

# Clinical Laboratory COVID-19 Response Call

Monday, April 19, 2021 at 3:00 PM EDT

- **Welcome**
  - Jasmine Chaitram, Division of Laboratory Systems, CDC
- **Opening Remarks**
  - Dr. Rochelle Walensky, Director, CDC
- **SARS-CoV-2 Variants Update**
  - Dr. Vivien Dugan, CDC Laboratory and Testing Task Force for the COVID-19 Response
- **Expansion of U.S. Testing Capacity Using Coordination Hubs**
  - Dr. Ellen Kersh, Testing and Diagnostics Workgroup, U.S. Department of Health and Human Services (HHS)
  - Dr. Matthew Humbard, Testing and Diagnostics Workgroup, U.S. Department of Health and Human Services (HHS)

# New Guidance for Reporting SARS-CoV-2 Sequencing Results

<https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/reporting-sequencing-guidance.html>

- CDC recommends that if laboratories and facilities sequence SARS-CoV-2 positive specimens, they can electronically report these data to state, local, tribal, or territorial public health departments
- Laboratories should also check with health departments for reporting requirements

The screenshot shows the CDC COVID-19 website interface. At the top, there is a navigation bar with 'COVID-19' and several icons for public health measures: 'WEAR A MASK', 'STAY 6 FEET APART', 'AVOID CROWDS', and 'GET A VACCINE'. Below this is a secondary navigation bar with links for 'Your Health', 'Vaccines', 'Cases & Data', 'Work & School', 'Healthcare Workers', 'Health Depts', 'Science', and 'More'. The main content area is titled 'Guidance for Reporting SARS-CoV-2 Sequencing Results' and includes a 'Key Points' section with two bullet points. A yellow callout box contains a statement about the importance of understanding genetic diversity. At the bottom, there is an 'On This Page' section with links to related documents.

**COVID-19**

WEAR A MASK STAY 6 FEET APART AVOID CROWDS GET A VACCINE

Home Your Health Vaccines Cases & Data Work & School Healthcare Workers Health Depts Science More

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 Coronavirus (2019-nCoV) Real-time RT-PCR Primers and Probes

Calculating Percent Positivity

## Guidance for Reporting SARS-CoV-2 Sequencing Results

Updated Apr. 9, 2021 Print

### Key Points

- CDC requests laboratories that are sequencing SARS-CoV-2 positive specimens to report those data to state, local, tribal, or territorial public health departments.
- The technical guidance provides detailed instructions and examples for how to report SARS-CoV-2 sequencing results to state, local, tribal, or territorial public health departments.

It is critically important for the nation's COVID-19 pandemic response to understand the genetic diversity, spread, and evolution of SARS-CoV-2, including variant viruses.

