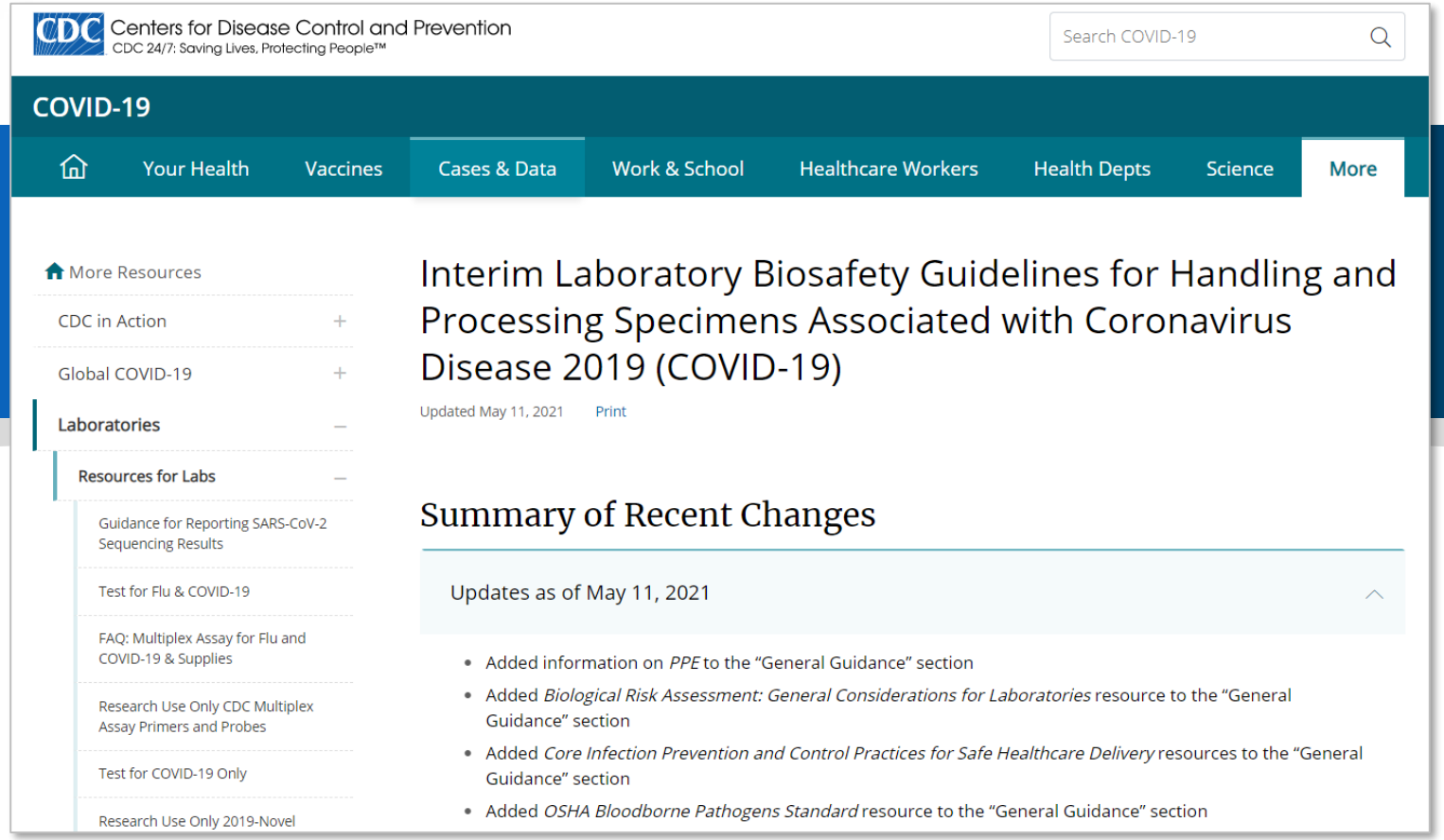
Biosafety Guidance Update

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

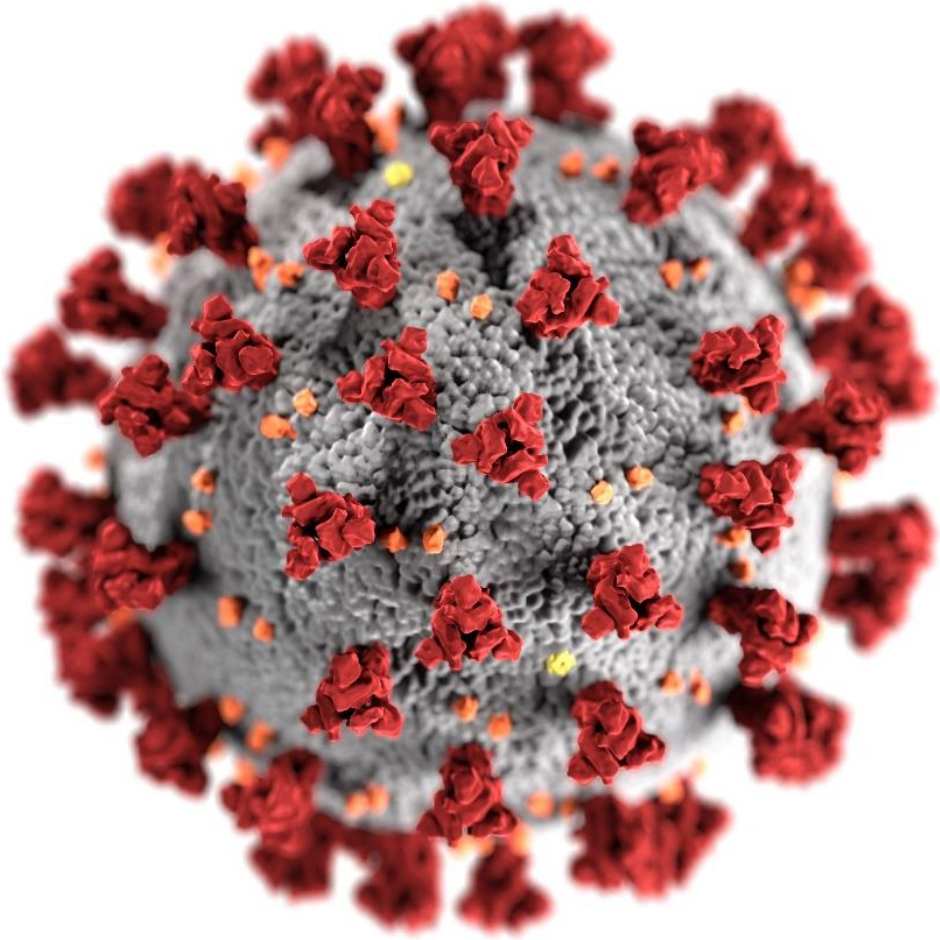


CDC Update on Activities for SARS-CoV-2 Variant Surveillance

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

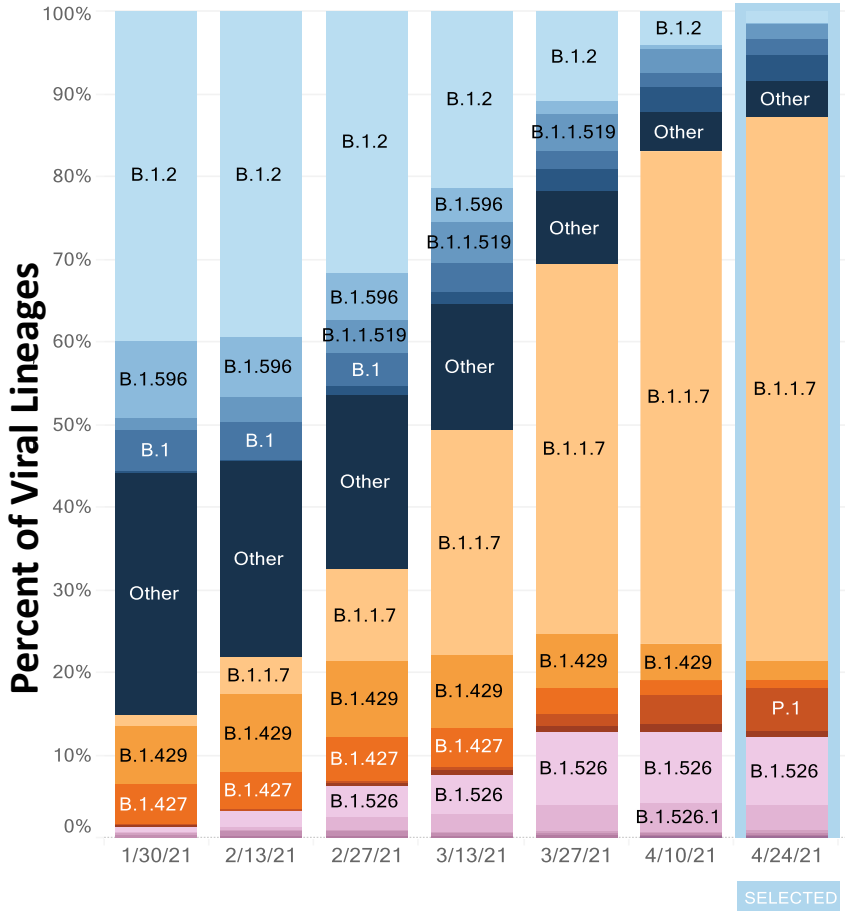
B.1.617 Lineages – Variants of Interest

Name (Pango lineage)	Spike Protein Substitutions	Name (Nextstrain)	First Detected		Attributes
