Clinical Laboratory COVID-19 Response Call  
Monday, July 12, 2021, at 3:00 PM EDT

- Welcome  
  - Jasmine Chaitram, CDC Division of Laboratory Systems (DLS)
- SARS-CoV-2 Variants Update  
  - Jessica Chen, CDC Laboratory and Testing Task Force for the COVID-19 Response
- Taking Back Control from COVID-19: ASU’s Response  
  - Mara Aspinall and Nate Wade, Arizona State University
- FDA Update  
  - Tim Stenzel, U.S. Food and Drug Administration (FDA)
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, July 26** from 3:00 PM to 4:00 PM EDT
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.
National Prevalence of SARS-CoV-2 Variants

U.S. 3/28/2021 – 06/19/2021

U.S. 6/6/2021 – 06/19/2021

- Weighted proportions for 6/6/21 – 6/19/21
- WHO names added last week
- ↓ B.1.1.7 (Alpha) decreased from 60.0% to 44.2%
- ↑ B.1.617.2 (Delta) increased from 10.0% to 30.4%
- ↓ P.1 (Gamma) decreased from 11.0% to 9.9%
- ↓ B.1.526 (Iota) decreased from 9.5% to 5.5%

### Specimen Collection Date, 2-weeks ending

#### Most common lineages #

<table>
<thead>
<tr>
<th>Lineage Type</th>
<th>%Total</th>
<th>95%CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>B.1.1.7 Alpha VOC</td>
<td>44.2%</td>
<td>39.8-48.8%</td>
</tr>
<tr>
<td>B.1.617.2 Delta VOC</td>
<td>30.4%</td>
<td>24.1-37.7%</td>
</tr>
<tr>
<td>P.1 Gamma VOC</td>
<td>9.9%</td>
<td>7.6-13.0%</td>
</tr>
<tr>
<td>B.1.526 Iota VOI</td>
<td>5.5%</td>
<td>4.3-6.9%</td>
</tr>
<tr>
<td>B.1</td>
<td>2.2%</td>
<td>1.4-3.5%</td>
</tr>
<tr>
<td>B.1.1.519</td>
<td>0.2%</td>
<td>0.1-0.4%</td>
</tr>
<tr>
<td>B.1.2</td>
<td>0.0%</td>
<td>0.0-0.1%</td>
</tr>
</tbody>
</table>

#### Additional VOI/VOC lineages #

<table>
<thead>
<tr>
<th>Lineage Type</th>
<th>%Total</th>
<th>95%CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>B.1.351 Beta VOC</td>
<td>0.2%</td>
<td>0.1-0.5%</td>
</tr>
<tr>
<td>B.1.429 Epsilon VOI</td>
<td>0.1%</td>
<td>0.0-0.4%</td>
</tr>
<tr>
<td>B.1.525 Eta VOI</td>
<td>0.1%</td>
<td>0.0-0.4%</td>
</tr>
<tr>
<td>B.1.617.1 Kappa VOI</td>
<td>0.0%</td>
<td>0.0-0.1%</td>
</tr>
<tr>
<td>B.1.617.3</td>
<td>0.0%</td>
<td>NA</td>
</tr>
<tr>
<td>P.2 Zeta VOI</td>
<td>0.0%</td>
<td>NA</td>
</tr>
<tr>
<td>Other*</td>
<td>6.9%</td>
<td>5.3-8.9%</td>
</tr>
</tbody>
</table>

* "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
# Sublineages of P.1 (P.1.1, P.1.2) and B.1.351 (B.1.351.1, B.1.351.2, B.1.351.3) are aggregated with the parental lineage

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**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 that may affect virus receptor binding, neutralization, or therapeutic efficacy
Regional Prevalence of SARS-CoV-2 Variants

- **B.1.617.2 (Delta)**
  - >30% in Regions 2 & 6-9
  - 72.0% in Region 7
  - 56.7% in Region 8

- **B.1.1.7 (Alpha)** >50% only in Regions 3, 5, 10
National Nowcast Estimates SARS-CoV-2 Lineages


<table>
<thead>
<tr>
<th>Specimen Collection Date, 2-weeks ending</th>
<th>Percent of Viral Lineages</th>
</tr>
</thead>
<tbody>
<tr>
<td>4/10/21</td>
<td>B.1.617.2 (Delta)</td>
</tr>
<tr>
<td>4/24/21</td>
<td>B.1.526</td>
</tr>
<tr>
<td>5/8/21</td>
<td>B.1.1.7</td>
</tr>
<tr>
<td>5/22/21</td>
<td>P.1</td>
</tr>
<tr>
<td>6/5/21</td>
<td>B.1.1.519</td>
</tr>
<tr>
<td>6/19/21</td>
<td>B.1.2</td>
</tr>
<tr>
<td>7/3/21</td>
<td>B.1.351</td>
</tr>
</tbody>
</table>

