# Clinical Laboratory COVID-19 Response Call

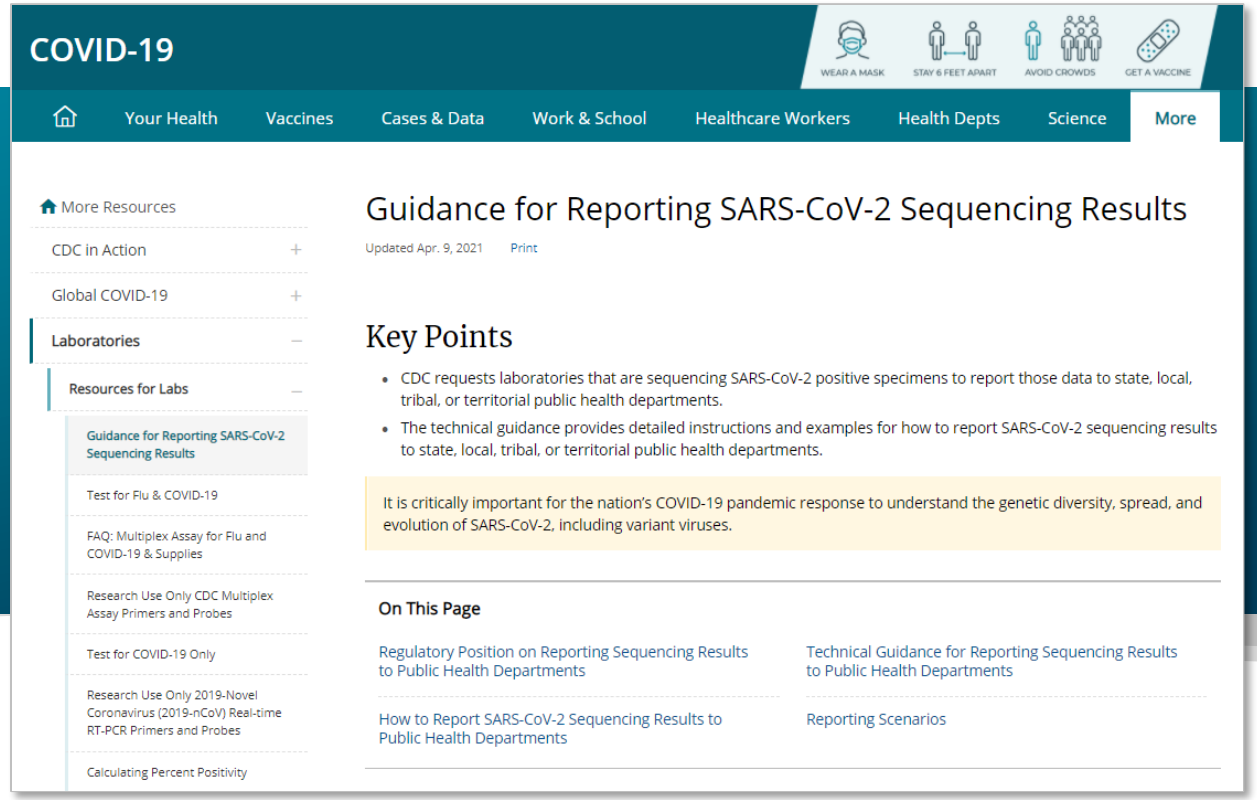
## Monday, April 19, 2021 at 3:00 PM EDT

- **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

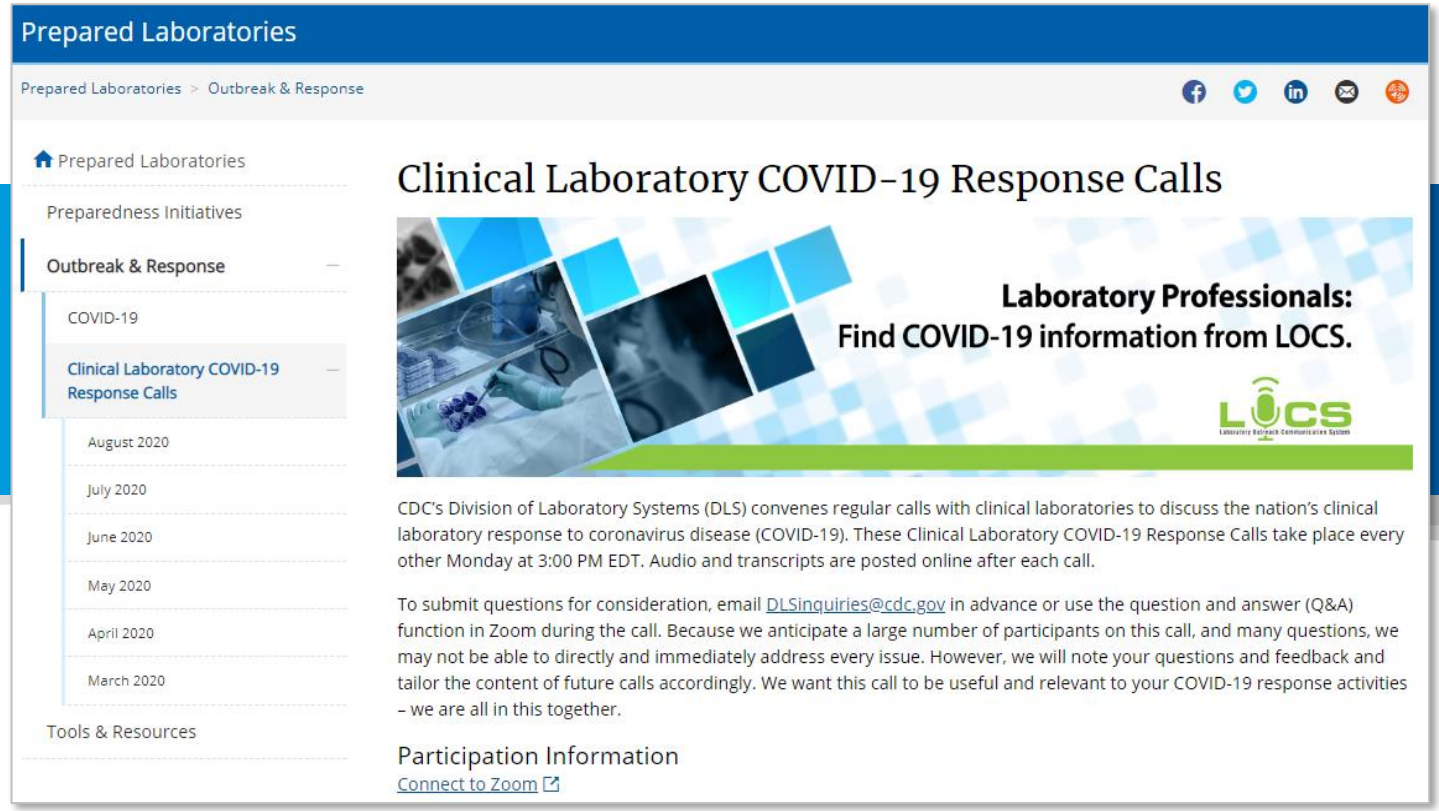
- CDC recommends that if laboratories and facilities sequence SARS-CoV-2 positive specimens, they can electronically report these data to state, local, tribal, or territorial public health departments
- Laboratories should also check with health departments for reporting requirements