B.1.617	**L452R, E484Q**, D614G	20A	India	February 2021	• 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	• 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	• 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	• Potential reduction in neutralization by some EUA monoclonal antibody treatments • Potential reduction in neutralization by post-vaccination sera

SARS-CoV-2 Variant Classifications and Definitions (cdc.gov)

National Prevalence of SARS-CoV-2 Variants

U.S. 1/17/2021 – 04/24/2021



Specimen Collection Date, 2-weeks ending

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%
	B.1.526		VOI	8.2%	5.9-11.1%
	P.1		VOC	5.0%	3.3-7.5%
	B.1.526.1		VOI	3.0%	2.2-4.0%
	B.1.526.2			3.0%	2.2-4.0%
	B.1.429		VOC	2.3%	1.5-3.6%
	B.1.1.519			1.9%	1.4-2.6%
	B.1			1.8%	1.5-2.2%
	B.1.2			1.3%	1.1-1.7%
	B.1.596			0.2%	0.1-0.3%
Additional VOI/VOC lineages	B.1.427		VOC	0.9%	0.6-1.4%
	B.1.351		VOC	0.9%	0.6-1.4%
	B.1.617.2		VOI	0.5%	0.3-0.7%
	B.1.525		VOI	0.3%	0.2-0.5%
	B.1.617.1		VOI	0.2%	0.1-0.2%
	P.2		VOI	0.1%	0.0-0.2%
	B.1.617.3	†	VOI	0.0%	0.0-0.1%
	B.1.617	†	VOI	0.0%	NA
Other*	Other			4.5%	3.8-5.2%

