

# Clinical Laboratory COVID-19 Response Call

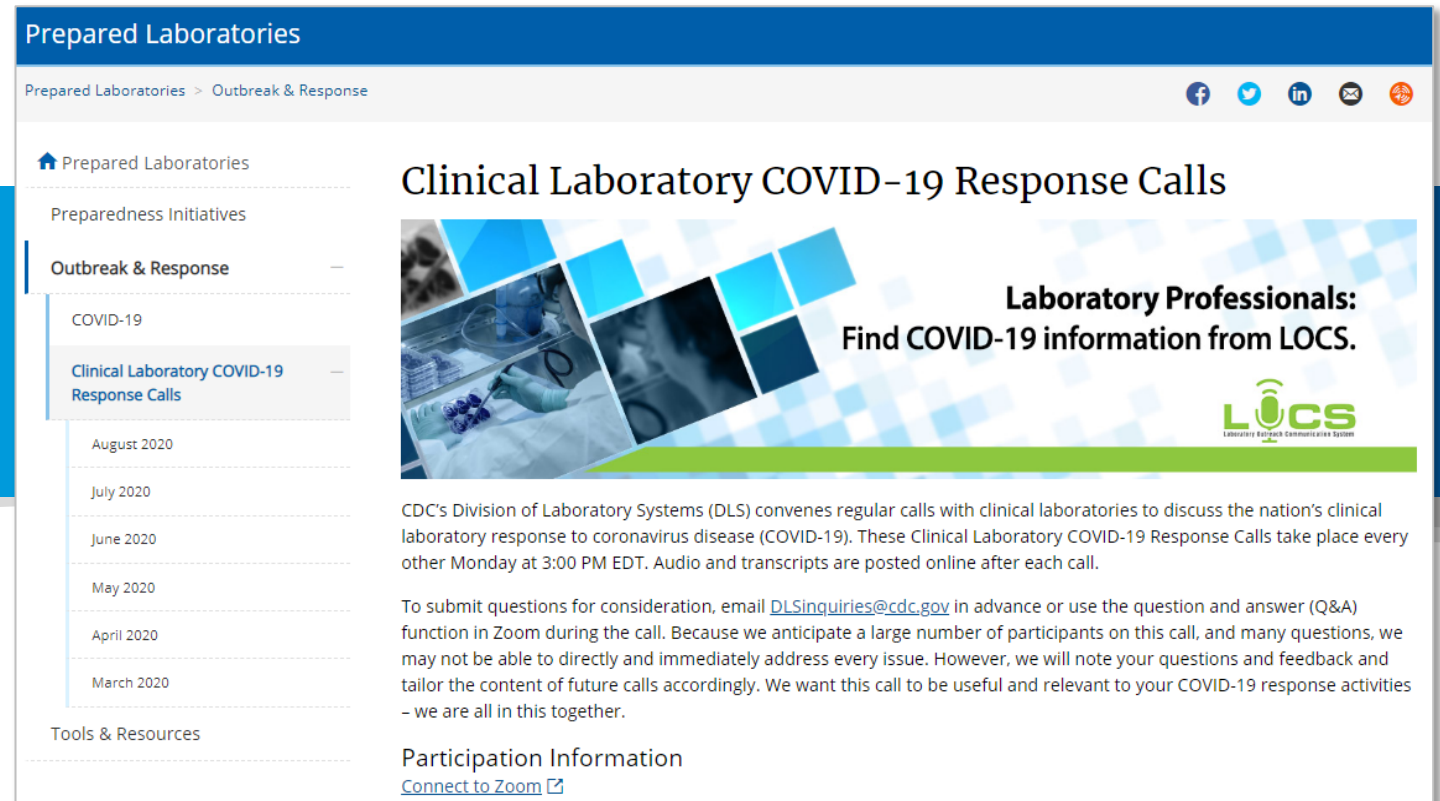
Monday, June 14, 2021, at 3:00 PM EDT

- **Welcome**
  - Jasmine Chaitram, CDC Division of Laboratory Systems (DLS)
- **SARS-CoV-2 Variants Update**
  - Steve Oberste, CDC Laboratory and Testing Task Force for the COVID-19 Response
- **National Wastewater Surveillance System**
  - Amy Kirby, CDC Division of Foodborne, Waterborne, and Environmental Diseases (DFWED)
- **Sodium Citrate Tubes Supply Shortage**
  - Tammy Beckham and Linda Ricci, U.S. Food and Drug Administration (FDA)
- **FDA Update**
  - Tim Stenzel, U.S. Food and Drug Administration (FDA)
- **COVID-19 Viral Testing Tool Update**
  - Muktha Natrajan, CDC Division of Laboratory Systems (DLS)

# 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 the heading is a banner image showing laboratory equipment and a person wearing a mask. To the right of the banner is the text 'Laboratory Professionals: Find COVID-19 information from LOCS.' and the LOCS logo. Below the banner 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 also provides instructions on how to submit questions for consideration via email or Zoom. At the bottom, there is a 'Participation Information' section with a 'Connect to Zoom' link.

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](mailto: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

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The next call will be on **Monday, June 28** from  
**3:00 PM to 4:00 PM EDT**

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# We Want to Hear from You!

## Training and Workforce Development

Questions about education and training?

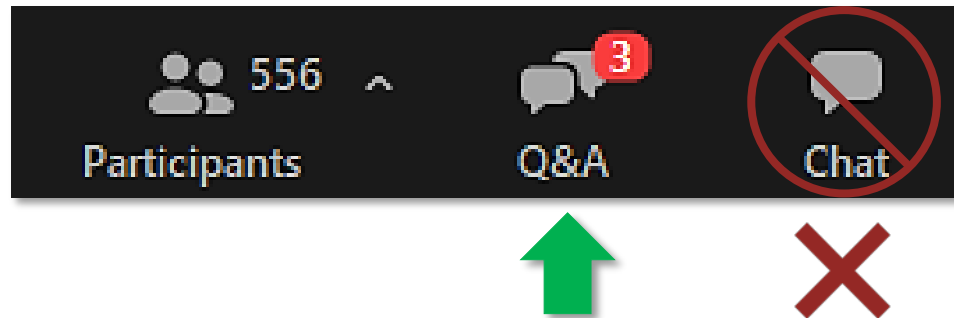
Contact [LabTrainingNeeds@cdc.gov](mailto:LabTrainingNeeds@cdc.gov)