# 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, May 3** from

**3:00 PM to 4:00 PM EDT**

# We Want to Hear from You!

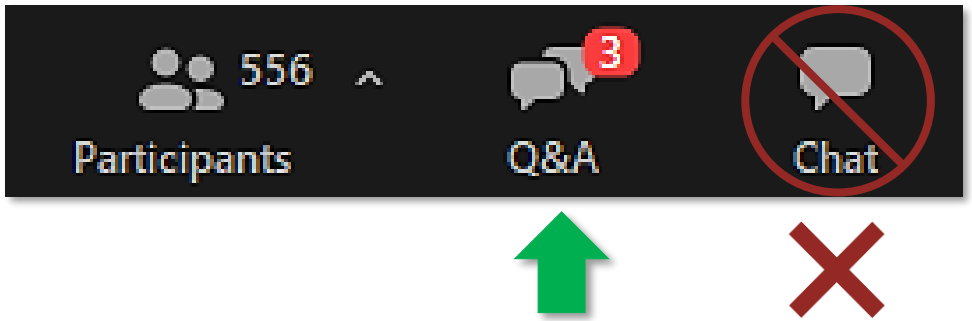
**Training and Workforce Development**

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.*

# Opening Remarks

**Dr. Rochelle Walensky**
Director, CDC

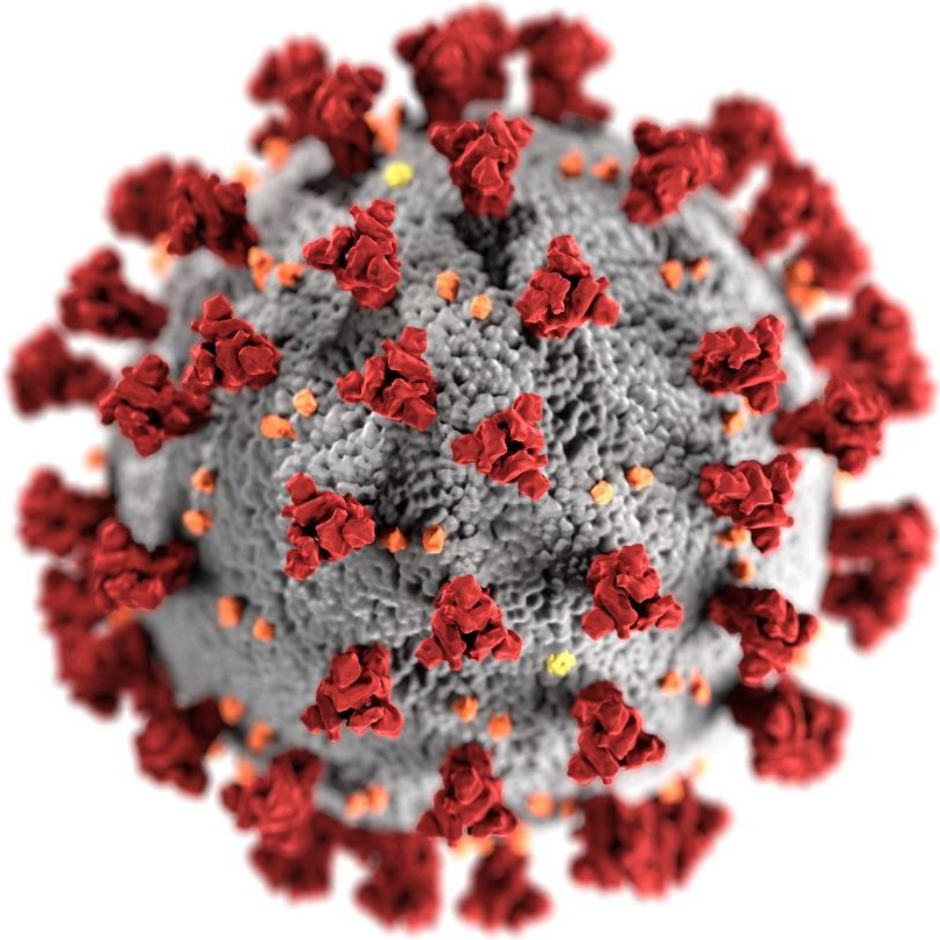


U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

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

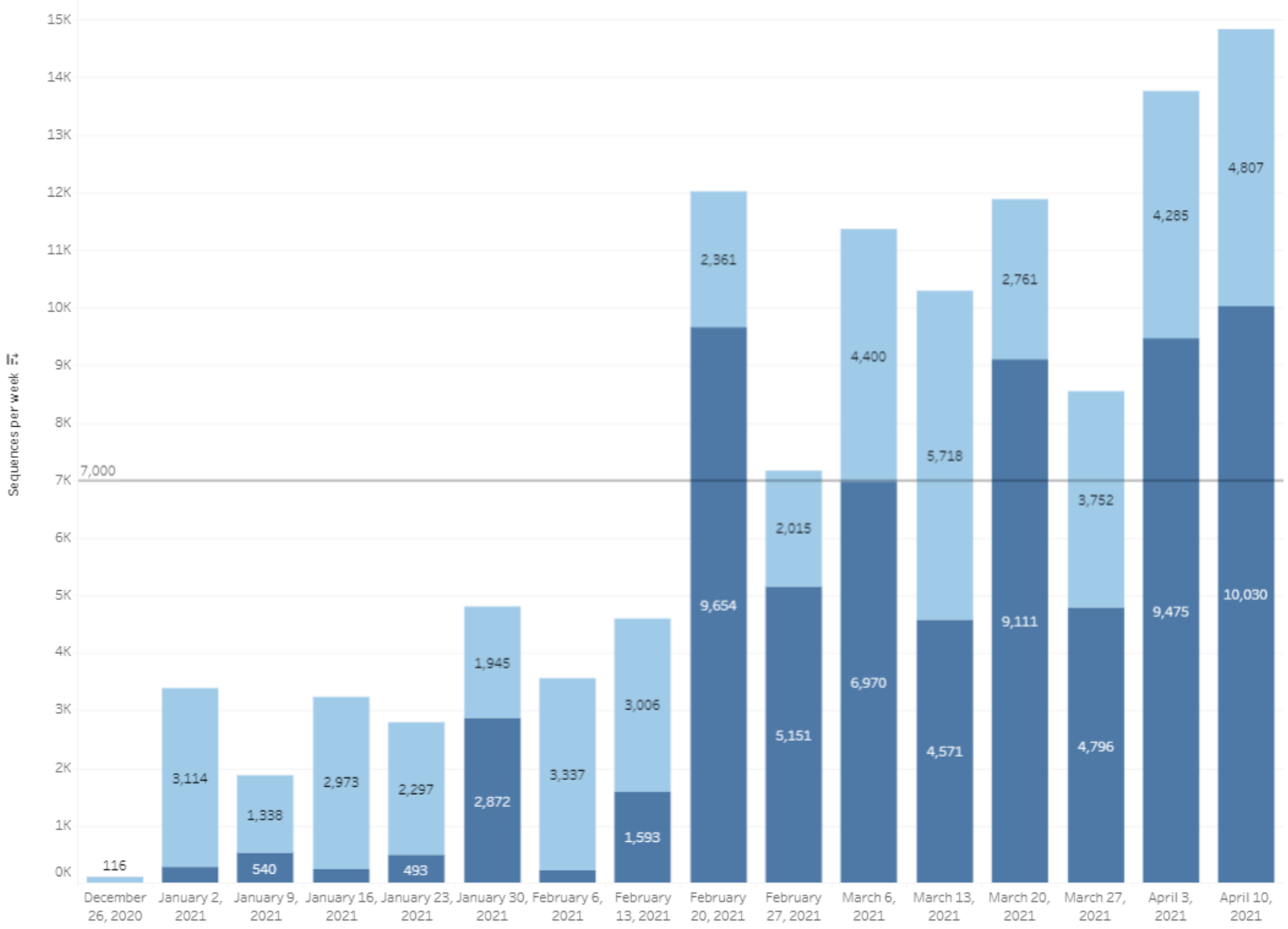
Vivien Dugan, Ph.D.
Lead, Surveillance and Emerging Variants Team
Laboratory and Testing Task Force
CDC COVID-19 Emergency Response