* 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**

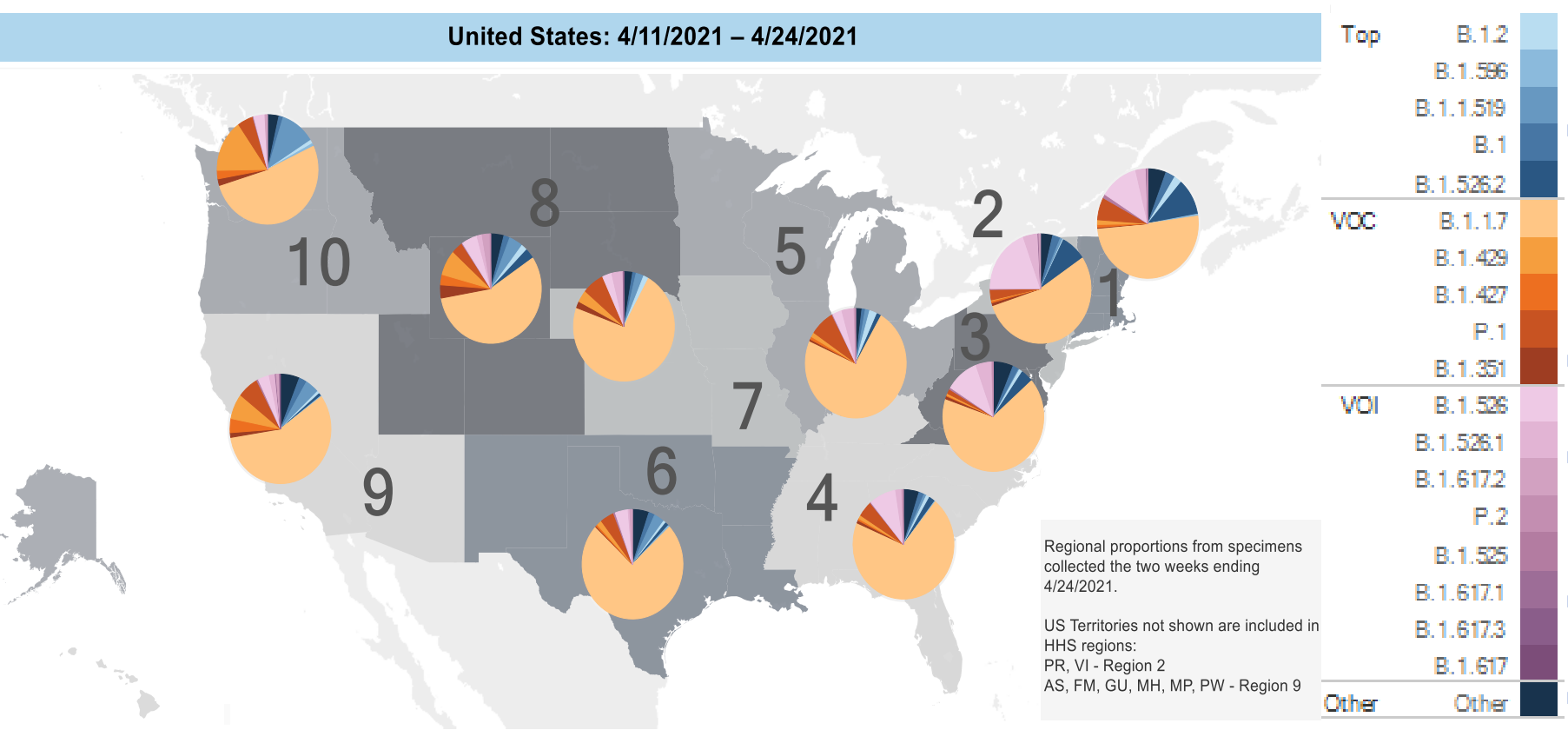
[Variant Proportions in the U.S. | CDC]