# 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](mailto: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.*

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

Steve Oberste, PhD

Surveillance and Emerging Variants Team

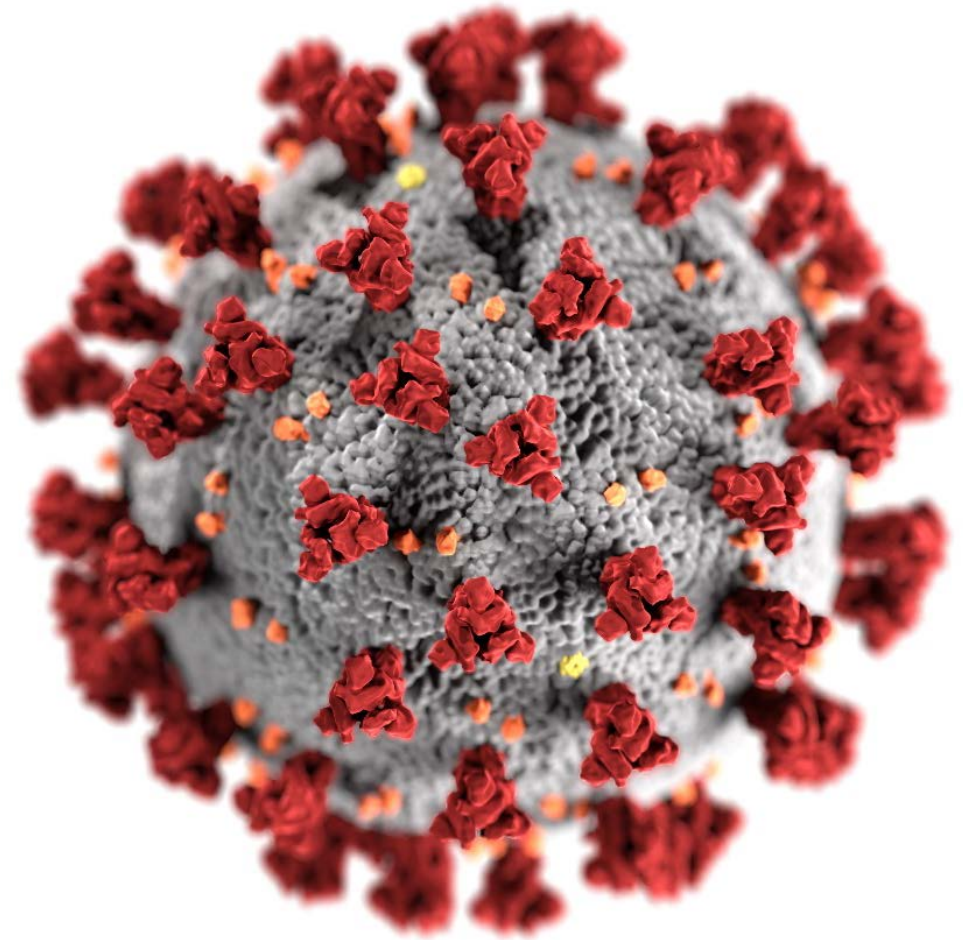
Laboratory and Testing Task Force

CDC COVID-19 Emergency Response

Senior Advisor for Laboratories,

Division of Viral Diseases, NCIRD

June 14, 2021



[cdc.gov/coronavirus](https://cdc.gov/coronavirus)

# SARS-CoV-2 Genomic Surveillance

- As expected, multiple variants of SARS-CoV-2 have been documented in the US and globally throughout the pandemic
  - Variants may have altered biological properties
    - Transmissibility, disease severity
    - Potential impact on critical SARS-CoV-2 countermeasures, including vaccines, therapeutics, and diagnostics
- National SARS-CoV-2 Strain Surveillance (NS3)
  - Sequencing at CDC of specimens received from state, local, and territorial public health laboratories
  - Contracts with large commercial diagnostic labs and academic partners
  - Support for health departments to improve sequencing capacity



# SARS-CoV-2 Variants

- Viral mutations and variants in the United States are routinely monitored through sequence-based surveillance, laboratory studies, and epidemiological investigations
- A US government interagency group (HHS/CDC, HHS/NIH, HHS/FDA, HHS/BARDA, DoD) developed a Variant Classification scheme that defines three classes of SARS-CoV-2 variants
  - Variant of Interest (VOI)
  - Variant of Concern (VOC)
  - Variant of High Consequence (VOHC)

# SARS-CoV-2 Variant Classification

- Variant of Interest (VOI)
  - Specific genetic markers that are predicted to affect transmission, diagnostics, therapeutics, or immune escape
  - Evidence that it is causing an increased proportion of cases or unique outbreak clusters
  - Limited prevalence or expansion in the US or in other countries
- Variant of Concern (VOC)
  - Evidence of impact on diagnostics, treatments, or vaccines
  - Evidence of increased transmissibility
  - Evidence of increased disease severity
- Variant of High Consequence (VOHC)
  - Impact on medical countermeasures (MCM)
  - Currently, no SARS-CoV-2 variants rise to the level of high consequence

# New WHO VOC and VOI Nomenclature

- Variants of Concern (VOC)

- Alpha B.1.1.7
- Beta B.1.351
- Gamma P.1
- Delta B.1.617.2

- Variants of Interest (VOI)

- Epsilon B.1.427/B.1.429
- Zeta P.2
- Eta B.1.525
- Theta P.3
- Iota B.1.526
- Kappa B.1.617.1

- The new nomenclature is intended to be easy-to-pronounce and non-stigmatizing, for communication with the public and media
- Pangolin lineages (and other naming conventions) will continue to be used in technical communications
- CDC has added the new names to our VOC and VOI tables, footnotes in other public webpages

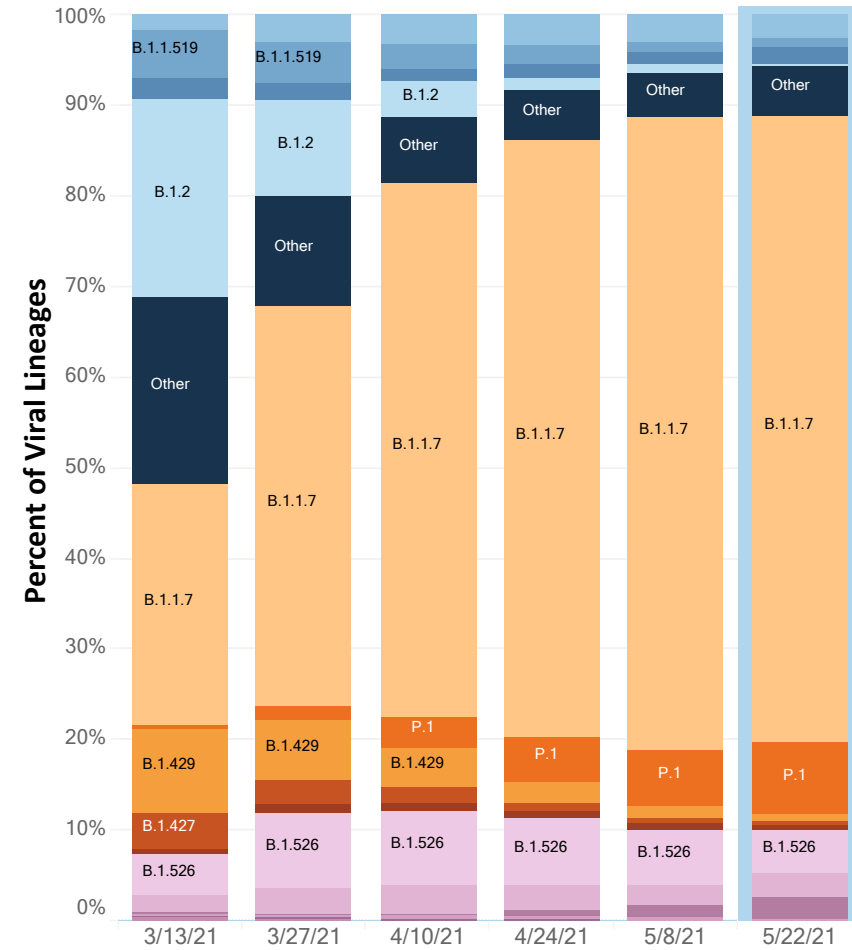
# Estimation of SARS-CoV-2 Variant Proportions

- Sequences from specimens collected in a 2-week period are used to estimate national and regional proportions for that period
- Estimates of weighted variant proportions are adjusted to correct for the potential non-random sampling of sequencing data over time and across states to provide more representative national and regional estimates
- Nowcast estimates use a multinomial regression model of weighted sequencing data to estimate variant proportions and prediction intervals
- Proportion data are updated on the CDC COVID Data Tracker every Tuesday, <https://covid.cdc.gov/covid-data-tracker/#variant-proportions>

