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)
Find CLCR call information, transcripts, and audio recordings on the CDC Preparedness Portal

The next call will be on **Monday, June 28** 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](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
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

[Link to CDC website](https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/variant-surveillance/variant-info.html)
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.

[https://www.who.int/en/activities/tracking-SARS-CoV-2-variants/]
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](https://covid.cdc.gov/covid-data-tracker/#variant-proportions).
National Prevalence of SARS-CoV-2 Variants

U.S. 2/27/2021 – 05/22/2021

Percent of Viral Lineages

- Most common lineages
  - B.1.1.7 VOC 69.2% 66.4-71.9%
  - P.1 VOC 8.1% 6.2-10.5%
  - B.1.526 VOI 4.7% 3.4-6.4%
  - B.1.526.2 VOI 2.7% 2.1-3.4%
  - B.1.526.1 VOI 2.5% 1.9-3.4%
  - B.1.617.2 VOI 2.5% 1.9-3.4%
  - B.1 1.8% 1.4-2.3%
  - B.1.1.519 0.9% 0.5-1.4%
  - B.1.2 0.1% 0.1-0.2%
  - Additional B.1.429 VOC 0.7% 0.4-1.1%

- Proportions for all VOI and VOC were within Nowcast prediction intervals

- 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%

U.S. 5/9/2021 – 05/22/2021

Specimen Collection Date, 2-weeks ending

- 3/13/21
- 3/27/21
- 4/10/21
- 4/24/21
- 5/8/21
- 5/22/21

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

* "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
Regional Prevalence of SARS-CoV-2 Variants

- **B.1.617.2 VOI**: 8.8% in region 8, 5.7% in region 7, ≥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

Regional proportions from specimens collected the two weeks ending 5/22/2021.
US Territories not shown are included in HHS regions:
PR, VI - Region 2
AS, FM, GU, MH, MP, PW - Region 9
National Nowcast Estimates SARS-CoV-2 Lineages

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 or decrease slightly

* 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

- 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


- P.1 proportion predicted to remain generally stable in most regions
- 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