**NOWCAST U.S. 6/20/2021 – 7/3/2021**

<table>
<thead>
<tr>
<th>Lineage Type</th>
<th>%Total</th>
<th>95%PI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Most common lineages #</td>
<td></td>
<td></td>
</tr>
<tr>
<td>B.1.617.2 Delta VOC</td>
<td>51.7%</td>
<td>46.3-57.0%</td>
</tr>
<tr>
<td>B.1.1.7 Alpha VOC</td>
<td>28.7%</td>
<td>24.1-33.4%</td>
</tr>
<tr>
<td>P.1 Gamma VOC</td>
<td>8.9%</td>
<td>6.1-11.9%</td>
</tr>
<tr>
<td>B.1.526 Iota VOI</td>
<td>3.0%</td>
<td>1.5-4.8%</td>
</tr>
<tr>
<td>B.1</td>
<td>1.1%</td>
<td>0.3-2.3%</td>
</tr>
<tr>
<td>B.1.1.519</td>
<td>0.1%</td>
<td>0.0-0.5%</td>
</tr>
<tr>
<td>B.1.2</td>
<td>0.0%</td>
<td>0.0-0.3%</td>
</tr>
<tr>
<td>Additional VOI/VOC lineages #</td>
<td></td>
<td></td>
</tr>
<tr>
<td>B.1.351 Beta VOC</td>
<td>0.2%</td>
<td>0.0-0.8%</td>
</tr>
<tr>
<td>B.1.525 Eta VOI</td>
<td>0.0%</td>
<td>0.0-0.3%</td>
</tr>
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<td>B.1.429 Epsilon VOI</td>
<td>0.0%</td>
<td>0.0-0.3%</td>
</tr>
<tr>
<td>B.1.617.1 Kappa VOI</td>
<td>0.0%</td>
<td>0.0-0.3%</td>
</tr>
<tr>
<td>B.1.427 Epsilon VOI</td>
<td>0.0%</td>
<td>0.0-0.3%</td>
</tr>
<tr>
<td>Other* Other</td>
<td>6.4%</td>
<td>3.5-9.6%</td>
</tr>
</tbody>
</table>

- **B.1.617.2 (Delta)** predicted to be the predominant variant nationally, at 51.7%
- **P.1 (Gamma)** predicted to maintain a downward trend

* 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
# Sublineages of P.1 (P.1.1, P.1.2) and B.1.351 (B.1.351.1, B.1.351.2, B.1.351.3) are aggregated with the parental lineage. AY.1 and AY.2 are aggregated with B.1.617.2
Regional Nowcast Prevalence of SARS-CoV-2 Variants

- **B.1.617.2 (Delta)**
  - >30% in all regions
  - >50% in Regions 2, 6-9
  - 80.7% in Region 7
  - 74.3% in Region 8

- **B.1.1.7 (Alpha)**
  - <50% in all regions
  - <25% in Regions 2, 7-9
Taking Back Control from COVID-19: ASU’s Response

Mara G. Aspinall
Professor of Practice, Arizona State University
Managing Director, Health Catalysts Group
Director – Abcam, Allscripts, Blue Cross Blue Shield
Arizona, Castle Biosciences, OraSure
Advisor, The Rockefeller Foundation

Nathaniel L. Wade, Ph.D.
Executive Director, Strategic Initiatives and Innovation
College of Health Solutions, Arizona State University

CDC
Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

Division of Laboratory Systems (DLS)
July 12, 2021
ASU COVID-19 Diagnostics Commons

ASUcovidcommons.com

Master Degree in Biomedical Diagnostics
A comprehensive resource and interactive dashboard providing information about COVID-19 tests including all approved tests and those in development worldwide. It currently profiles more than 2400 tests.

The first interactive national repository of information on COVID-19 test research.

An employer community of practice for bringing employees back to the workplace. Resources include a worldwide employer survey, interactive results dashboard and guidance from experts.