# National Prevalence of SARS-CoV-2 Variants

U.S. 2/27/2021 – 05/22/2021

U.S. 5/9/2021 – 05/22/2021



	Lineage	Type	%Total	95%CI	
Most common lineages	B.1.1.7	VOC	69.2%	66.4-71.9%	<span style="color: orange;">■</span>
	P.1	VOC	8.1%	6.2-10.5%	<span style="color: orange;">■</span>
	B.1.526	VOI	4.7%	3.4-6.4%	<span style="color: pink;">■</span>
	B.1.526.2		2.7%	2.1-3.4%	<span style="color: lightblue;">■</span>
	B.1.526.1	VOI	2.5%	1.9-3.4%	<span style="color: pink;">■</span>
	B.1.617.2	VOI	2.5%	1.9-3.4%	<span style="color: purple;">■</span>
	B.1		1.8%	1.4-2.3%	<span style="color: darkblue;">■</span>
	B.1.1.519		0.9%	0.5-1.4%	<span style="color: darkblue;">■</span>
Additional VOI/VOC lineages	B.1.2		0.1%	0.1-0.2%	<span style="color: lightblue;">■</span>
	B.1.429	VOC	0.7%	0.4-1.1%	<span style="color: orange;">■</span>
	B.1.351	VOC	0.6%	0.4-0.9%	<span style="color: brown;">■</span>
	B.1.427	VOC	0.4%	0.2-0.8%	<span style="color: orange;">■</span>
	B.1.525	VOI	0.1%	0.1-0.3%	<span style="color: pink;">■</span>
	B.1.617.1	VOI	0.1%	0.0-0.2%	<span style="color: purple;">■</span>
	B.1.617	† VOI	0.0%	NA	<span style="color: purple;">■</span>
	B.1.617.3	† VOI	0.0%	NA	<span style="color: purple;">■</span>
Other*	P.2	† VOI	0.0%	NA	<span style="color: purple;">■</span>
	Other		5.6%	4.7-6.7%	<span style="color: darkblue;">■</span>

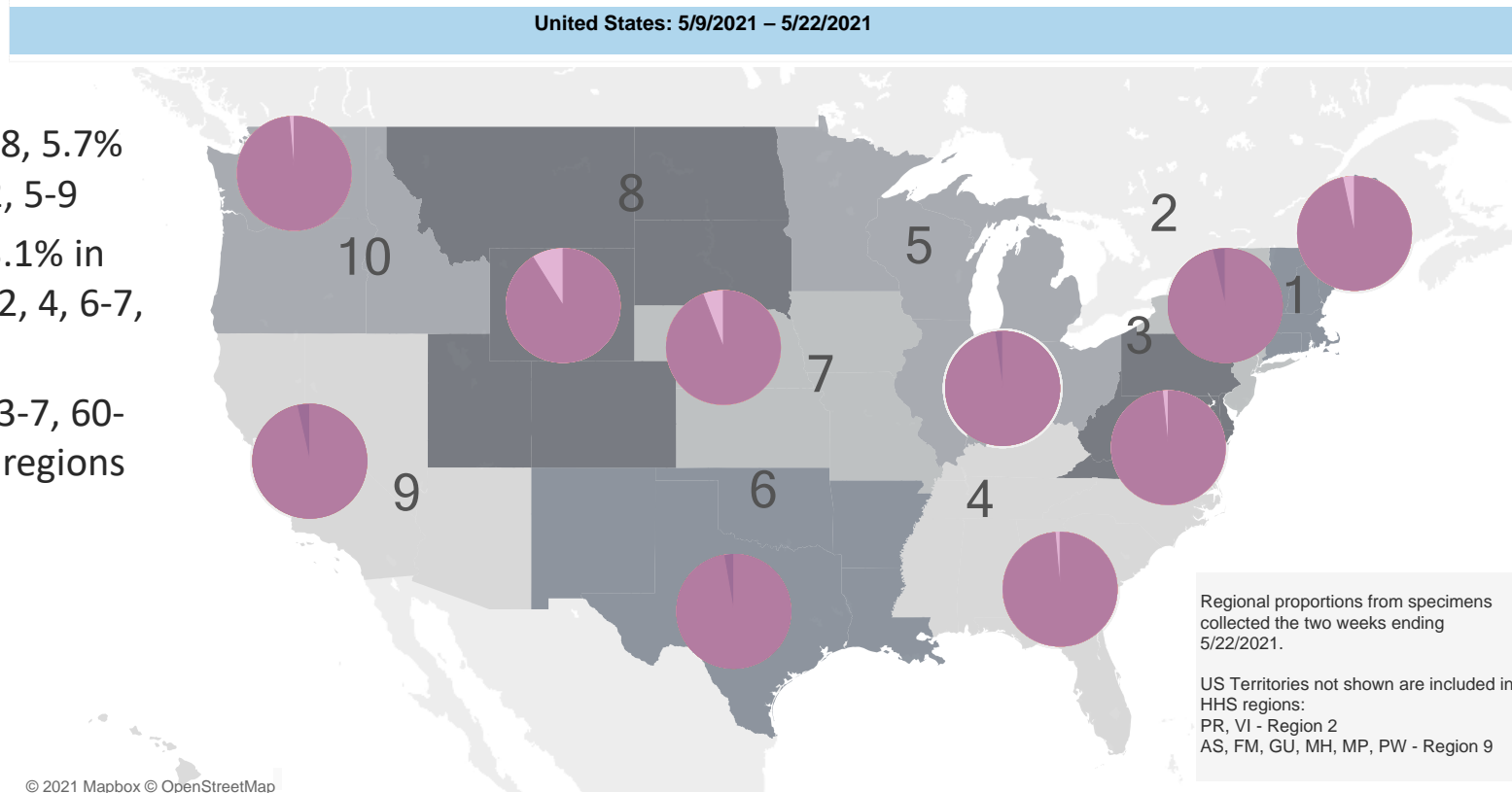
\* "Other" represents >200 additional lineages, which are each circulating at <1% of total viruses  
 † Fewer than 10 observations of this variant during the selected time/location context

- Weighted proportions for most lineages declined slightly or remained steady
- Exceptions:
  - P.1 increased from 6.9% to 8.1%
  - B.1.617.2 increased from 1.3% to 2.5%
- Proportions for all VOI and VOC were within Nowcast prediction intervals

**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



- **B.1.617.2 VOI:** 8.8% in region 8, 5.7% in region 7,  $\geq 2\%$  in regions 1-2, 5-9
- **P.1 VOC:** 11.1% in region 5, 13.1% in region 10, 5-10% in regions 1-2, 4, 6-7, 9
- **B.1.1.7 VOC:**  $>70\%$  in regions 3-7, 60-70% in regions 8-9, 50-60% in regions 1-2, 10

© 2021 Mapbox © OpenStreetMap

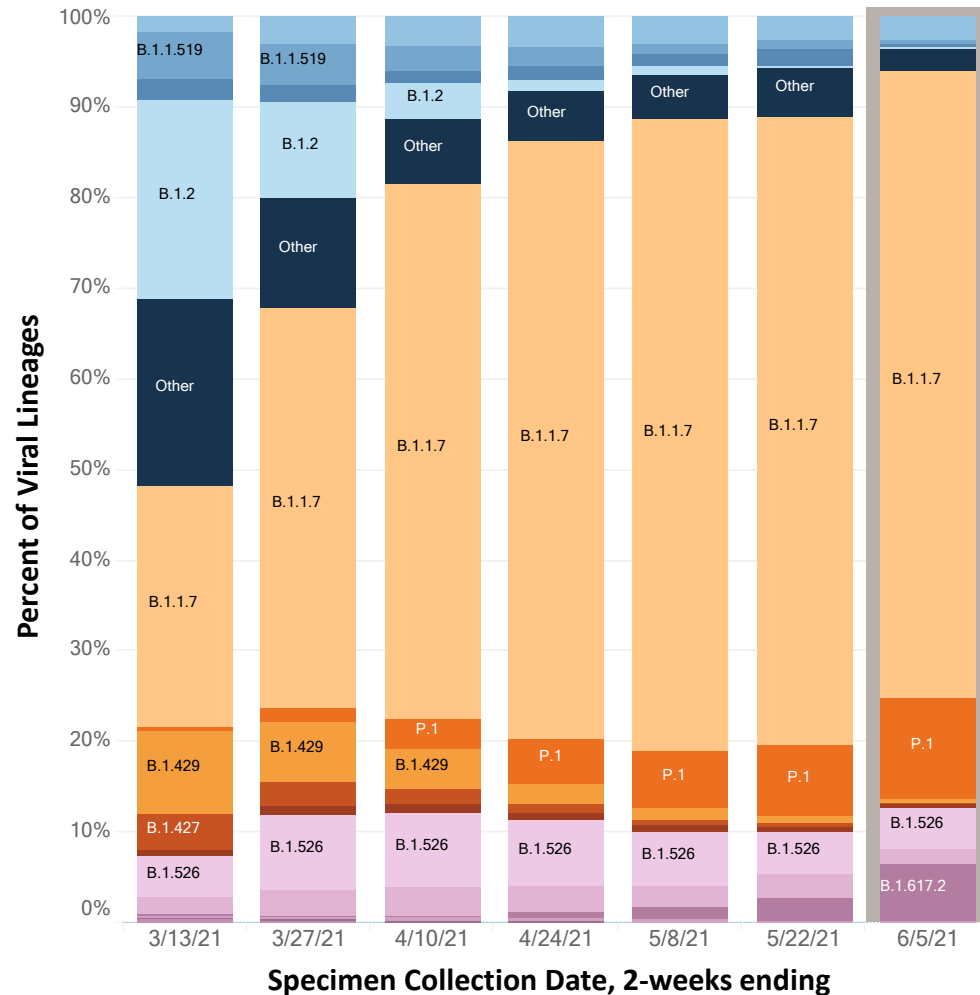
# National Nowcast Estimates SARS-CoV-2 Lineages