Deputy Director, Influenza Division
NCIRD, CDC
April 19, 2021



cdc.gov/coronavirus

# Published SARS-CoV-2 Sequences

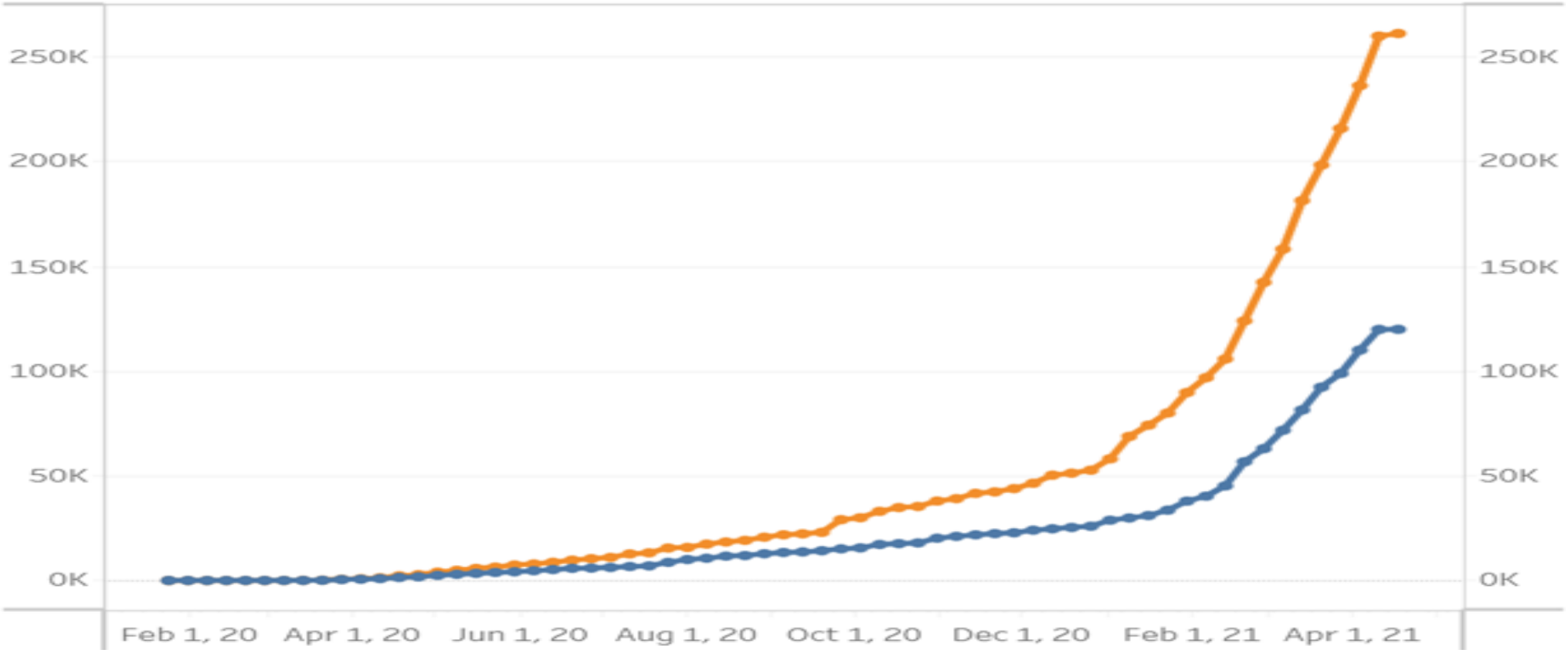



- Sequences published in NCBI and GISAID, deduplicated
- Includes data from CDC National SARS-CoV-2 surveillance, contracts and public health laboratories
- Data available to inform public health actions before being published
- Public Health Labs
  - 48,225 total sequences
  - 4,807 sequences last week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

[CDC COVID Data Tracker]

# U.S. Sequences Available in Public Repositories

As of April 11, 2021




**260,860**

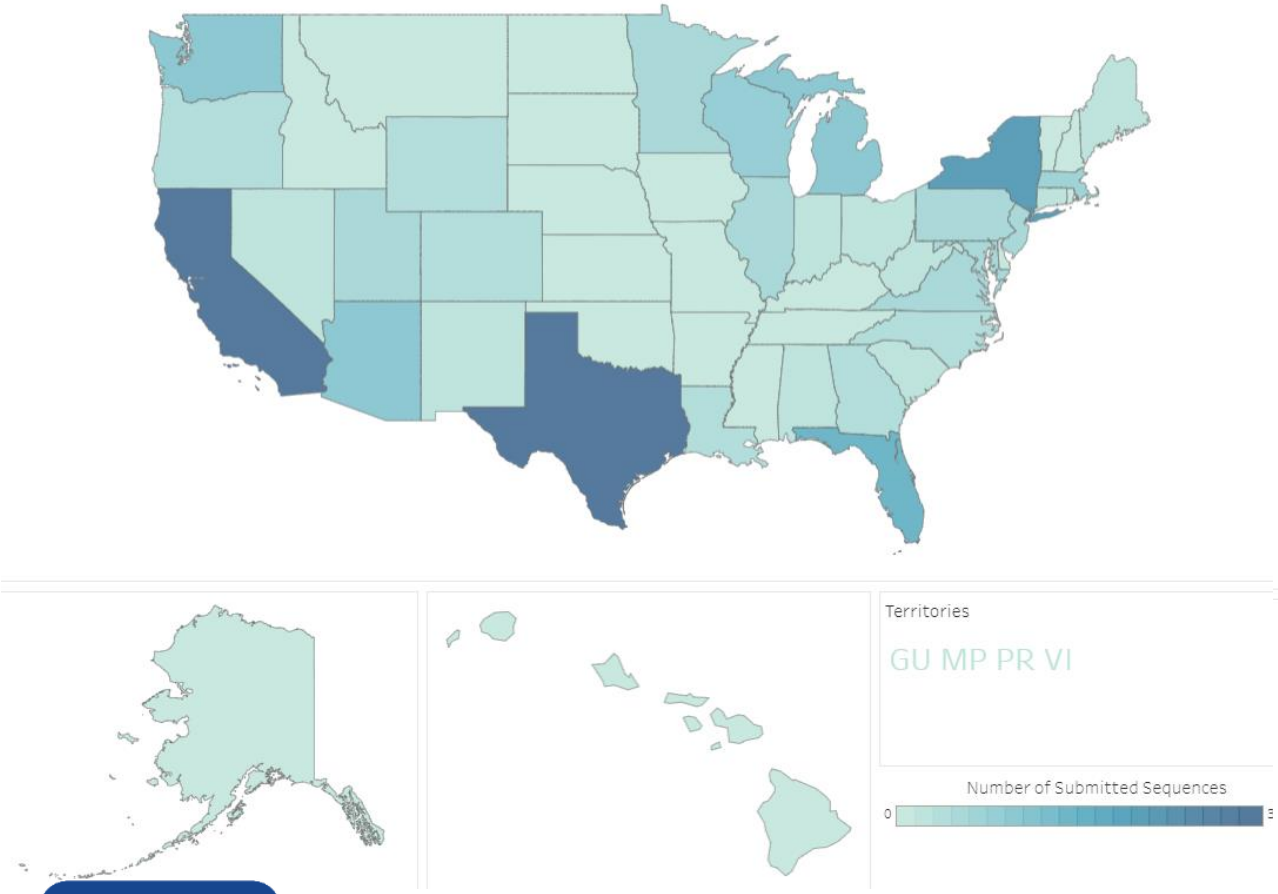
**119,771**

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.