A tool to help businesses locate and buy COVID-19 tests. Developed in collaboration with WhenToTest.org and Project N95, Connect to Test allows users to make informed and speedy COVID-19 testing decisions.
Upon entering the site, you will be greeted with these interactive parameters which can be easily adjusted to fit your company’s area(s) of interest regarding COVID-19 testing. Each of the above options has its own drop-down menu to allow for customized data.
From there, you can hover over any parameter for more detailed information on the number of tests that fit your criteria.
TestingCommons.com Pandemic Review

- **FDA EUA**: Molecular, Antigen, Serology, & T-Cell Tests, Patient Management, Combination Respiratory Panels, and Collection Kits
- **LDT**: Schedule IV notifications & Umbrella Molecular EUAs
- **CE-IVD**: EU self-certification
- **Research Use Only**: Authorized by government jurisdiction in country outside of US/EU
- **Development**: Tests & Technologies publicly announced to be under development
- **FDA Revoked**: Revoked, Rejected, Withdrawn, Warning letter, Fraud (DOJ)

1. n/a after 10/7/20 when HHS/FDA announced policy to not require authorization for any LDT
2. 19% of tests with approval internationally have been granted EUA by the US FDA

Pandemic Total through 6/30/21
ASUWorkplaceCommons.com

- Engaging with Employers in all industries
  - US
  - UK
  - Around the World
- Understanding of how they Keep Their Workers Well
- Community of Practice
  - Employer Surveys (1100+ participants)
  - Employer Case Studies
  - Interactive Websites
- Three installments of Survey
Facing Uncertainty:
The Challenges of COVID-19 in the Workplace
Survey Overview

Top 10 industries represented in rank order (Left-Right)

1. Technology and Software
2. Business + Professional Services (Accounting, Brokers, Corporate Banking, Legal, etc.)
3. Manufacturing
4. Construction
5. Healthcare, Hospitals, and Clinics
6. Retail Stores
7. Government and Quasi-Public
8. Education (Pre-K to 12)
9. Education (Colleges & Universities)
10. Energy & Utilities

6 Continents | 24 Industries | 31 Countries | 1,168 Companies | 1,339 Facilities

ASU WORKPLACE COMMONS - PHASE 2 SURVEY | 6
Top 10 Insights

Vaccination
Strong Support by Employers

- 88% of employers plan to require or encourage their employees to be vaccinated against COVID-19
- 56% of employers plan to incentivize their employees to be vaccinated against COVID-19
- 80% of employers will require employees to demonstrate proof of vaccination against COVID-19

Employee Wellbeing
Mental Health is now Central

- 77% of employers indicated that employee mental health and wellbeing has become a top priority for their company
- 68% increase in employee mental health concerns during the pandemic compared to pre-pandemic according to employers

Testing
Significant Increase by Employers

- 68% of employers are performing COVID-19 testing for at least some of their employees

Work from Home
Here to Stay

- 63% of employers intend to allow their employees to work from home full-time through 2021
- 69% of employers describe their anticipated future work environment as either hybrid (41%) or all virtual (28%)
- 72% of employers intend to offer more flexible or expanded work from home policies for their employees post-pandemic
- But ... 68% of employers believe that employees should be in the office at least 20 hours per week
Companies’ policies for employees regarding COVID-19 vaccination

88% Of employers will require or encourage vaccination for employees

40% Require all employees to be vaccinated against COVID-19

32% Encourage but not require employees to be vaccinated against COVID-19

16% Require some employees to be vaccinated against COVID-19

8% We don’t have a policy developed at this time

4% We don’t plan to encourage or require our employees to be vaccinated against COVID-19

What are the consequences for lack of compliance with vaccination policy?

- 1% Change of work responsibilities
- 15% Disciplinary action up to termination
- 27% No Consequences
- 31% Not allowed to return to the physical work environment
- Other

ASU Workplace Commons

ASU Arizona State University

With support from

Covid-19
Workplace Commons

College of Health Solutions
Arizona State University
Vaccination

There are three ways to end a pandemic – the virus burns itself out, it becomes endemic and we live with COVID-19 like we live with the flu or we achieve herd immunity through vaccines or prior infection. The great news is that effective vaccines were developed in record time. The COVID-19 vaccines were developed within one year where previous vaccines took seven to ten years to create. The advent of vaccines and their rapid distribution, however, raises questions and concerns that many employers are grappling with for the first time.

Our survey showed surprisingly high support for vaccination with almost 90% of employers planning to require or at least encourage their employees to get vaccinated. Our survey asked employers their stance on a variety of other issues related to COVID-19 vaccination and their employees, and their responses indicate that vaccination is perceived as significantly important for keeping the workplace and their employees safe.