U.S. 2/27/2021 – 05/22/2021

NOWCAST U.S. 5/23/2021 – 6/5/2021

For the period ending 6/5/21, Nowcast national estimates predict:

- ↔ B.1.1.7 to remain at 69.2%
- ↑ P.1 to increase from 8.1% to 11.2%
- ↑ B.1.617.2 to increase from 2.5% to 6.1%
- Others to remain the same of decrease slightly



	Lineage	Type	%Total	95%PI	
Most common lineages	B.1.1.7	VOC	69.2%	64.0-74.2%	■
	P.1	VOC	11.2%	7.7-14.8%	■
	B.1.617.2	VOI	6.1%	3.7-8.9%	■
	B.1.526	VOI	4.6%	2.5-7.1%	■
	B.1.526.2		2.5%	0.9-4.3%	■
	B.1.526.1	VOI	1.8%	0.6-3.4%	■
	B.1.1.519		0.5%	0.0-1.2%	■
	B.1		0.3%	0.0-1.2%	■
Additional VOI/VOC lineages	B.1.2		0.1%	0.0-0.3%	■
	B.1.351	VOC	0.4%	0.0-1.2%	■
	B.1.429	VOC	0.3%	0.0-0.9%	■
	B.1.427	VOC	0.1%	0.0-0.6%	■
	B.1.525	VOI	0.1%	0.0-0.6%	■
	B.1.617.1	VOI	0.1%	0.0-0.6%	■
	P.2	VOI	0.0%	0.0-0.3%	■
Other*	Other		2.7%	0.6-5.8%	■

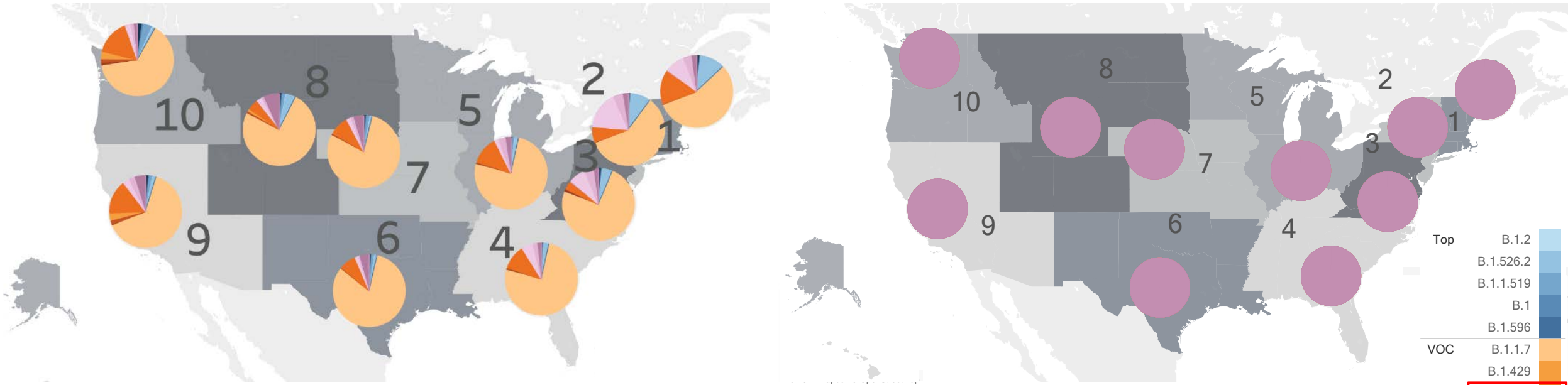
\* Other represents >200 additional lineages, which are each circulating at <1% of total viruses

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

# Regional Nowcast Prevalence of SARS-CoV-2 Variants

Nowcast 5/9/2021 – 5/22/2021

Nowcast 5/23/2021 – 6/5/2021



- P.1 proportion predicted to remain generally stable in most regions
  - Implications for efficacy of certain therapeutic mAb products
- B.1.617.2 proportion predicted to increase, particularly in Regions 6-9

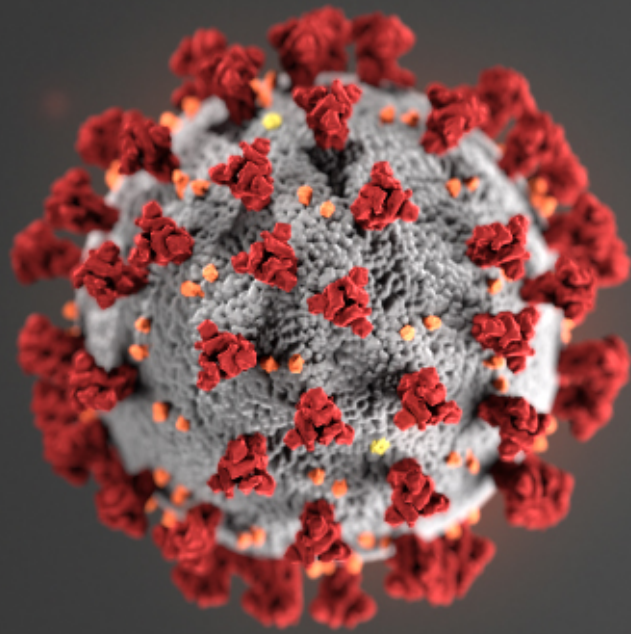


# Variant of Concern Proportions by State, as of June 8

- Each week, unweighted VOC proportions are updated for states that have submitted at least 300 sequences in a given 4-week period
- B.1.1.7 predominates nationwide
- B.1.351 proportions remain low
- B.1.427/B.1.429 have been declining but remain elevated in a few states, primarily in the west
- P.1 proportion is high in IL/IN, MA, and several western states