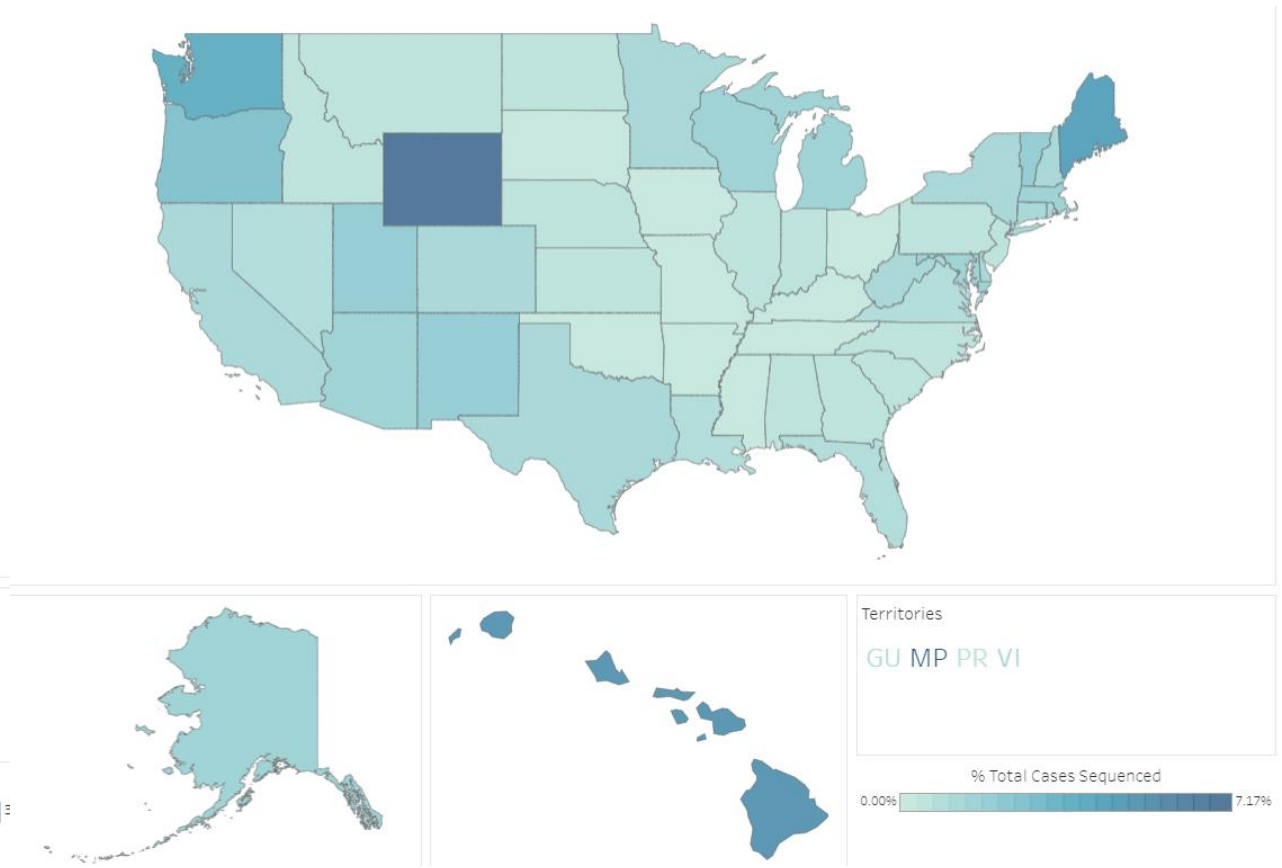
[National SARS-CoV-2 Genomic Surveillance Dashboard | CDC]