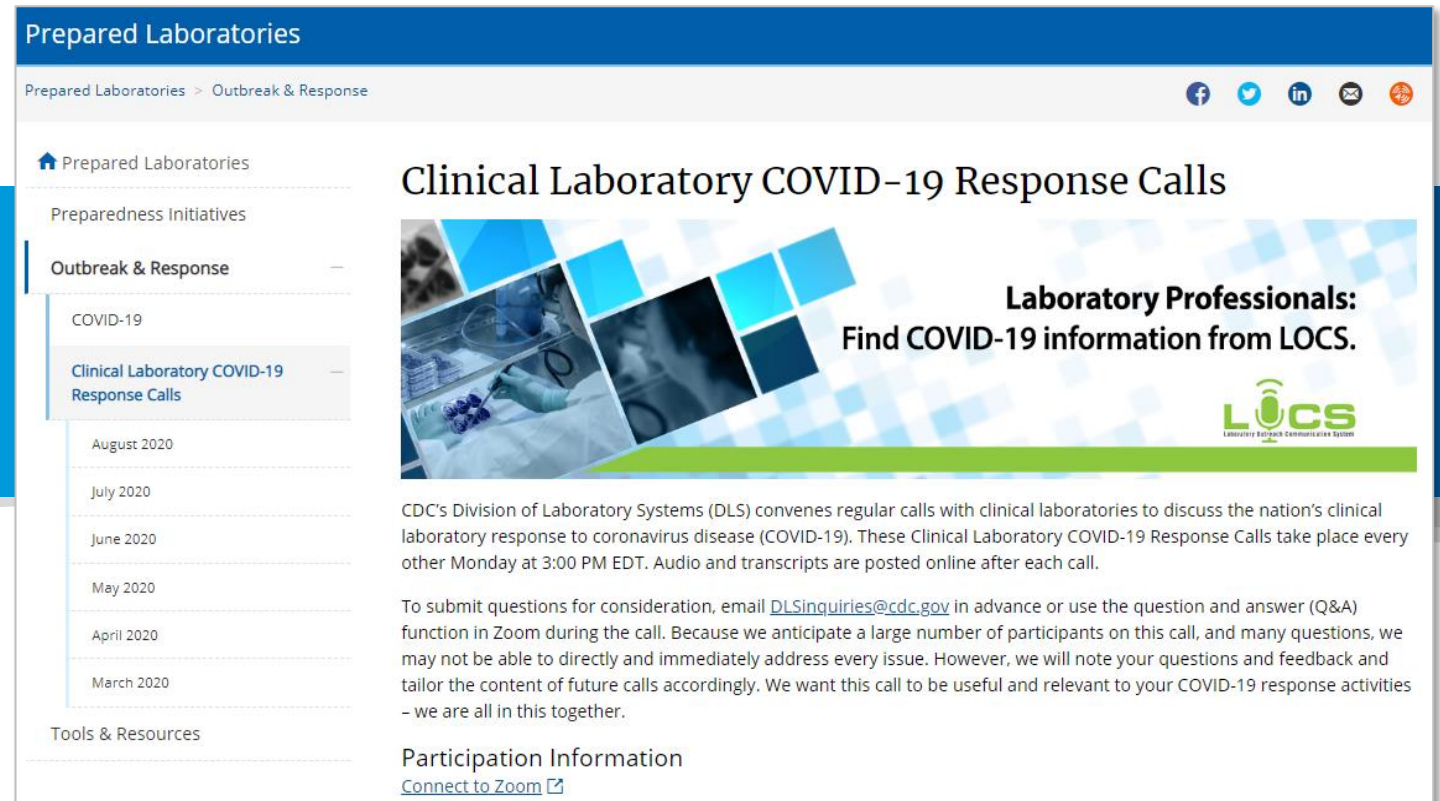
#### On This Page

- Regulatory Position on Reporting Sequencing Results to Public Health Departments
- Technical Guidance for Reporting Sequencing Results to Public Health Departments
- How to Report SARS-CoV-2 Sequencing Results to Public Health Departments
- Reporting Scenarios

# 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 sub-heading 'Laboratory Professionals: Find COVID-19 information from LOCS.' and the LOCS logo. The text describes the calls as regular meetings convened by CDC's Division of Laboratory Systems (DLS) to discuss clinical laboratory response to COVID-19. It provides contact information for submitting questions and details about the Q&A function in Zoom. A 'Participation Information' section includes a 'Connect to Zoom' link. On the left side of the page, there is a navigation menu with options for 'Preparedness Initiatives', 'Outbreak & Response', 'COVID-19', 'Clinical Laboratory COVID-19 Response Calls', and 'Tools & Resources'. A list of months from August 2020 to March 2020 is visible under the 'Clinical Laboratory COVID-19 Response Calls' section.

# Schedule for Clinical Laboratory COVID-19 Response Calls

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The next call will be on **Monday, May 3** 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?

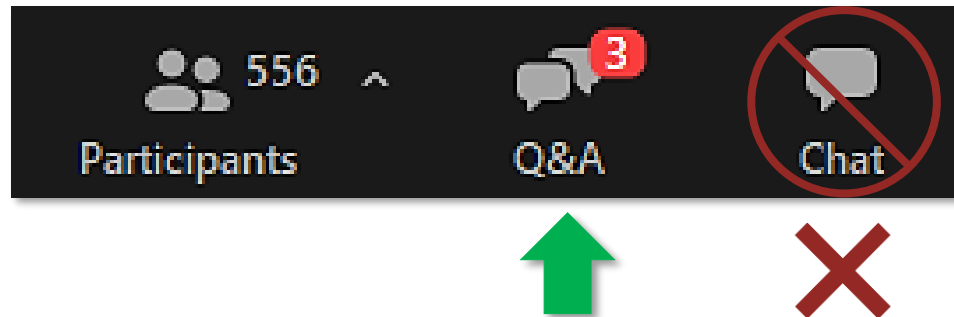
Contact [LabTrainingNeeds@cdc.gov](mailto:LabTrainingNeeds@cdc.gov)




# 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.*

# Opening Remarks

**Dr. Rochelle Walensky**  
Director, CDC



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



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

Vivien Dugan, Ph.D.