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

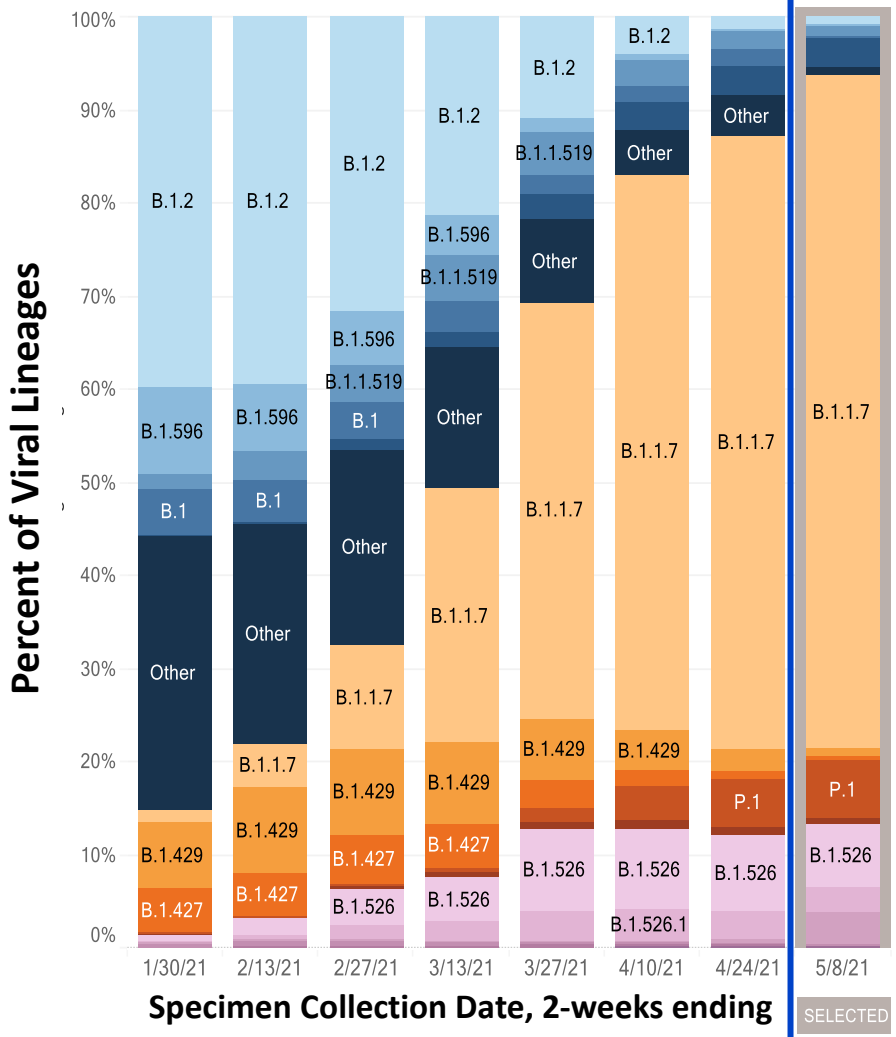
Two weeks ending April 24, 2021



- ↑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

Variant Proportions in the U.S. | CDC

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%
	B.1.526	VOI	6.8%	4.2-9.6%
	P.1	VOC	6.2%	3.7-9.1%
	B.1.617.2	VOI	3.3%	1.4-5.7%
	B.1.526.2		3.1%	1.4-5.1%
	B.1.526.1	VOI	2.8%	1.1-4.5%
	B.1.1.519		1.2%	0.3-2.3%
	B.1.2		0.7%	0.0-1.7%
	B.1		0.3%	0.0-1.1%
	B.1.596		0.1%	0.0-0.6%
Additional VOI/VOC lineages	B.1.429	VOC	0.9%	0.0-2.0%
	B.1.351	VOC	0.6%	0.0-1.4%
	B.1.427	VOC	0.4%	0.0-1.1%
	B.1.525	VOI	0.2%	0.0-0.8%
	B.1.617.1	VOI	0.2%	0.0-0.6%
	P.2	VOI	0.0%	0.0-0.3%
	B.1.617.3	VOI	0.0%	0.0-0.3%
Other*	Other		0.8%	0.0-4.0%

* Other represents >200 additional lineages, which are each circulating at <1% of viruses