59% Plan to incentivize employees to be vaccinated
84% Would allow vaccinations to be administered to employees at their facility
61% Plan to change safety mitigation measures once broad vaccination is achieved
60% Will require employees to demonstrate proof of vaccination
Testing remains the most effective way to measure and confirm the success of virus mitigation efforts including vaccination. It is in this area where we saw the most dramatic change in employer behavior. In our earlier study in the fall of 2020, we saw 17% of companies testing any of their employees. Although the fall study had smaller companies on average, we were surprised, but pleased, to see a dramatic increase. In this study, we saw a full 68% of companies reporting that they were testing at least some part of their workforce.

Why the big increase in testing? First, the test supply situation has fundamentally changed since the end of 2020. In the spring of 2021, it became relatively easy to acquire tests and hire testing service providers. There are more labs and companies with EUAs and most have enough capacity that there are few shortages. For lab-based tests, results are most often returned within 48 hours, often faster. For rapid tests, performance including pros and cons are better understood. Second, with this competition and improved technologies, the cost to test has dramatically decreased. Lastly, and maybe most importantly, knowledge of how a testing program can work has increased confidence amongst employers that testing can be integrated without too much disruption.
Reasons why companies choose not to test*

30% Too costly
29% Too complicated to implement

22% Worried about employee privacy
19% Concerned about test accuracy
18% Worried about liability
17% Test availability
15% Other
13% Time to obtain test results
11% Lack of knowledge or information

* Multiple responses are allowed
* The above distribution represents 68% of companies that test their workers

Future plans for companies who aren’t testing

36% Uncertain
34% Don’t test and don’t plan to test
Employee Wellbeing

77% Of employers indicated that employee mental health wellbeing has become a top priority for their company.

It is almost too obvious to say that everyone’s health and wellbeing has been impacted by the pandemic. While physical health has taken the center stage, mental health is now being acknowledged as every bit a crisis as well. Loneliness, depression and anxiety are present in every demographic. Work has been comes to those challenges—too little work for some and too much work for others.

Our survey focused on five key areas of employee wellbeing: mental health, burnout, productivity, morale and engagement. The goal was to understand employees’ perceptions of how their employees’ wellbeing changed during the pandemic.

The good news is that employers understand. More than three-quarters said that employee mental health is now a top priority. More than half of employers reported an increase in the use of available company resources related to mental health. Perhaps most impressive however is that through all of this stress, employees reported employee engagement and morale increased by over 40%.

The bad news for us is that so many are working so hard to keep it all together – to balance work, family, friends and even some fun. For the most part, it has worked, but we are not sure how much longer that balancing act can last.

50% Of employers reported an increase in the use of available company resources related to mental health since the pandemic began.

How Employee Wellbeing Changed During the Pandemic Compared to Pre-Pandemic

- Mental Health Concerns
  - 57.8% Concerned
  - 11.1% Concerned!

- Engagement
  - 51.8% Concerned
  - 19.6% Concerned!

- Burnout
  - 50.6% Concerned
  - 14.1% Concerned!

- Productivity
  - 46.8% Concerned
  - 19.5% Concerned!

- Morale
  - 44.3% Concerned
  - 26.3% Concerned!

- Productivity
  - 26% Concerned
  - 26% Concerned!

- Burnout
  - 20% Concerned
  - 31% Concerned!

- Morale
  - 21% Concerned
  - 21% Concerned!

ASUWorkplaceCommons.com
Future of Work Overview

72% Intend to offer flexible or expanded work from home policies post-pandemic

68% Believe employees should be in the office at least 20 hours a week

63% Intend to allow employees to work from home full-time through 2021

How will the pandemic change our work life in the future? Will it improve? The answer is clearly in the eyes of the beholder. Our survey showed that the “Work From Home” phenomenon will not end soon and will not end as abruptly as it began.