# SARS-CoV-2 Sequences By State

## Total Sequences Publicly Available



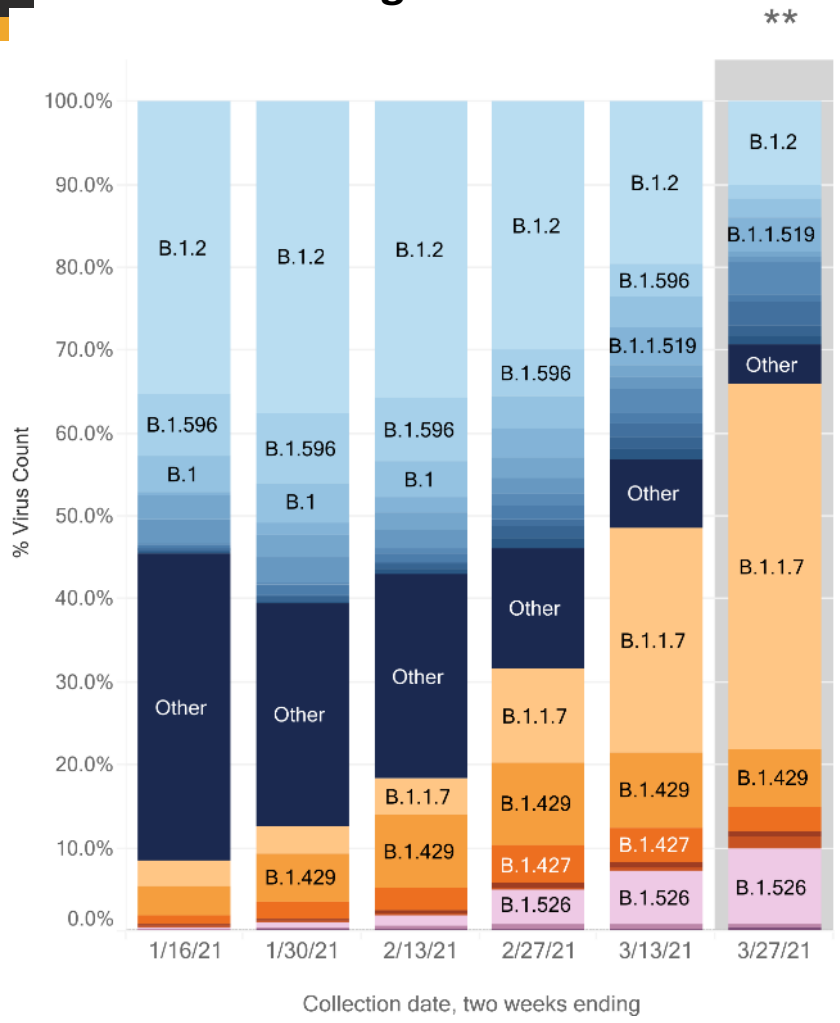

## Percentage (%) of Cumulative Cases Sequenced




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

# National Prevalence of SARS-CoV-2 Variants

## Rolling 12-week Period




## Two weeks ending March 27, 2021

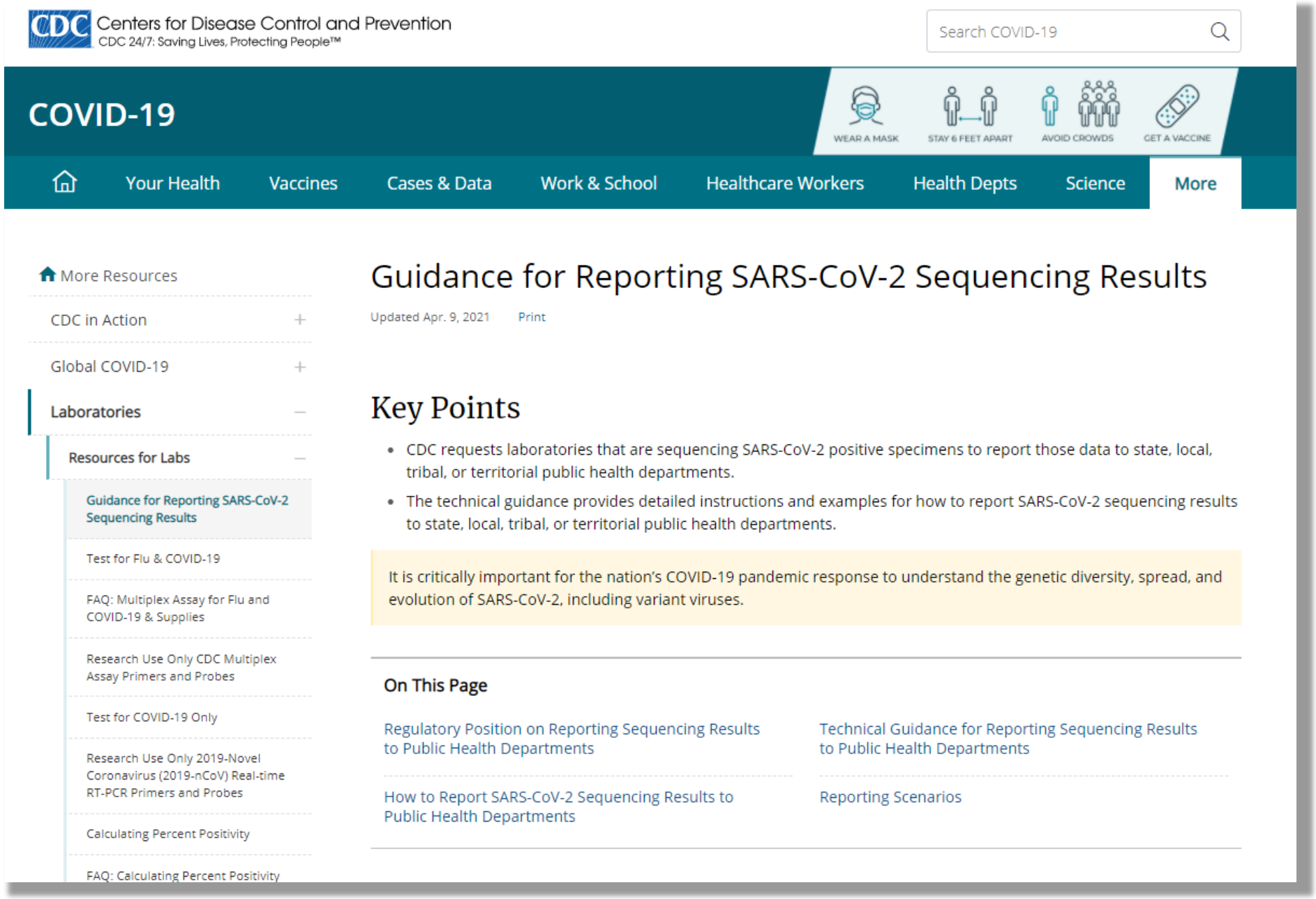
| | Lineage | % Total | 95%CI | Type |
|---|---|---|---|---|
| Most common lineages | B.1.1.7 | 44.1% | 41.2-47.1% | VOC |
| | B.1.2 | 10.0% | 8.9-11.2% | |
| | B.1.526 | 9.2% | 7.2-11.7% | VOI |