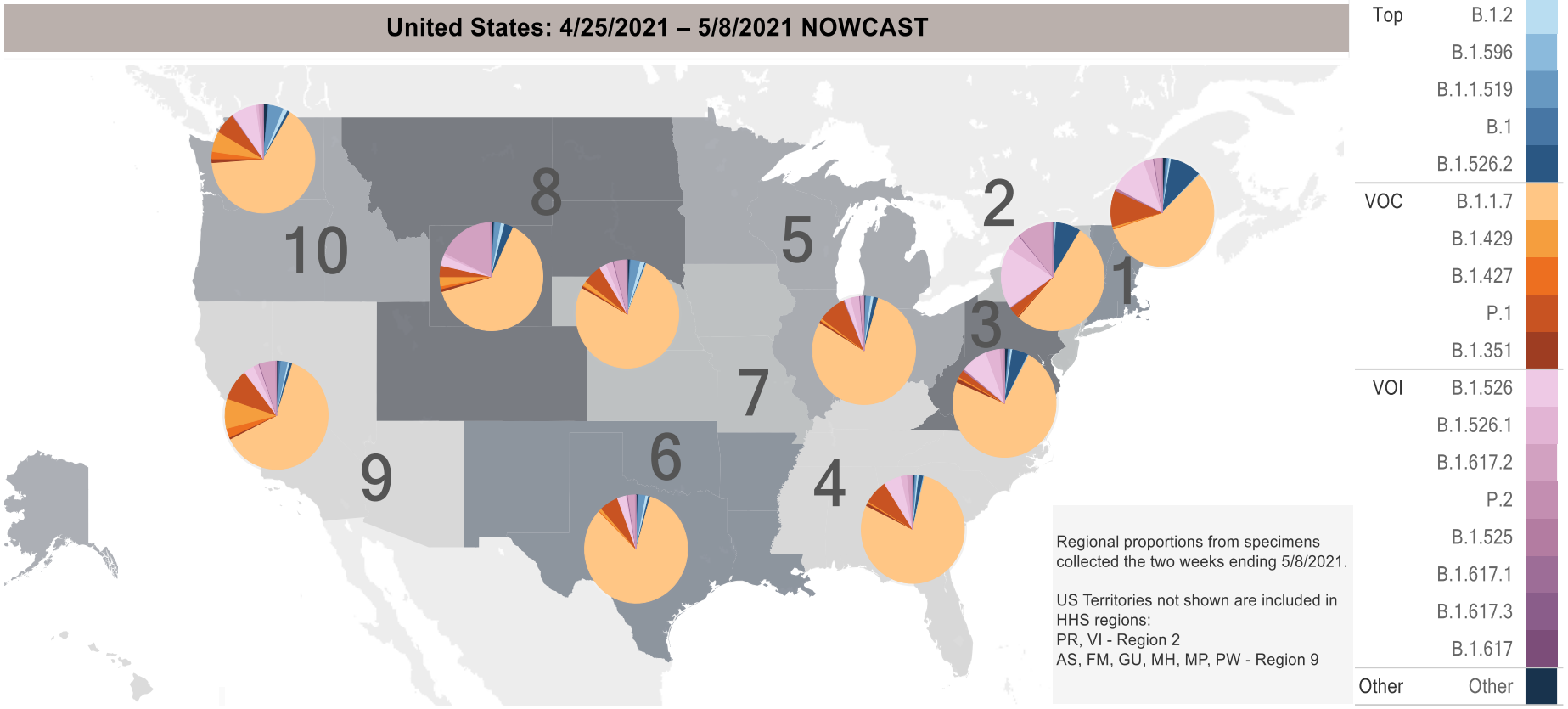
** These data include Nowcast estimates, which are modeled projections that may differ from weighted estimates generated at later dates

[Variant Proportions in the U.S. | CDC]

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%

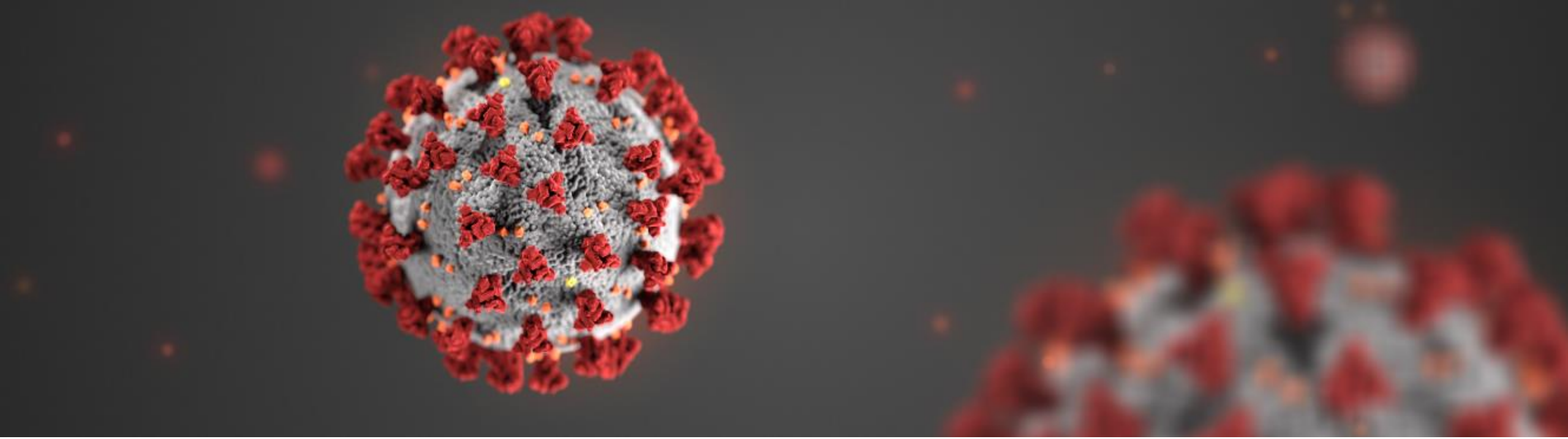
Regional Nowcast Estimates of SARS-CoV-2 Variants



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

Variant Proportions in the U.S. | CDC



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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

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

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. 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/

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

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Thank You For Your Time!