Lead, Surveillance and Emerging Variants Team

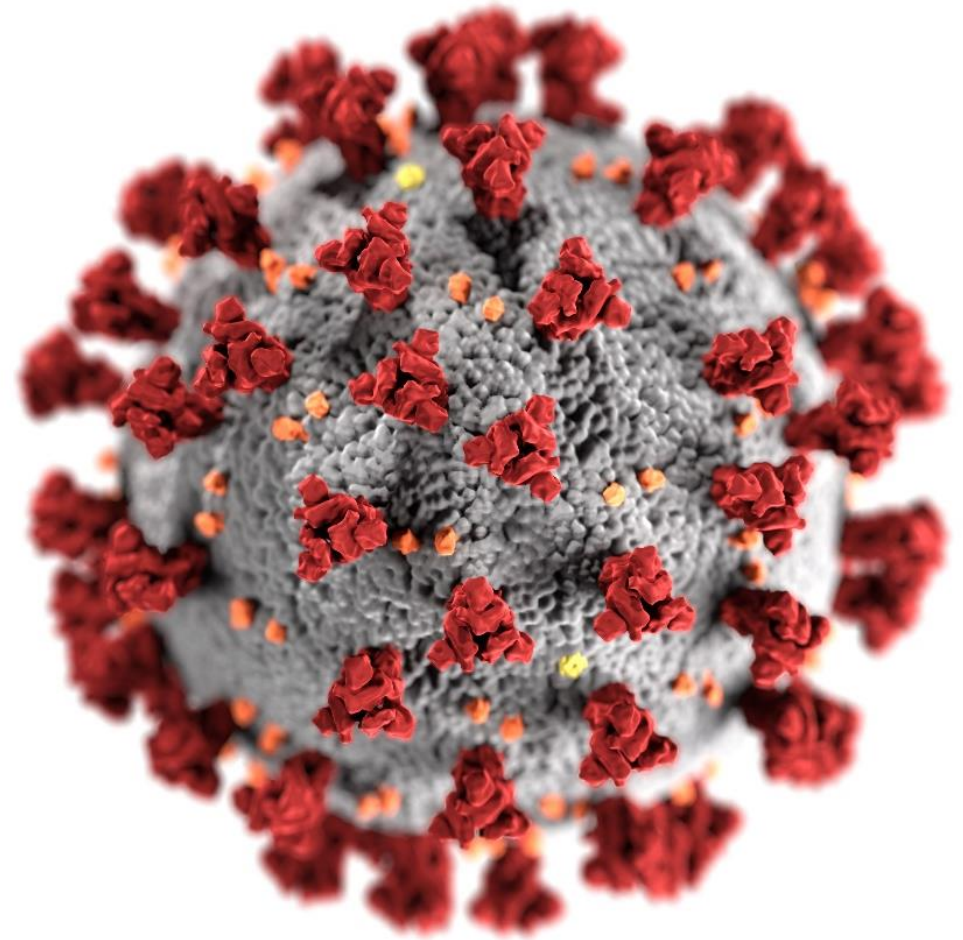
Laboratory and Testing Task Force

CDC COVID-19 Emergency Response

Deputy Director, Influenza Division

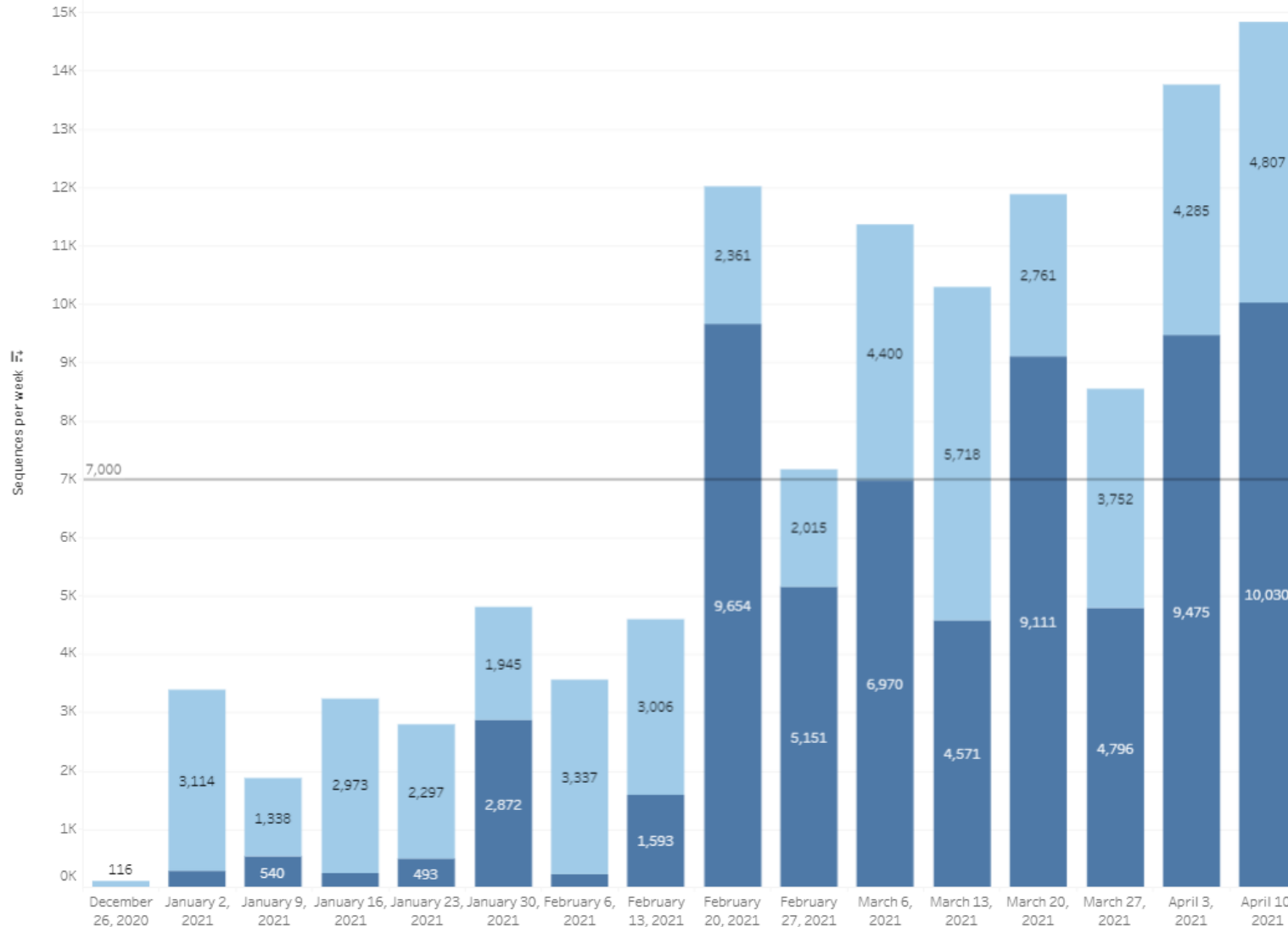
NCIRD, CDC

April 19, 2021



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

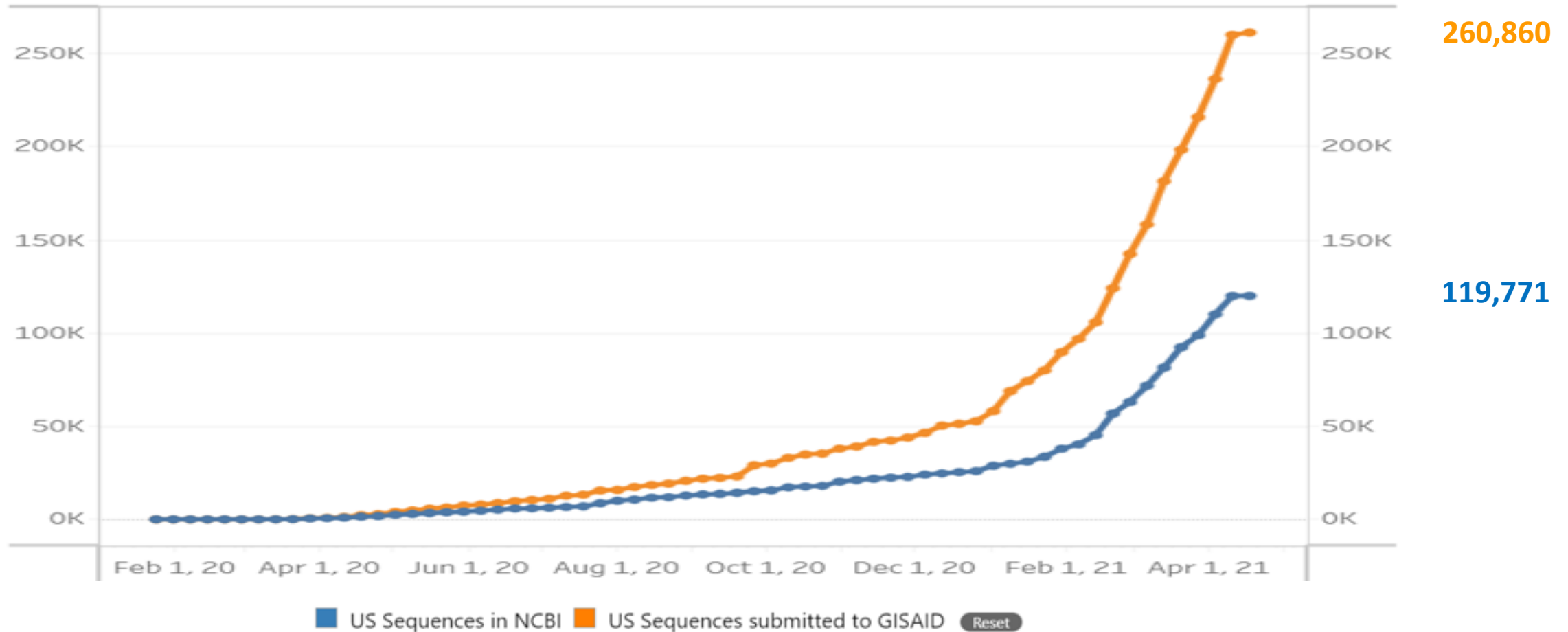
# Published SARS-CoV-2 Sequences



- Sequences published in NCBI and GISAID, deduplicated
- Includes data from CDC National SARS-CoV-2 surveillance, contracts and public health laboratories
- Data available to inform public health actions before being published
- Public Health Labs
  - 48,225 total sequences
  - 4,807 sequences last week
- CDC NS3 plus contract labs