| | B.1.429 | 6.9% | 5.1-9.4% | VOC |
| | B.1.1.519 | 4.1% | 3.4-5.0% | |
| | B.1.526.1 | 3.9% | 3.3-4.7%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

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.

- 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

CDC 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.




Guidance for Reporting SARS-CoV-2 Sequencing Results | CDC
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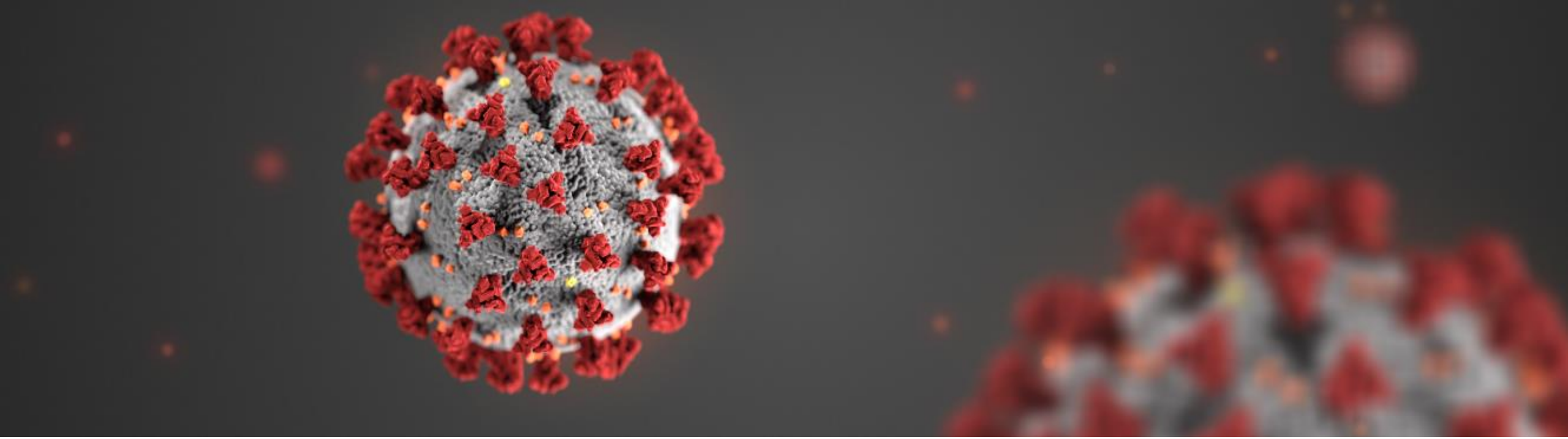
# Technical Guidance for Reporting Sequencing Results to Public Health Departments