State	B.1.1.7	B.1.351	B.1.427 / B.1.429	P.1	Other lineages	Total Available Sequences
Arizona	66.3%	1.1%	7.2%	8.9%	16.5%	732
California	54.5%	1.1%	9.3%	10.1%	25.1%	5,792
Colorado	68.3%	0.5%	7.4%	4.6%	19.3%	2,429
Connecticut	54.6%	0.8%	0.9%	3.1%	40.5%	1,115
Florida	69.0%	0.4%	1.4%	9.8%	19.4%	9,255
Georgia	79.3%	1.4%	1.1%	4.4%	13.7%	1,398
Illinois	61.1%	1.0%	2.3%	22.4%	13.2%	3,854
Indiana	72.9%	0.7%	1.4%	10.8%	14.2%	1,682
Kentucky	76.4%		0.8%	4.5%	18.3%	382
Maine	37.5%	0.8%	1.9%	3.6%	56.2%	363
Maryland	72.8%	1.1%	0.4%	0.6%	25.0%	1,167
Massachusetts	51.6%	0.1%	1.2%	13.6%	33.5%	7,307
Michigan	81.3%	0.4%	1.1%	2.4%	14.9%	4,892
Minnesota	79.3%	1.0%	5.0%	2.0%	12.7%	7,780
Missouri	79.3%	1.2%	1.0%	6.0%	12.4%	483
Nevada	63.8%	2.1%	7.9%	3.3%	22.8%	329
New Hampshire	48.9%		2.9%	6.2%	42.1%	763
New Jersey	50.6%	0.2%	0.8%	3.2%	45.3%	2,925
New Mexico	68.9%	0.3%	3.6%	1.1%	26.2%	366
New York	53.8%	0.9%	1.2%	4.4%	39.7%	1,607
North Carolina	63.3%	1.2%	0.7%	2.4%	32.5%	2,243
Ohio	75.2%	0.7%	0.9%	5.6%	17.6%	1,095
Oregon	47.3%	3.3%	15.9%	9.4%	24.2%	736
Pennsylvania	64.6%	0.8%	0.9%	2.5%	31.2%	4,503
Puerto Rico	72.5%		2.3%	2.9%	22.3%	345
Rhode Island	44.7%		1.9%	9.5%	43.9%	1,269
Tennessee	85.3%	0.1%	1.0%	3.4%	10.2%	1,152
Texas	75.4%	0.3%	1.6%	5.7%	17.1%	4,021
Vermont	71.0%		2.2%	2.5%	24.3%	490
Virginia	74.2%	1.2%		2.8%	21.8%	899
Washington	59.6%	1.9%	13.9%	8.8%	15.8%	1,372
West Virginia	60.5%	0.1%	0.6%	0.2%	38.5%	821
Wisconsin	65.5%	0.1%	4.4%	6.2%	23.8%	844

Variant proportions are based on representative CDC sequence data (NS3 + CDC-funded contract sequencing) coll..



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



# National Wastewater Surveillance System

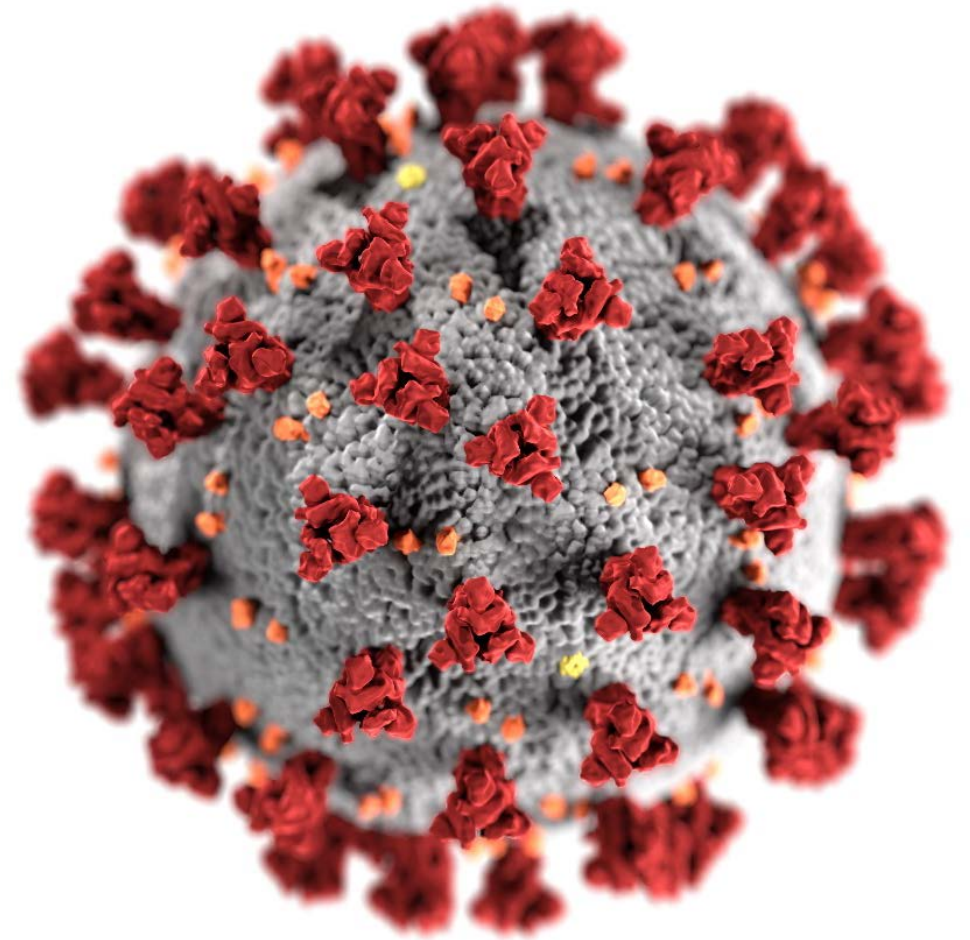
## Implementation Update

Amy E. Kirby, PhD MPH  
NWSS@cdc.gov

CLCR Call  
June 14, 2021



NATIONAL™  
WASTEWATER  
SURVEILLANCE  
SYSTEM



[cdc.gov/coronavirus](https://cdc.gov/coronavirus)

# Wastewater Surveillance | Public Health Toolbox

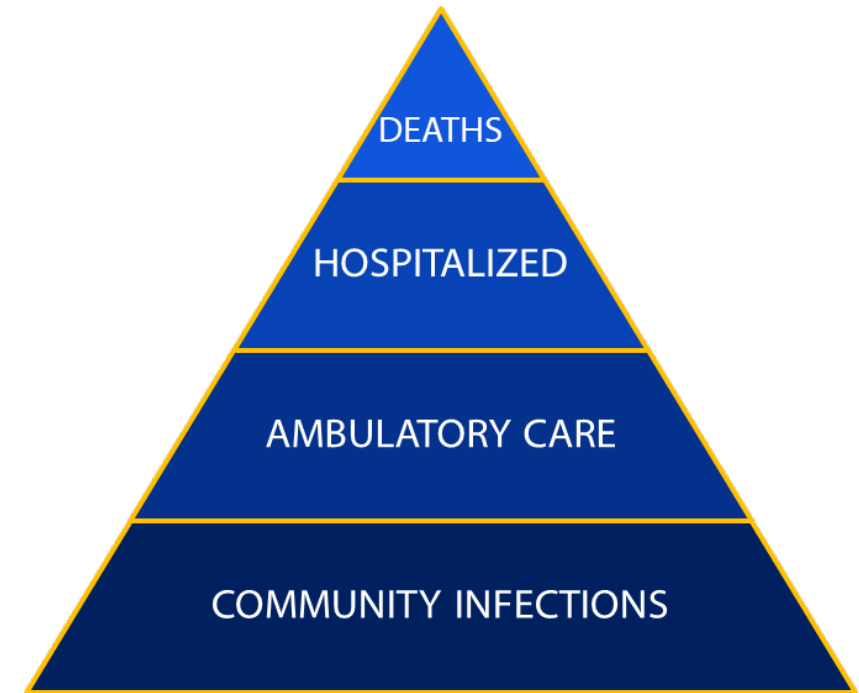
- Captures sub-clinical infections
- Independent of healthcare-seeking behavior and testing access
- Wastewater serves as an efficient pooled sample of community (or sub-community) infection levels
- Data available within days of viral shedding onset versus up to 2-week lag for other surveillance data