  - 66,024 total sequences
  - 10,030 published last week

# U.S. Sequences Available in Public Repositories

As of April 11, 2021



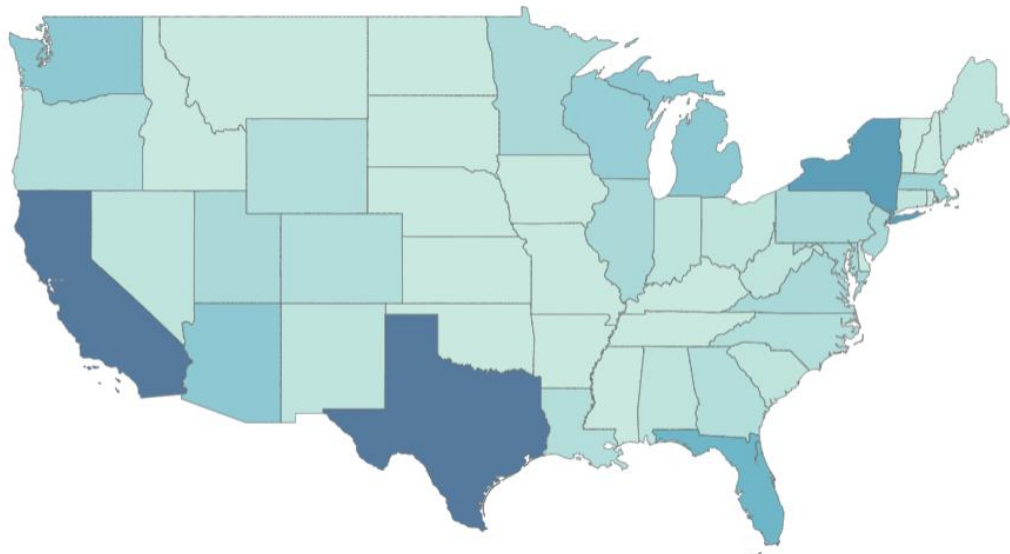
This line chart captures the cumulative number of published SARS-CoV-2 sequences by collection date from laboratories in states and territories across the US from January 2020 to the present. The blue line represents US sequences available in NCBI, the National Center for Biotechnology Information, and the orange represents sequences available in GISAID, a global initiative that maintains a repository of virus sequence data.



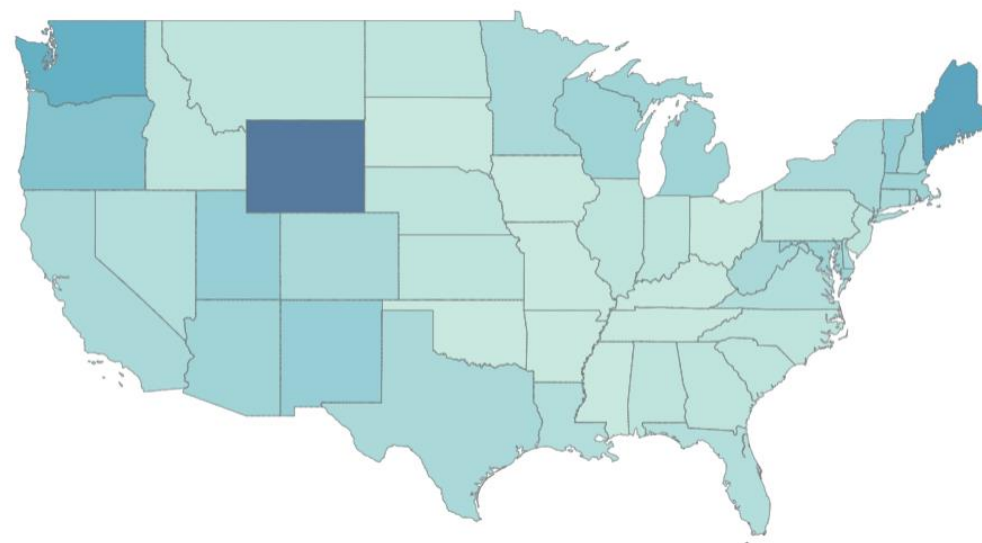
[National SARS-CoV-2 Genomic Surveillance Dashboard | CDC](#)