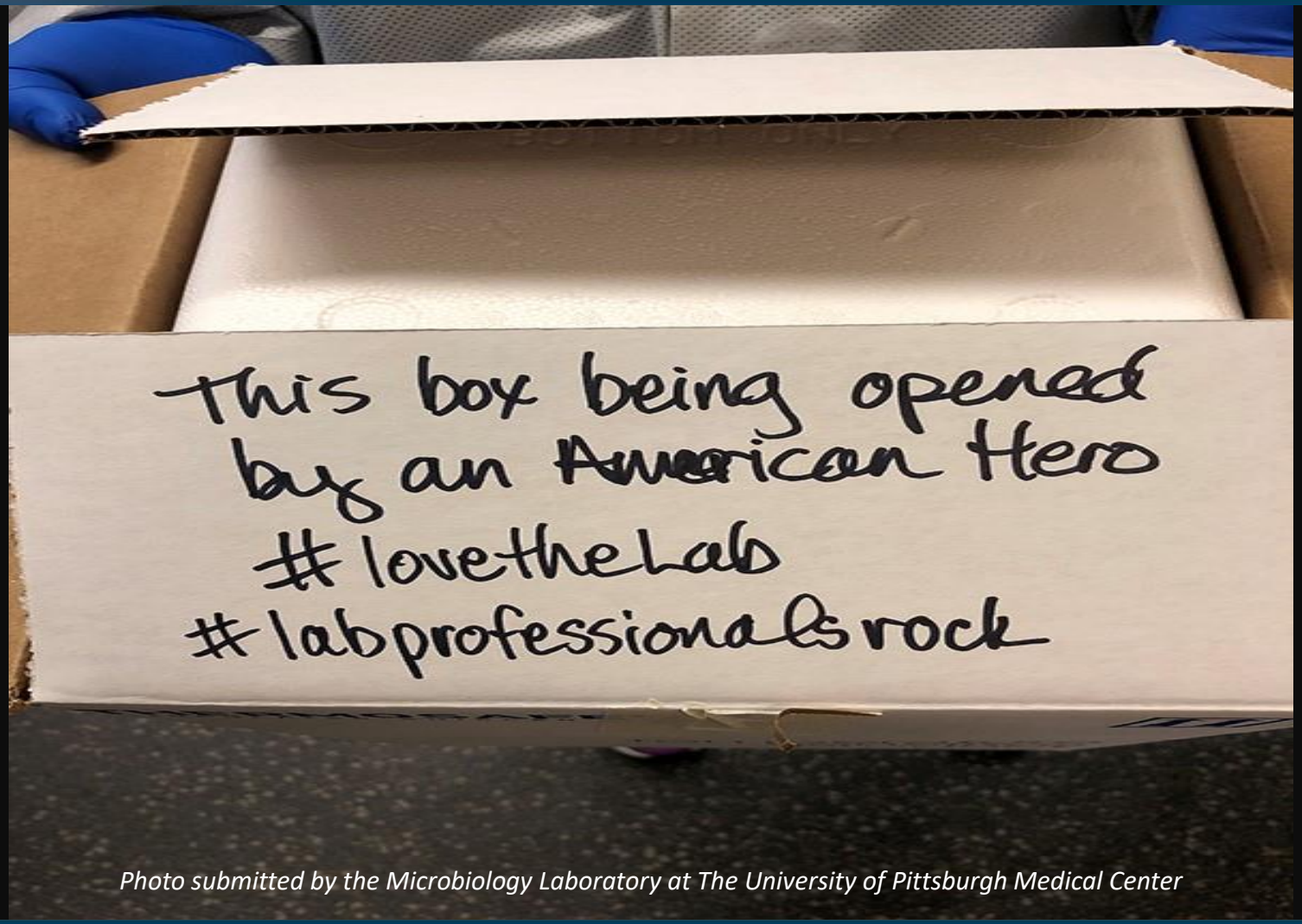

Photo submitted by the Microbiology Laboratory at The University of Pittsburgh Medical Center