Companies reported that 67% of their employees are still remote and almost two-thirds of employers plan to allow their employees to remain remote through 2021. Yet employers understand the value of people coming together under one roof – over two-thirds of global employers believe that employees should be in the office at least 20 hours per week citing their top reason as it allows for social connections to be formed and maintained amongst colleagues. Interestingly, the most commonly cited challenge by employers for not returning to the physical workspace is that employees did not want to return, and they indicated that personal health and facility safety were the top concerns of their workforce.
Users hover over each option at the top to see real survey answers regarding each question or topic.
MS Biomedical Diagnostics

Program Overview

- Unique graduate program focusing on biomedical diagnostics
- Graduates of the program will have a broad understanding of the business and practices of diagnostics
- Program includes Applied Project – Field work for every student
- Work opportunities for graduates are wide and varied

30 Credits
1 year to 1.5 year
100% Online
Part-Time & Full-Time
Two starts: Aug & Jan
ASU Biomedical Diagnostics Mission

- Educate next generation of healthcare executives to understand and appreciate Diagnostics in clinical medicine and scientific research
- Educate students to be active and impactful members of the healthcare and life science communities through coursework and exposure to industry
- Shape Diagnostic policy worldwide through research and partnerships with industry
- Establish the field of Diagnostics as a discipline distinct and unique from, yet integral to, other fields within Health and Life Sciences
First and only interactive national repository of research on COVID-19 tests & testing.
ConnectToTest.com

- Connect to Test is a new tool that helps organizations and individuals find the right COVID-19 tests for their unique needs.
- Online tool to locate and purchase available tests from Project N95.org
- Developed in collaboration with WhenToTest.org.
Testing Technology Trends (T3)

Short analyses of COVID-19 testing related topics including wastewater testing, variant surveillance and test accuracy.

Viral load and Ct values – How do we use quantitative PCR quantitatively?
April 10, 2021 | Mara G. Assaf

Viral load impacts disease severity, and most COVID-19 testing identifies it, but this data rarely gets reported. This blog explains why and looks at some challenges in sharing viral load test results with clinicians and epidemiologists.

COVID-19 testing: Going to the dogs?
April 2, 2021 | Omar Joseph, Mara G. Assaf

You may not be feeling sick as a dog, but if you’ve been infected with COVID-19, there’s a good chance a dog would sniff it out.

SARS-CoV-2 diagnostics: A moving target
March 22, 2021 | I.C. Gwynn Timefort

Variants, vaccination and testing: Factor all three into COVID-19 diagnostics, and things get complicated. Variants have the potential to impact the accuracy of some tests, while vaccination raises the possibility of false positives.

All eyes on Israel and Brazil
February 8, 2021 | Mara G. Assaf

Which COVID-19 strains are most worrisome? Can they re-infect people who’ve already recovered from one bout of the virus? Do mutations threaten to derail our testing strategies, treatment protocols and vaccine effectiveness?
Taking Back Control Webinars

**Webinars**

- **Global Perspectives on COVID-19 Variants, Vaccines and Testing**
  March 25, 2021 | [View recording](#)

- **Roadmap to Reopening K-12 Schools**
  Feb. 23, 2021 | [View recording](#)

- **Local, National and Global Decision Making During COVID-19**
  Jan. 14, 2021 | [View recording](#)

- **Taking Back Control During COVID-19: Leading Innovation Through Uncertain Times**
  Dec. 16, 2020 | [View recording](#)

- **COVID-19: Impact on Health & Wellbeing of our Employees**
  Sept. 11, 2020 | [View recording](#)

- **Worker Testing, Contact Tracing and Physical Movement**
  Sept. 10, 2020 | [View recording](#)

- **COVID-19 Information Overload: Taking Back Control**
  Sept. 9, 2020 | [View recording](#)

- **COVID-19: A Blueprint for Keeping the U.S. Economy Open**
  July 22, 2020 | [View recording](#)

- **COVID-19 and effective diagnostics: The key to recovery of health, society, and the economy**
  April 17, 2020 | [View recording](#)

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**Speakers**

- **Larry Gadea**
  Envoy

- **Dr. Rajiv Shah**
  The Rockefeller Foundation

- **The Honorable Kate Gallego**
  Mayor, City of Phoenix

- **John Dony**
  National Safety Council

- **Jason Kelly**
  Ginkgo BioWorks

- **Deepak Nath**
  Siemens Healthineers

- **Trent Burner**
  Society for Human Resource Management

- **Suzanna Jemsby**
  Washington International School

- **Robert Margolis**
  Duke-Margolis Center for Health Policy

- **Tamsin Berry**
  Population Health Partners

- **Mara G. Aspinall**
  Arizona State University

- **Alan Tennenberg**
  World Economic Forum

- **Mike Magee**
  Chiefs for Change

- **Roger Steen**
  ASA

- **Dr. Michael Crow**
  Arizona State University
Don’t Forget to Follow us on Social Media:

-asuhealth-
asuhealthsolutions
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

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