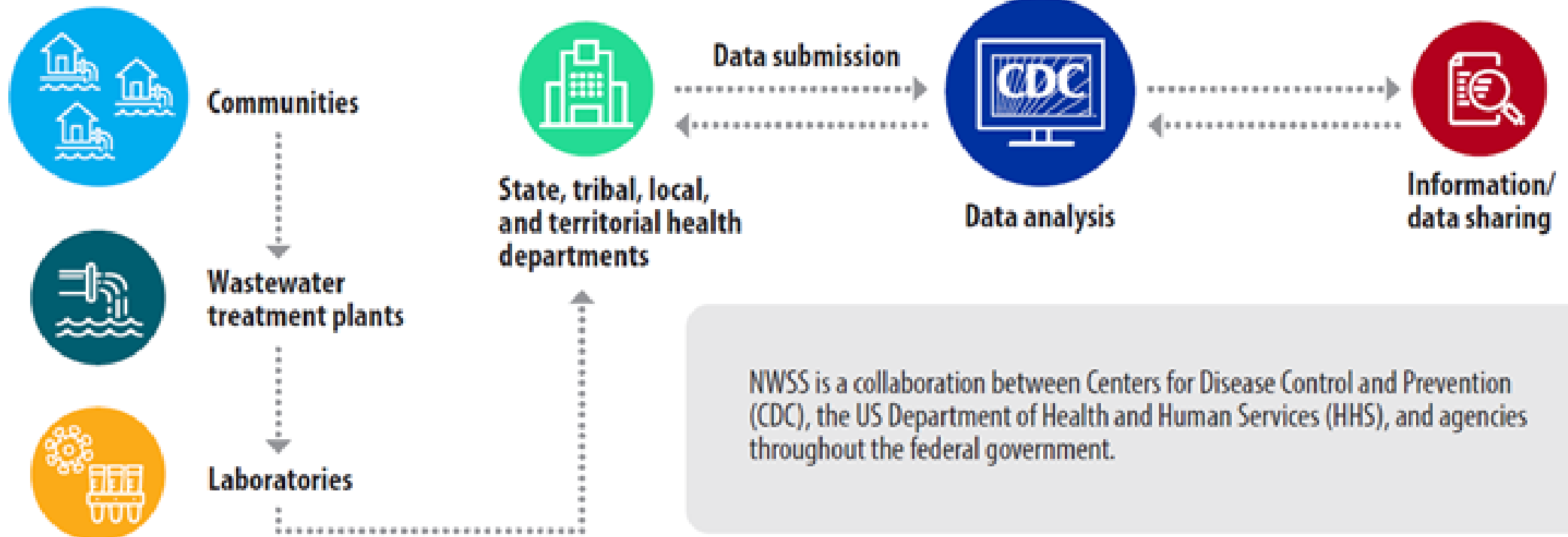
# Use of Wastewater Data in Response Decisions

Wastewater data can complement case- and symptom-based surveillance by providing-

- ✓ Independent confirmation of true increases or decreases in cases
- ✓ Infection data for communities where clinical testing data are not available
- ✓ Case or hospital utilization forecasting
- ✗ Wastewater should not be used to estimate point prevalence or case counts



# NATIONAL WASTEWATER SURVEILLANCE SYSTEM (NWSS)



NWSS is a collaboration between Centers for Disease Control and Prevention (CDC), the US Department of Health and Human Services (HHS), and agencies throughout the federal government.

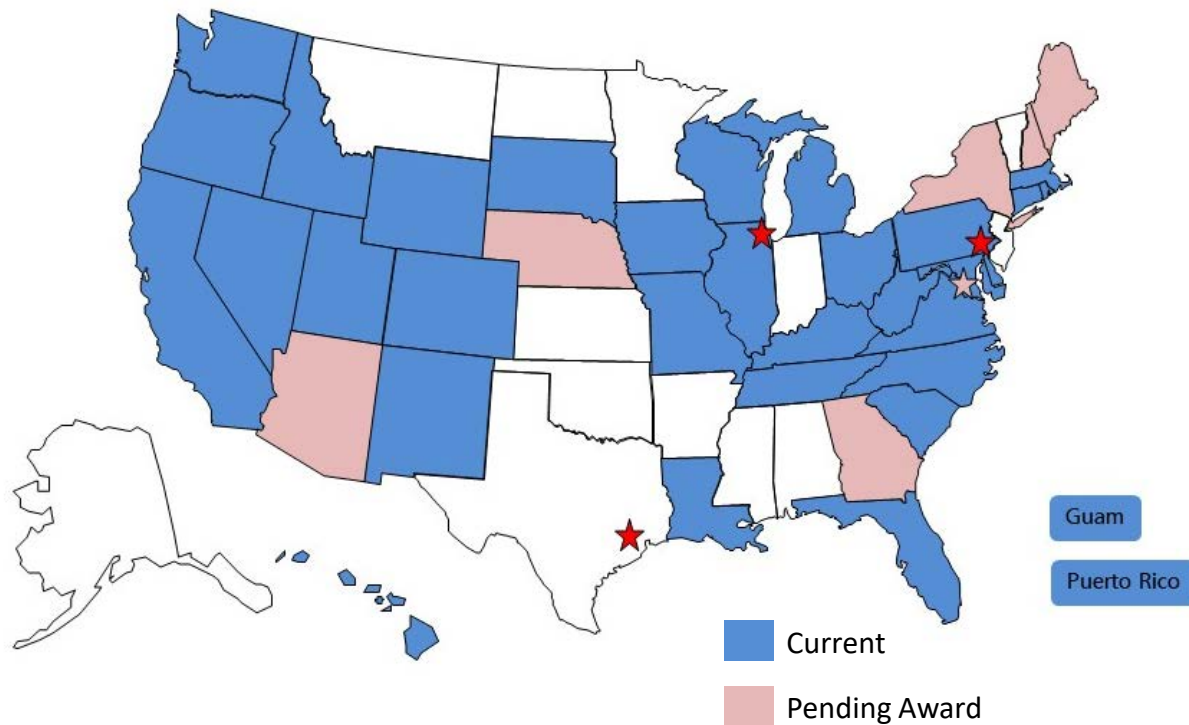


**U.S. Department of  
Health and Human Services**  
Centers for Disease  
Control and Prevention

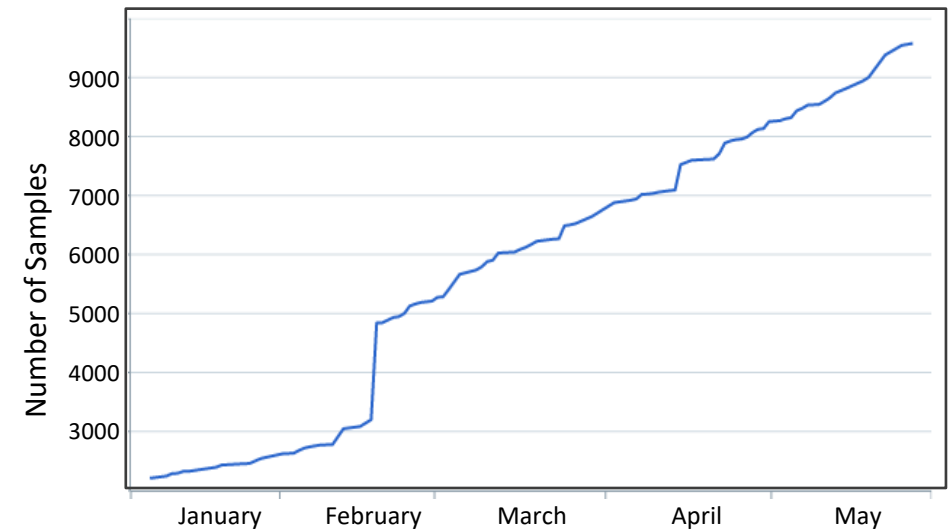
[cdc.gov/coronavirus](https://cdc.gov/coronavirus)