# SARS-CoV-2 Sequences By State

## Total Sequences Publicly Available



## Percentage (%) of Cumulative Cases Sequenced



Territories

GU MP PR VI

Number of Submitted Sequences



Territories

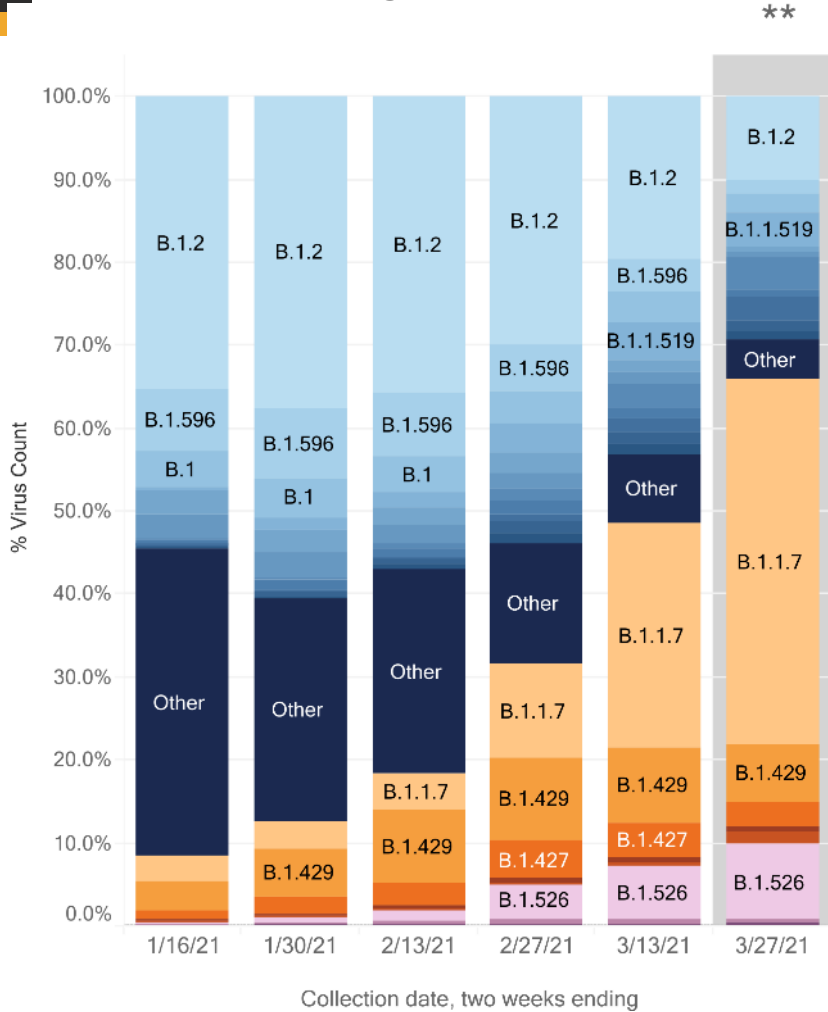
GU MP PR VI

% Total Cases Sequenced



# National Prevalence of SARS-CoV-2 Variants

Rolling 12-week Period



Two weeks ending March 27, 2021

	Lineage	% Total	95%CI	Type	
Most common lineages	B.1.1.7	44.1%	41.2-47.1%	VOC	<span style="color: orange;">■</span>
	B.1.2	10.0%	8.9-11.2%		<span style="color: lightblue;">■</span>
	B.1.526	9.2%	7.2-11.7%	VOI	<span style="color: purple;">■</span>
	B.1.429	6.9%	5.1-9.4%	VOC	<span style="color: orange;">■</span>
	B.1.1.519	4.1%	3.4-5.0%		<span style="color: lightblue;">■</span>
	B.1.526.1	3.9%	3.3-4.7%		<span style="color: blue;">■</span>
	B.1.526.2	2.9%	2.3-3.8%		<span style="color: blue;">■</span>
	B.1.427	2.9%	2.2-3.9%	VOC	<span style="color: orange;">■</span>
	B.1	2.4%	2.0-3.0%		<span style="color: lightblue;">■</span>
	B.1.596	1.7%	1.3-2.1%		<span style="color: lightblue;">■</span>
Additional VOI/VOC lineages	P.1	1.4%	1.0-1.8%	VOC	<span style="color: brown;">■</span>
	R.1	1.2%	0.8-1.6%		<span style="color: blue;">■</span>
	B.1.575	1.1%	0.9-1.5%		<span style="color: blue;">■</span>
	B.1.1	0.9%	0.6-1.5%		<span style="color: blue;">■</span>
	B.1.243	0.6%	0.4-1.0%		<span style="color: lightblue;">■</span>
	B.1.234	0.5%	0.3-0.7%		<span style="color: lightblue;">■</span>
	B.1.351	0.7%	0.5-1.0%	VOC	<span style="color: brown;">■</span>
Other*	B.1.525	0.5%	0.3-0.7%	VOI	<span style="color: purple;">■</span>
	P.2	0.3%	0.2-0.4%	VOI	<span style="color: purple;">■</span>
Other*	Other	4.7%	4.1-5.4%		<span style="color: darkblue;">■</span>

- B.1.1.7 VOC remains the most frequent lineage sequenced, with an estimated prevalence of 44.1%
- Small decrease for B.1.427 and B.1.429 VOCs at 2.6% and 6.9%, respectively
- P.1 VOC increased from 0.5% to 1.4%
- B.1.351 VOC increased from 0.5% to 0.7%
- B.1.526 VOI increasing overall

Summary data in table include specimen collection dates from March 14- 27, 2021  
 \*Other represents >200 additional lineages, each circulating at <1% of viruses.  
 \*\*Most recent data (Shaded) are subject to change as samples from that period are still being processed.