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 |
|---|---|---|---|---|---|---|---|
| | Federal / CDC / HHS | State / Local / Tribal / Territorial PHD | Ordering Provider / EHR* | | | | |
| **Test result (performed and values)** | | | | Must use harmonized LOINC codes, when available | SARS-CoV-2 pango lineage identified | LOINC: 96741-4 : SARS-CoV-2 (COVID-19) variant [Type] in Specimen by Sequencing<br><br>OBX-2 = ST<br><br>Example answers so far:<br>SARS-CoV-2 – B.1.1.7 lineage<br>SARS-CoV-2 – B.1.351 lineage | OBX-3 |

- 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])

Guidance for Reporting SARS-CoV-2 Sequencing Results | CDC
https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/reporting-sequencing-guidance.html



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.

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

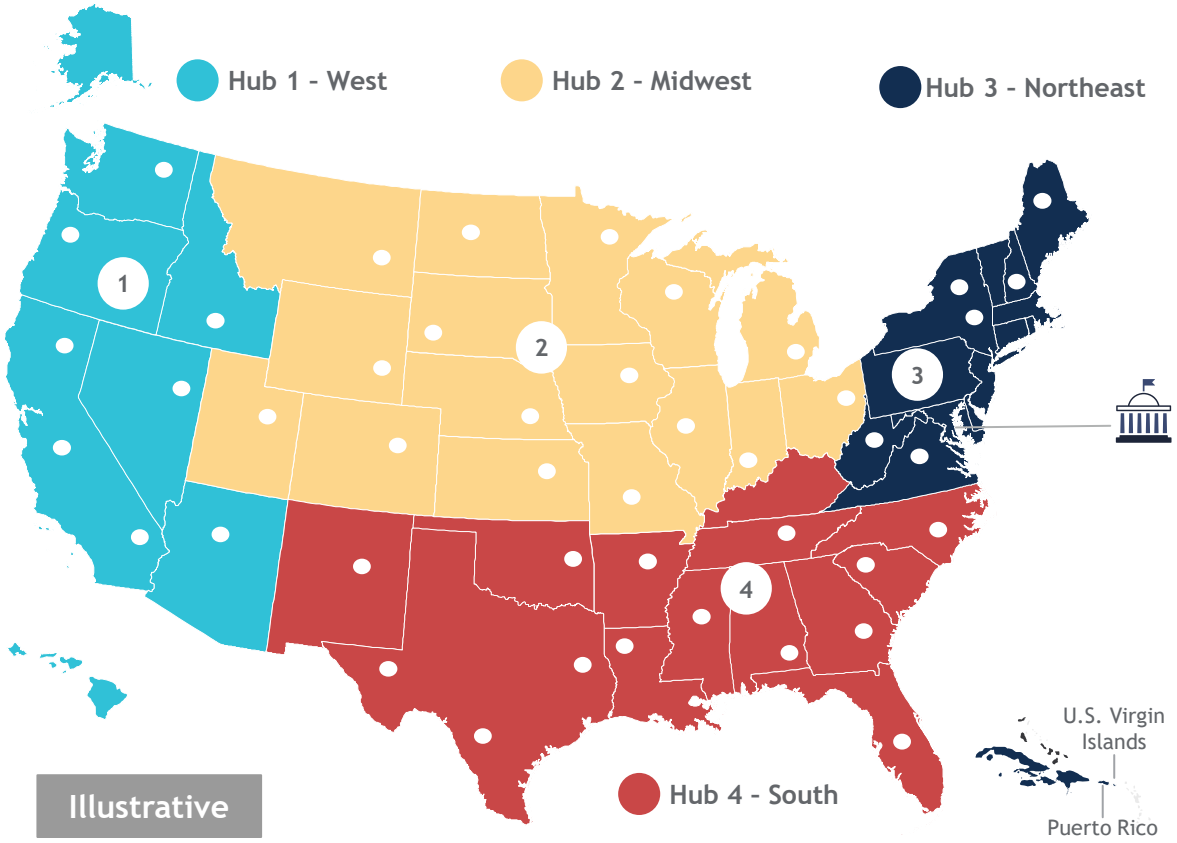
*Presentation for Clinical Lab call on 4/19/2021*