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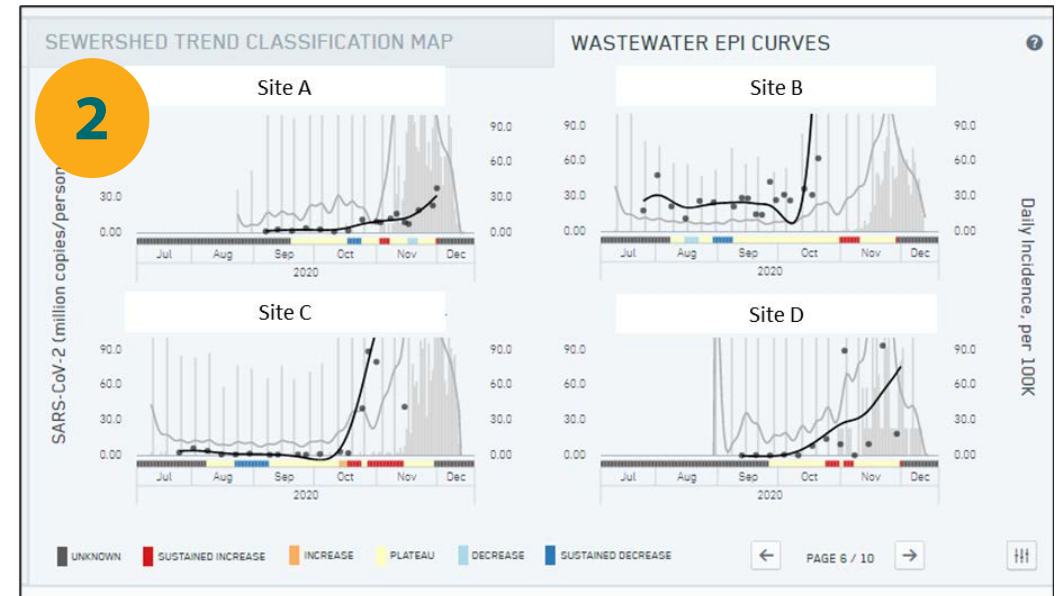
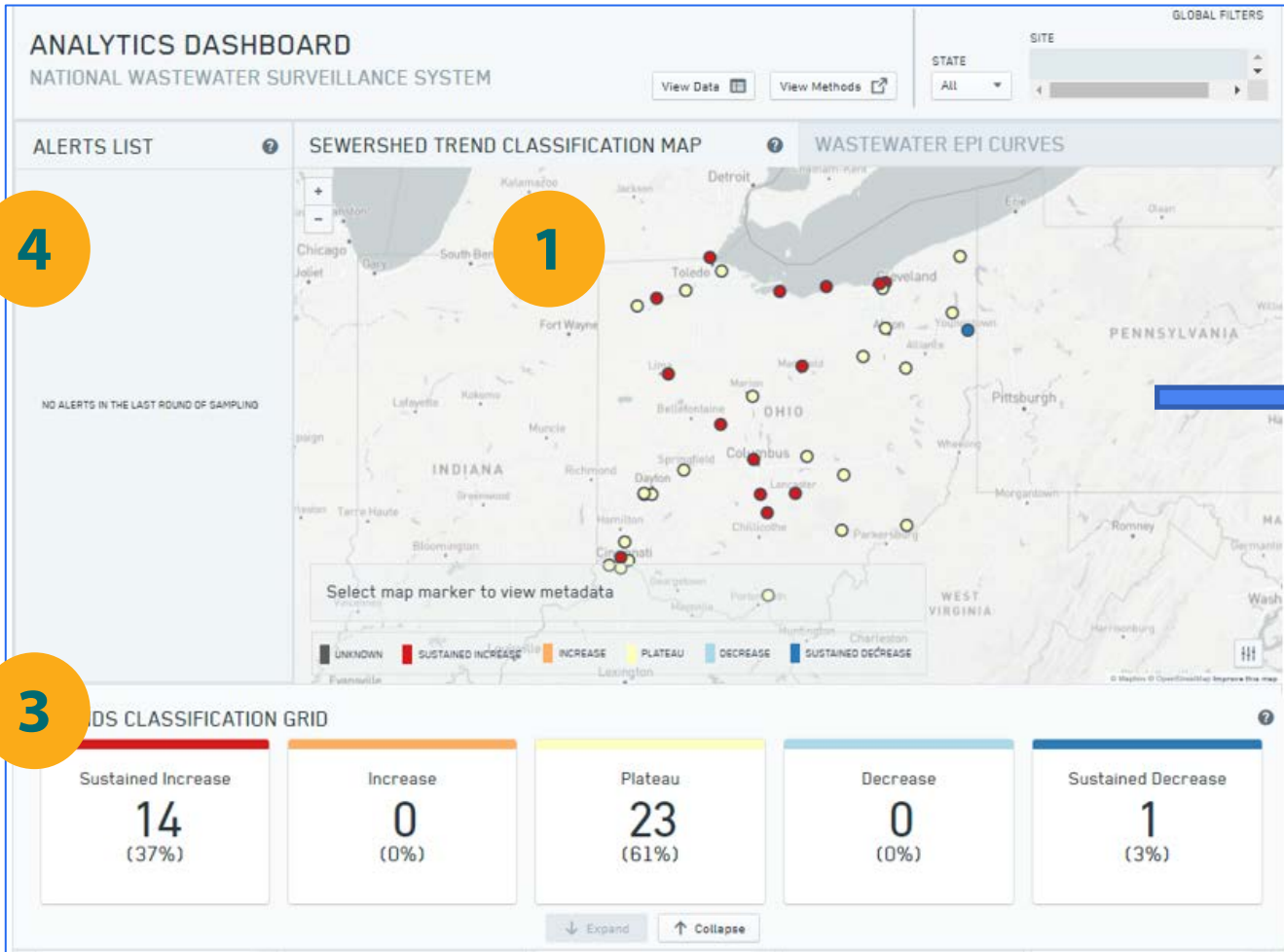
# Participation in NWSS is growing quickly