[CDC COVID Data Tracker](https://www.cdc.gov/covid/data-tracker/)

† Estimated weights come from laboratory data providing the number of RT-PCR tests and number of positive RT-PCR test results stratified by state, specimen collection date, and genomic surveillance data source, using a survey-design-based approach. COVID-19 laboratory data sources include commercial and reference laboratories, public health laboratories, hospital laboratories, and other testing locations. Methods for sub-national estimation are being developed as more data are received.



# COVID-19



WEAR A MASK



STAY 6 FEET APART



AVOID CROWDS



GET A VACCINE



Your Health

Vaccines

Cases & Data

Work & School

Healthcare Workers

Health Depts

Science

More

## More Resources

CDC in Action +

Global COVID-19 +

Laboratories -

Resources for Labs -

Guidance for Reporting SARS-CoV-2 Sequencing Results

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Calculating Percent Positivity

FAQ: Calculating Percent Positivity

## Guidance for Reporting SARS-CoV-2 Sequencing Results

Updated Apr. 9, 2021 [Print](#)

### Key Points

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### On This Page

[Regulatory Position on Reporting Sequencing Results to Public Health Departments](#)

[Technical Guidance for Reporting Sequencing Results to Public Health Departments](#)

[How to Report SARS-CoV-2 Sequencing Results to Public Health Departments](#)

[Reporting Scenarios](#)



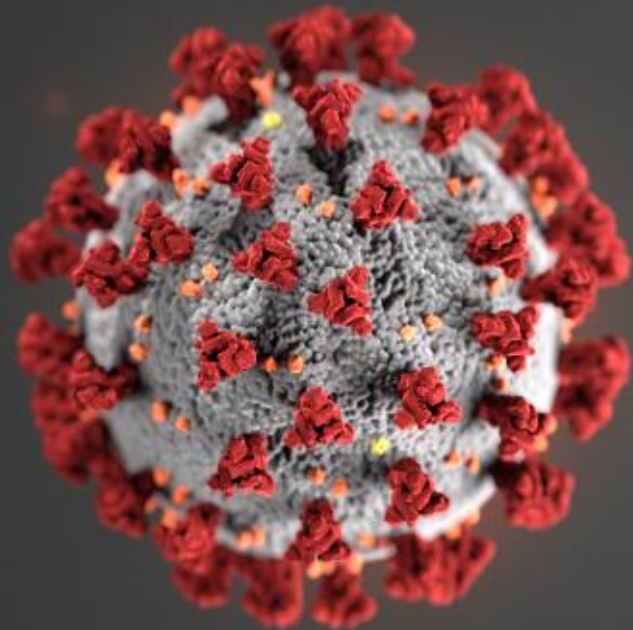
# Technical Guidance for Reporting Sequencing Results to Public Health Departments

The table below provides detailed guidance on reporting SARS-CoV-2 sequencing results to state, local, tribal, or territorial public health departments and includes examples for packaging data elements. This technical guidance is **subject to change as new information becomes available about the impact of SARS-CoV-2 evolution on public health**. For simplicity, only the fields needing more guidance in the additional observations for the variant lineage and the ID for the sequence sample are highlighted here. Other data elements normally part of each Observation/Result Segment (OBX), such as the result date, still need to be packaged as well.

Data Element	Reporting Requirement	Technical Specifications	Notes	Example	HL7 Field
	State / Federal / CDC / HHS / Tribal / Territorial PHD	Ordering Provider / EHR*			
Test result (performed and values)		Must use <a href="#">harmonized LOINC codes, when available</a>	SARS-CoV-2 pango lineage identified	LOINC: <a href="#">96741-4</a> : SARS-CoV-2 (COVID-19) variant [Type] in Specimen by Sequencing  OBX-2 = ST  Example answers so far: SARS-CoV-2 – B.1.1.7 lineage  SARS-CoV-2 – B.1.351 lineage	<a href="#">OBX-3</a>

- Electronic reporting of SARS-CoV-2 sequencing results to public health departments
- Includes examples for packaging data elements
- Should include all the original patient demographic data, along with both the viral test report content and the second ordered test with viral genetic lineage identified
- Labs performing sequencing should upload sequence data to a public database (National Center for Biotechnology Information [NCBI] , Global Initiative on Sharing Avian Influenza Data [GISAID])





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.







# Expansion of U.S. Testing Capacity Using Coordination Hubs

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*Presentation for Clinical Lab call on 4/19/2021*