*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

# 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:

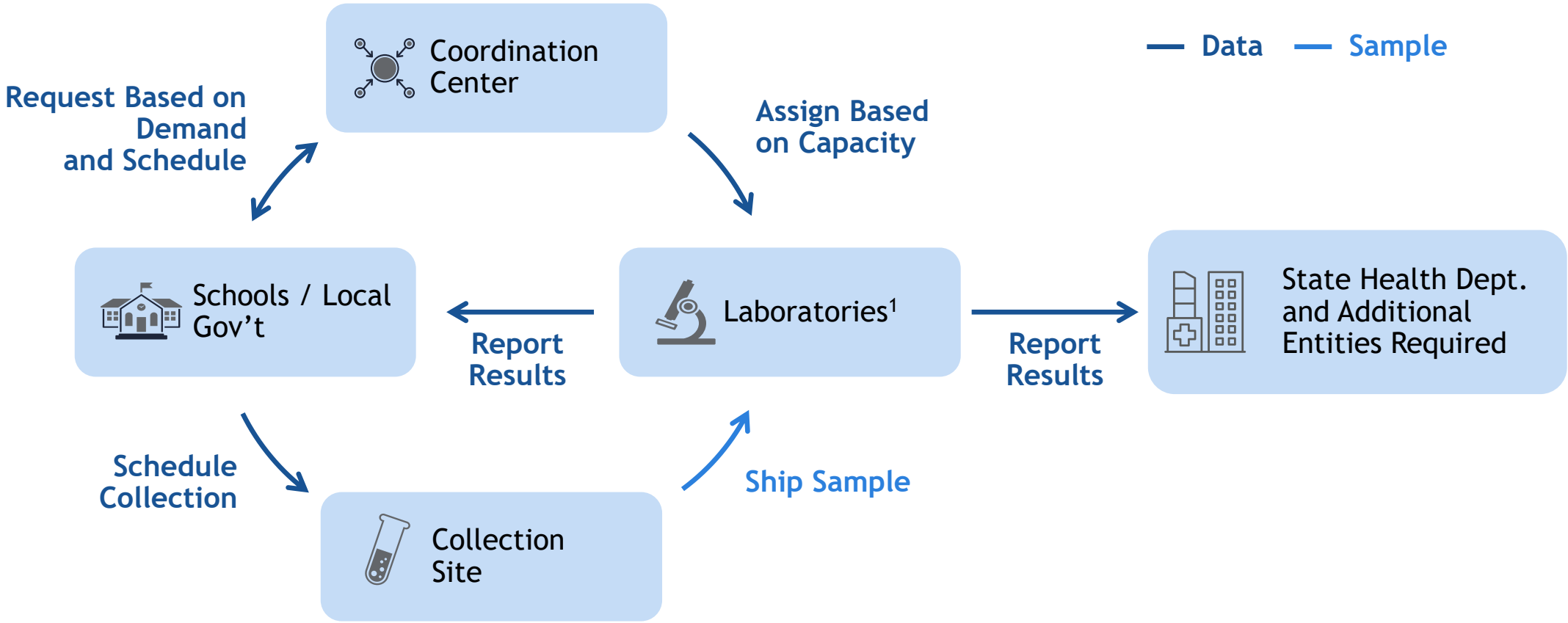
### Technical SMEs

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.

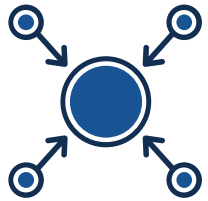
# Public-private partnership will coordinate excess testing capacity to enable school re-opening and reach underserved populations




**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


**Feb 18:**
Industry RFI posted

**Mar 2:**
**Informational webinar**

**Mar 4:**
Industry Day

**March:**
Application period

**April:**
Expect first coordinating center to stand up

# 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!

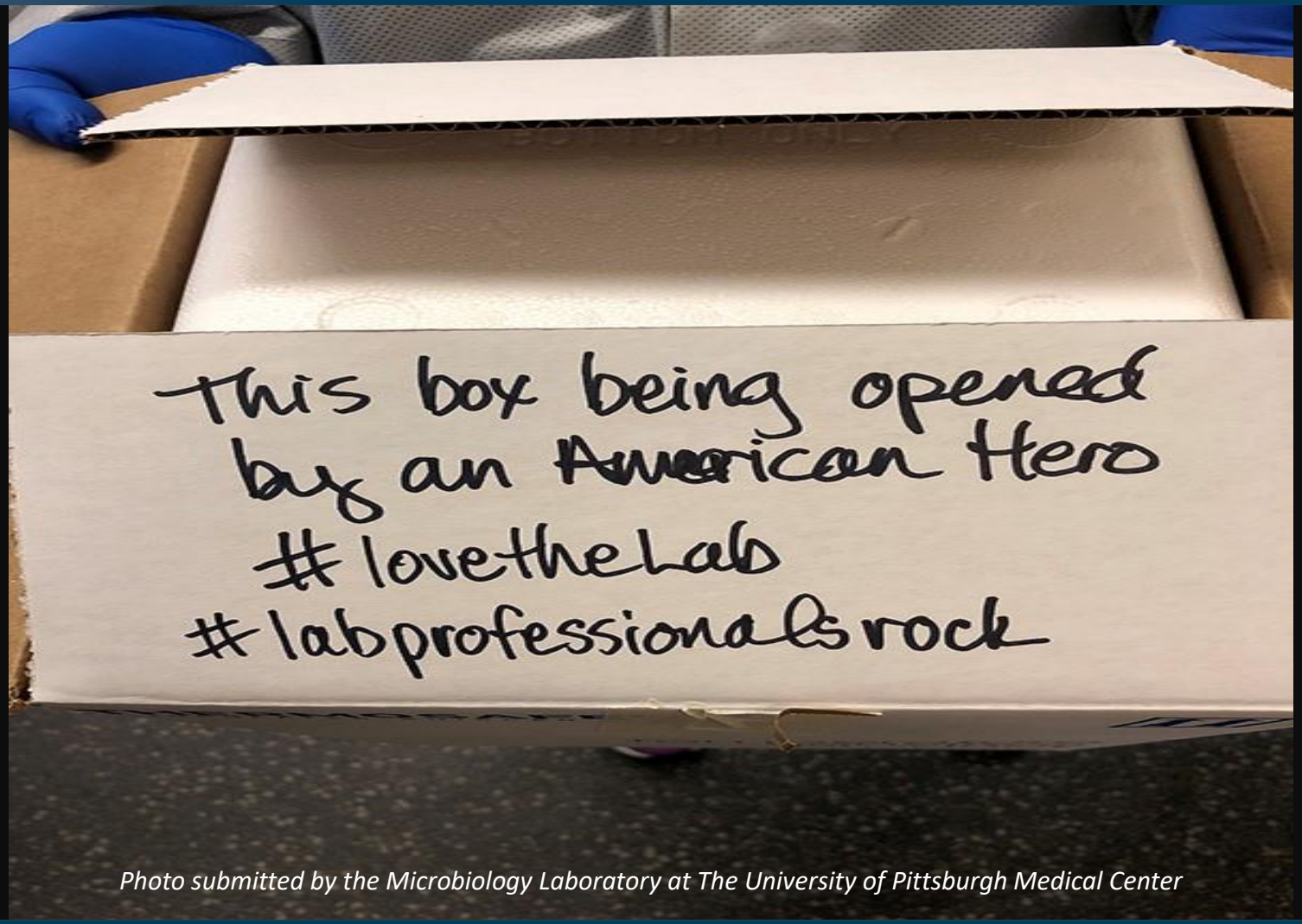



*Photo submitted by the Microbiology Laboratory at The University of Pittsburgh Medical Center*