Cumulative Samples in DCIPHER Since January 2021



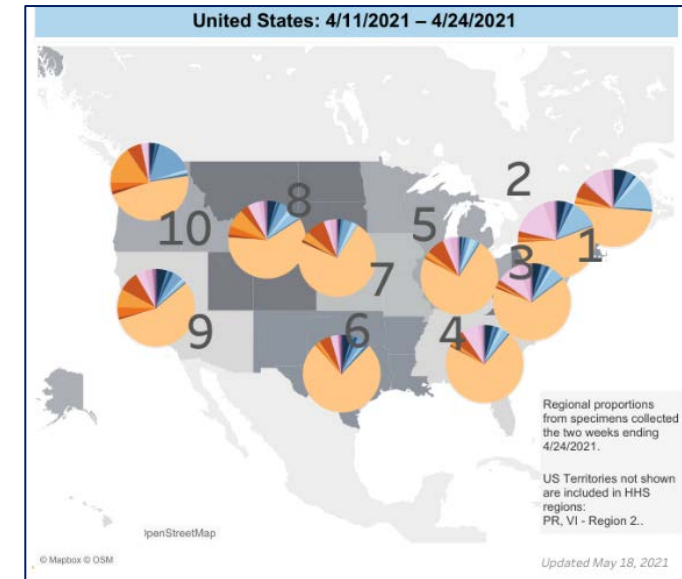
# NWSS DCIPHER Results Dashboard



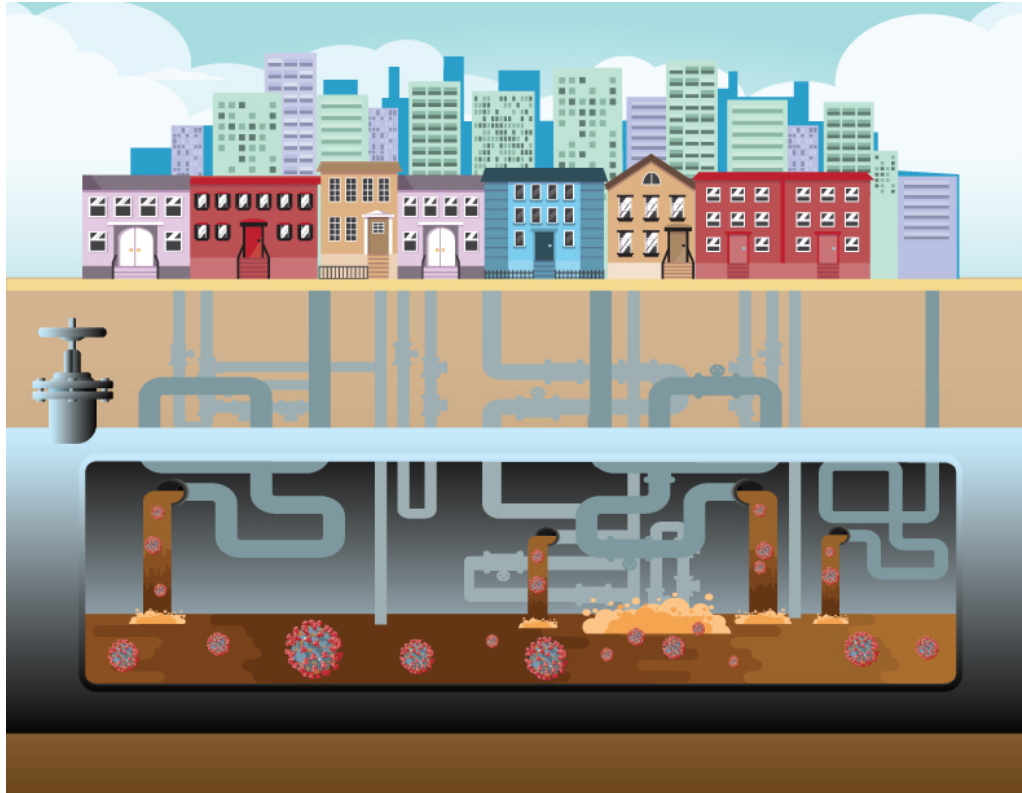


# SARS-CoV-2 Variant Tracking in Wastewater

- Interpretation is limited by
  - fragmented genomes present in wastewater
  - unknown method sensitivity
  - potential variation in shedding dynamics between variants
- Wastewater sequencing may be useful for variant **detection** and **tracking** but unlikely to be useful for variant discovery
- Pursuing multiple avenues (BAA, contracts, collaborations) to secure wastewater sequence data for evaluation
- Working with NCBI to establish database and preliminary analysis pipeline for wastewater SARS-CoV-2 sequence data



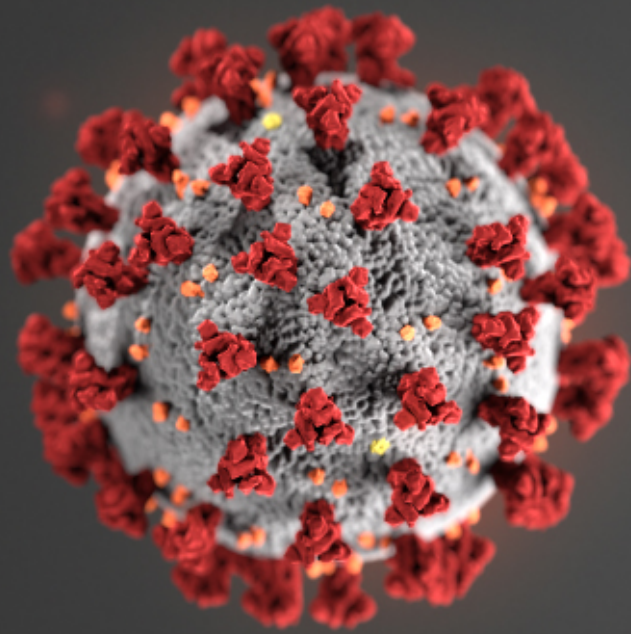
# NWSS | Beyond COVID



- **Flexible** surveillance platform for **multiple** health targets
- Nimble structure to **rapidly adapt** to changing public health needs

## Potential additional targets

- Antibiotic resistance
- Foodborne infections
- Emerging infections



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

NWSS Email: [NWSS@cdc.gov](mailto:NWSS@cdc.gov)

<https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/wastewater-surveillance.html>

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.



# Sodium Citrate Tubes Supply Shortage

**Tammy Beckham and Linda Ricci**  
U.S. Food and Drug Administration (FDA)



## 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](mailto: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>

# COVID-19 Viral Testing Tool Update

**Muktha Natrajan**

CDC Division of Laboratory Systems (DLS)



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



# CDC Social Media

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



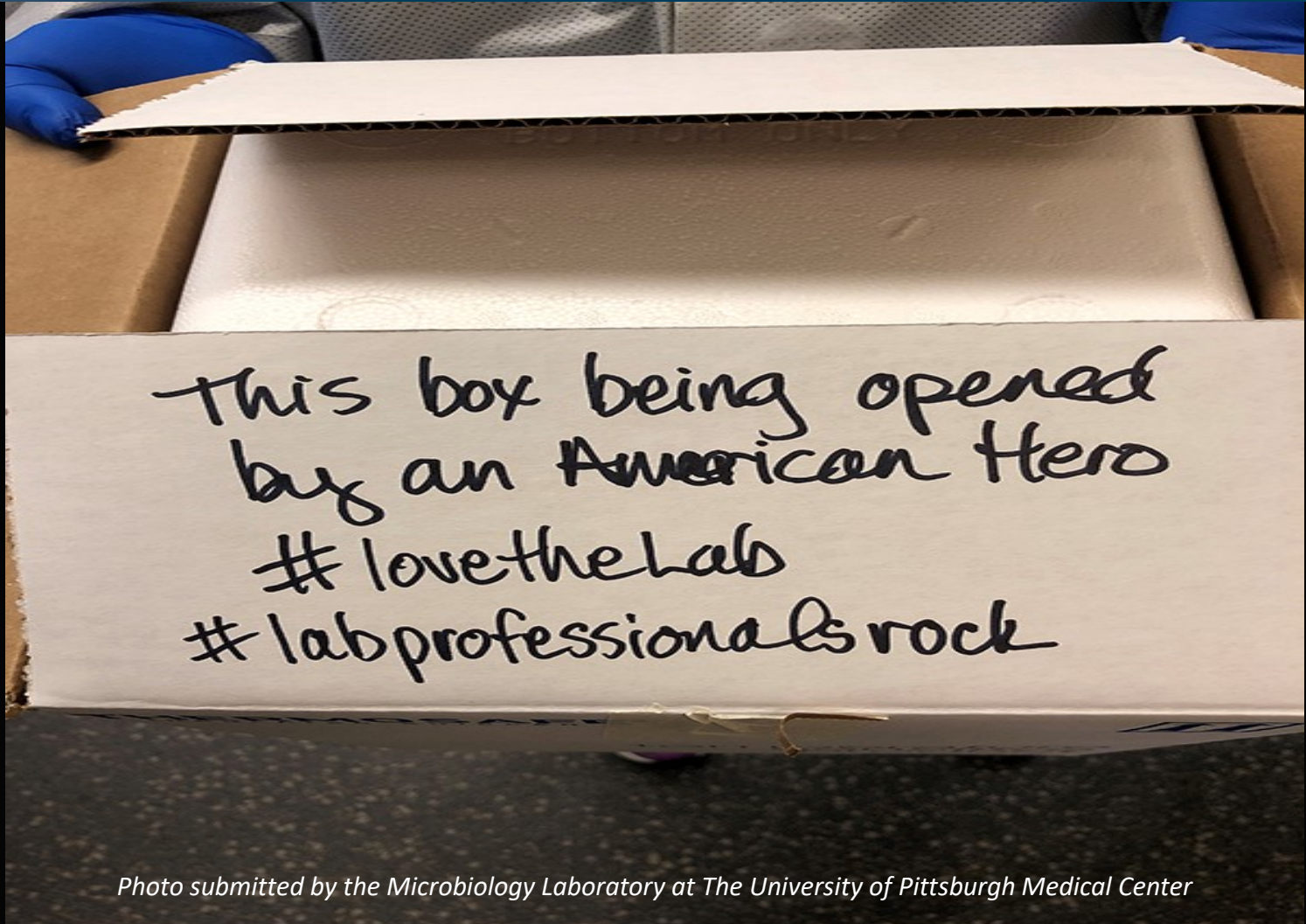
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*Photo submitted by the Microbiology Laboratory at The University of Pittsburgh Medical Center*