*HHS Testing and Diagnostics Work Group*

*Ellen Kersh, PhD - State Engagement Team Lead*

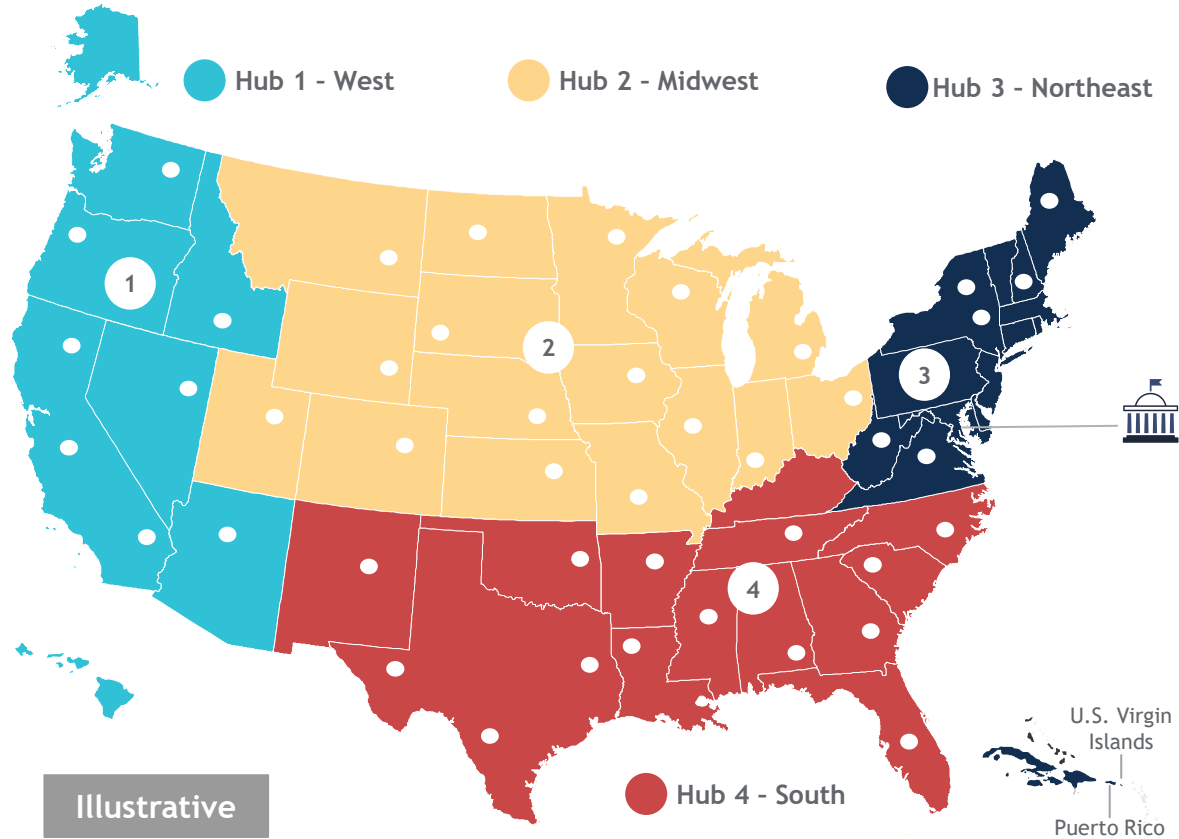
Goal of program is to expand national COVID testing to **re-open K-8 schools and reach underserved populations** by establishing national public-private partnership



**25M**

Target distribution  
of 25M tests per  
month

# To achieve ambition, will establish a national public-private partnership to put-to-use spare testing capacity



## US Government

Sets strategic direction executed at the state level  
Manages external affairs, communications, resources  
Provide guidance on tests and kits



## Coordination Centers

Four centers that facilitate testing and reporting across geographical regions



## Testing laboratories

Access unused capacity and untapped talent to expand testing capacity (e.g., large universities, commercial laboratories, laboratory consortium, or non-profit potentially partnered with CLIA laboratories)

## Additional support:

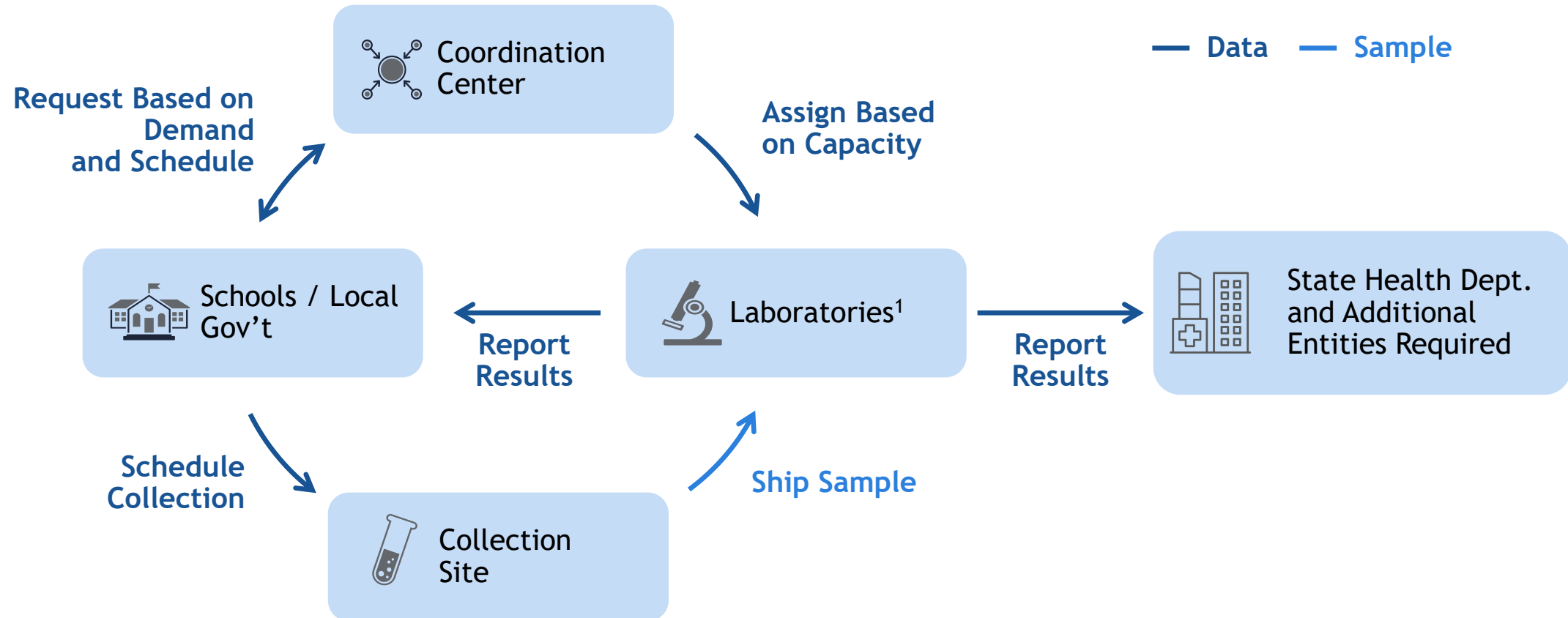
### Technical SMEs

Available to support HHS, Coordination Centers, schools, and laboratories on logistics, information, technology, regulatory, quality assurance, and other areas related to collection, handling, processing, resulting, and disposition

### Testing Manufacturers

USG will maintain a list of preferred EUA test suppliers with known areas of excess capacity, which may be amended as needed from time to time.