<table>
<thead>
<tr>
<th>State</th>
<th>B.1.1.7</th>
<th>B.1.351</th>
<th>B.1.427 / B.1.429</th>
<th>P.1</th>
<th>Other lineages</th>
<th>Total Available Sequences</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arizona</td>
<td>66.3%</td>
<td>1.1%</td>
<td>7.2%</td>
<td>8.9%</td>
<td>16.5%</td>
<td>732</td>
</tr>
<tr>
<td>California</td>
<td>54.5%</td>
<td>1.1%</td>
<td>9.3%</td>
<td>10.1%</td>
<td>25.1%</td>
<td>5,762</td>
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<tr>
<td>Colorado</td>
<td>68.3%</td>
<td>0.5%</td>
<td>7.4%</td>
<td>4.8%</td>
<td>19.3%</td>
<td>2,429</td>
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<td>Connecticut</td>
<td>54.6%</td>
<td>0.8%</td>
<td>0.9%</td>
<td>3.1%</td>
<td>40.5%</td>
<td>1,115</td>
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<tr>
<td>Florida</td>
<td>69.0%</td>
<td>0.4%</td>
<td>1.4%</td>
<td>9.8%</td>
<td>19.4%</td>
<td>9,255</td>
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<tr>
<td>Georgia</td>
<td>79.3%</td>
<td>1.4%</td>
<td>1.1%</td>
<td>4.4%</td>
<td>13.7%</td>
<td>1,368</td>
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<tr>
<td>Illinois</td>
<td>61.1%</td>
<td>1.0%</td>
<td>2.3%</td>
<td>22.4%</td>
<td>13.2%</td>
<td>3,854</td>
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<tr>
<td>Indiana</td>
<td>72.5%</td>
<td>0.7%</td>
<td>1.4%</td>
<td>10.8%</td>
<td>14.2%</td>
<td>1,662</td>
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<tr>
<td>Kentucky</td>
<td>76.4%</td>
<td>0.8%</td>
<td>0.8%</td>
<td>4.5%</td>
<td>18.3%</td>
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</tr>
<tr>
<td>Maine</td>
<td>37.5%</td>
<td>0.8%</td>
<td>1.9%</td>
<td>3.6%</td>
<td>56.2%</td>
<td>363</td>
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<tr>
<td>Maryland</td>
<td>72.8%</td>
<td>1.1%</td>
<td>0.4%</td>
<td>0.6%</td>
<td>25.0%</td>
<td>1,167</td>
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<tr>
<td>Massachusetts</td>
<td>51.6%</td>
<td>0.1%</td>
<td>1.2%</td>
<td>13.6%</td>
<td>33.5%</td>
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<td>Michigan</td>
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<td>0.4%</td>
<td>1.1%</td>
<td>2.4%</td>
<td>14.9%</td>
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</tr>
<tr>
<td>Minnesota</td>
<td>79.3%</td>
<td>1.0%</td>
<td>5.0%</td>
<td>2.0%</td>
<td>12.7%</td>
<td>7,780</td>
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<tr>
<td>Missouri</td>
<td>79.3%</td>
<td>1.2%</td>
<td>1.0%</td>
<td>6.0%</td>
<td>12.4%</td>
<td>460</td>
</tr>
<tr>
<td>Nevada</td>
<td>63.8%</td>
<td>2.1%</td>
<td>7.9%</td>
<td>3.3%</td>
<td>22.8%</td>
<td>329</td>
</tr>
<tr>
<td>New Hampshire</td>
<td>46.9%</td>
<td>2.9%</td>
<td>6.2%</td>
<td>42.1%</td>
<td>763</td>
<td></td>
</tr>
<tr>
<td>New Jersey</td>
<td>50.5%</td>
<td>0.2%</td>
<td>0.8%</td>
<td>3.2%</td>
<td>45.3%</td>
<td>2,925</td>
</tr>
<tr>
<td>New Mexico</td>
<td>60.8%</td>
<td>0.3%</td>
<td>3.0%</td>
<td>1.1%</td>
<td>20.2%</td>
<td>366</td>
</tr>
<tr>
<td>New York</td>
<td>53.9%</td>
<td>0.9%</td>
<td>1.2%</td>
<td>4.4%</td>
<td>39.7%</td>
<td>1,807</td>
</tr>
<tr>
<td>North Carolina</td>
<td>53.5%</td>
<td>1.2%</td>
<td>0.7%</td>
<td>2.4%</td>
<td>32.5%</td>
<td>2,243</td>
</tr>
<tr>
<td>Ohio</td>
<td>75.2%</td>
<td>0.7%</td>
<td>0.9%</td>
<td>5.6%</td>
<td>17.6%</td>
<td>1,065</td>
</tr>
<tr>
<td>Oregon</td>
<td>47.3%</td>
<td>3.3%</td>
<td>15.9%</td>
<td>9.4%</td>
<td>24.2%</td>
<td>736</td>
</tr>
<tr>
<td>Pennsylvania</td>
<td>64.6%</td>
<td>0.8%</td>
<td>0.9%</td>
<td>2.5%</td>
<td>31.2%</td>
<td>4,503</td>
</tr>
<tr>
<td>Puerto Rico</td>
<td>72.5%</td>
<td>2.3%</td>
<td>2.9%</td>
<td>22.3%</td>
<td>345</td>
<td></td>
</tr>
<tr>
<td>Rhode Island</td>
<td>44.7%</td>
<td>1.9%</td>
<td>9.5%</td>
<td>43.9%</td>
<td>1,269</td>
<td></td>
</tr>
<tr>
<td>Tennessee</td>
<td>85.3%</td>
<td>0.1%</td>
<td>1.0%</td>
<td>3.4%</td>
<td>10.2%</td>
<td>1,152</td>
</tr>
<tr>
<td>Texas</td>
<td>75.4%</td>
<td>0.3%</td>
<td>1.6%</td>
<td>5.7%</td>
<td>17.1%</td>
<td>4,021</td>
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<tr>
<td>Vermont</td>
<td>71.0%</td>
<td>2.2%</td>
<td>2.5%</td>
<td>24.3%</td>
<td>490</td>
<td></td>
</tr>
<tr>
<td>Virginia</td>
<td>74.2%</td>
<td>1.2%</td>
<td>2.5%</td>
<td>21.8%</td>
<td>859</td>
<td></td>
</tr>
<tr>
<td>Washington</td>
<td>59.6%</td>
<td>1.9%</td>
<td>13.9%</td>
<td>8.8%</td>
<td>15.8%</td>
<td>1,372</td>
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<tr>
<td>West Virginia</td>
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<td>0.1%</td>
<td>0.6%</td>
<td>0.2%</td>
<td>38.5%</td>
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<tr>
<td>Wisconsin</td>
<td>65.5%</td>
<td>0.1%</td>
<td>4.4%</td>
<td>6.2%</td>
<td>23.8%</td>
<td>844</td>
</tr>
</tbody>
</table>

Variant proportions are based on representative CDC sequence data (NS3 + CDC-funded contract sequencing) coll...
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.
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
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.
Participation in NWSS is growing quickly

Cumulative Samples in DCIPHER Since January 2021

Number of Samples

January February March April May

Currently 7000, 9000, and 8000 in January, February, and March, respectively.

Pending Award

Guam
Puerto Rico
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)

NWSS Email: NWSS@cdc.gov


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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 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


COVID-19 Frequently Asked Questions


COVID-19 Updates


FDA Townhall Meetings


Independent Evaluations of COVID-19 Serological Tests

https://open.fda.gov/apis/device/covid19serology/
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
COVID-19 Viral Testing Tool Update

Muktha Natrajan
CDC Division of Laboratory Systems (DLS)
Thank You For Your Time!

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