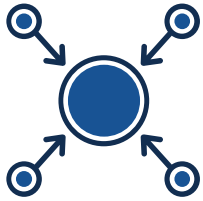
# Public-private partnership will coordinate excess testing capacity to enable school re-opening and reach underserved populations



**Objective is to go from sample to reporting in <48 hours, threshold of <72 hours**

1. Patient specific results from non-CLIA certified laboratory cannot be reported to individuals or health care providers, but population-level aggregate results may be reported to public health agencies

# Preliminary target characteristics of partners



## Coordination Centers

- Geographical distribution
- Quality project management
- Ability to establish or leverage existing lab network
- Innate data and tech infrastructure to support logistics requirements
- Technical expertise with diagnostics, clinical data management
- Ensure regulatory compliance
- Experience collaborating with public health and state authorities



## Laboratories

- Geographical distribution
- Excess capacity to reach >150K tests/week quickly across all laboratories, without interfering with current volumes
- Achieve 48hr turnaround from sample collection to reporting
- Electronic reporting capability
- Ability to preserve specimens and document referral pathway for positive test results
- Space and personnel for testing operations; available infrastructure or ability to grow

# Preliminary timeline and key milestones for program





**Thank you!**

# CDC Social Media



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



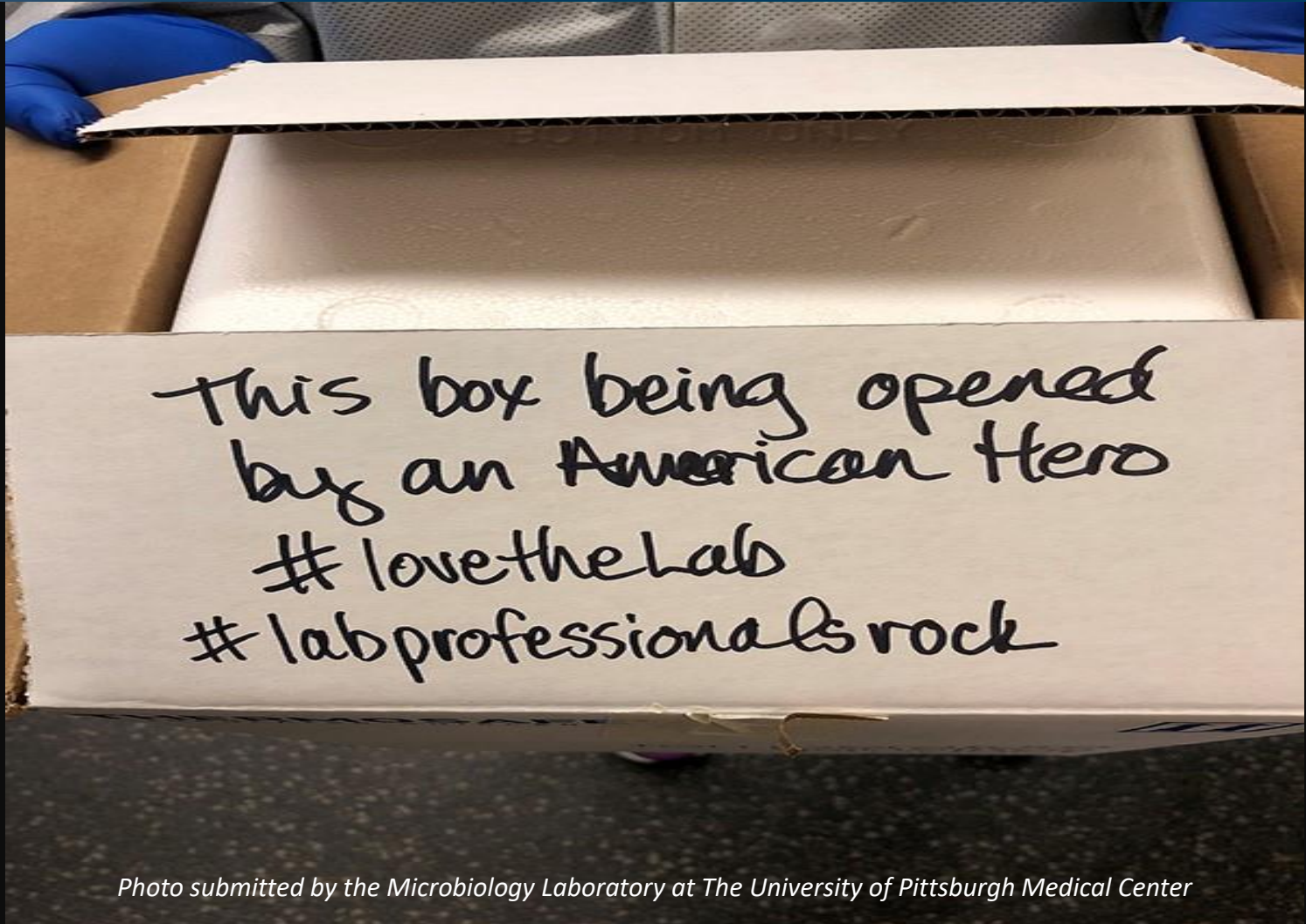
<https://twitter.com/cdcgov>



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



# Thank You For Your Time!



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

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