

# Clinical Laboratory COVID-19 Response Call

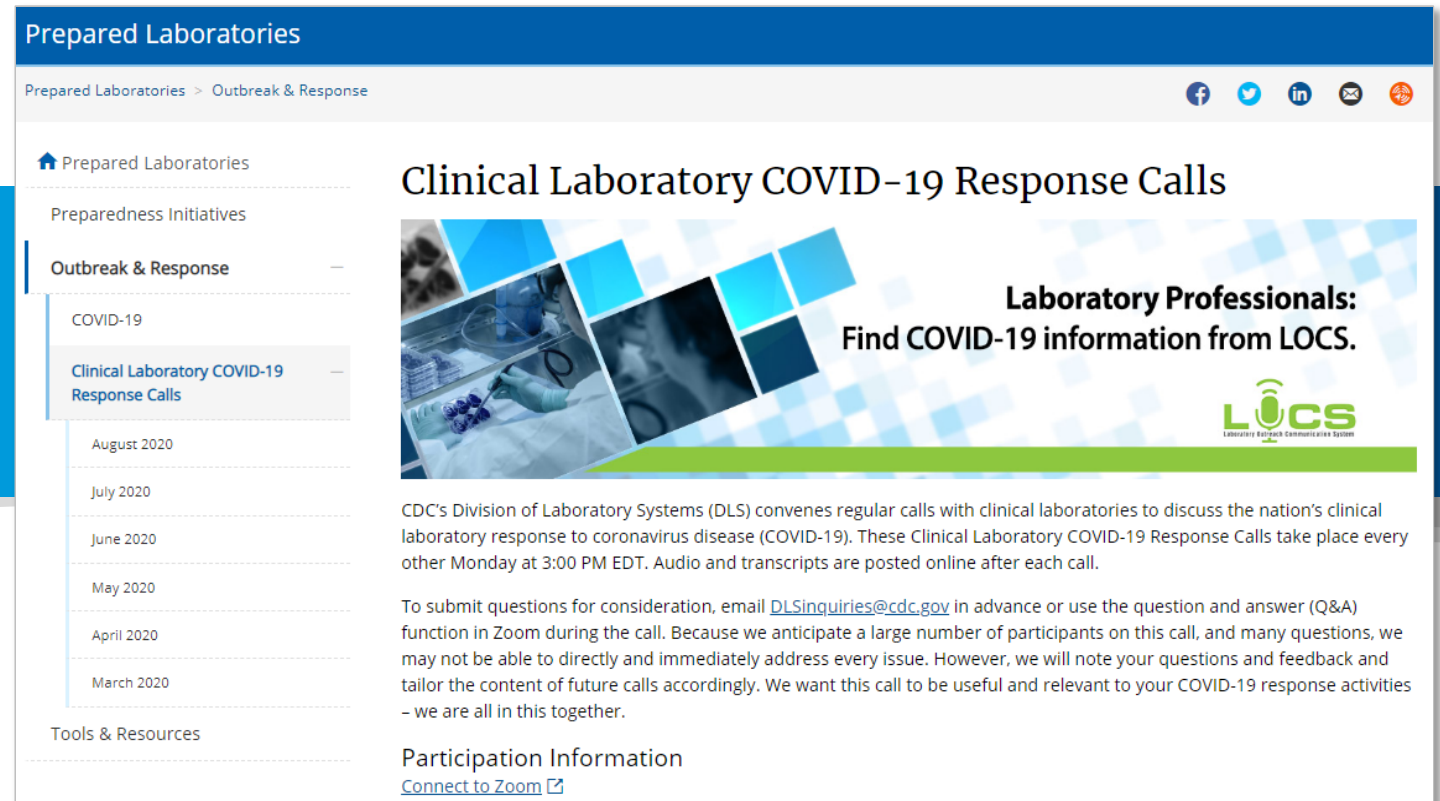
Monday, July 12, 2021, at 3:00 PM EDT

- **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)

# 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 in a lab coat. 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 of text explaining the purpose of the calls and how to submit questions. At the bottom, there is a 'Participation Information' section with a 'Connect to Zoom' link. On the left side of the page, there is a navigation menu with options like 'Preparedness Initiatives', 'Outbreak & Response', 'COVID-19', 'Clinical Laboratory COVID-19 Response Calls', and 'Tools & Resources'. The 'Clinical Laboratory COVID-19 Response Calls' option is selected, and a list of months from August 2020 to March 2020 is visible.

Prepared Laboratories

Prepared Laboratories > Outbreak & Response

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.

LOCS  
Laboratory Outreach Communications System

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, July 26** 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?

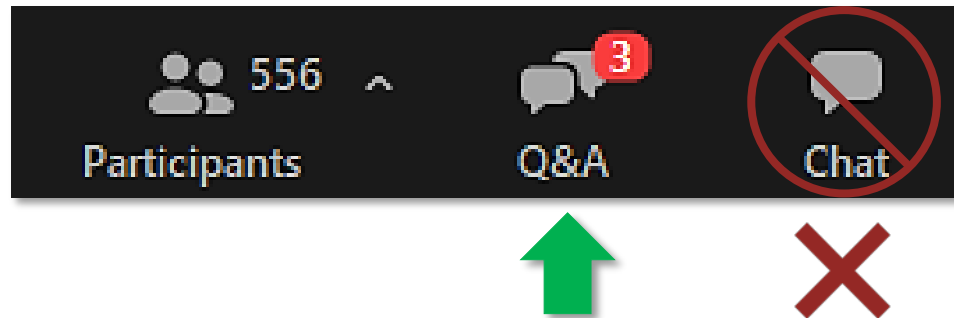
Contact [LabTrainingNeeds@cdc.gov](mailto:LabTrainingNeeds@cdc.gov)




# 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

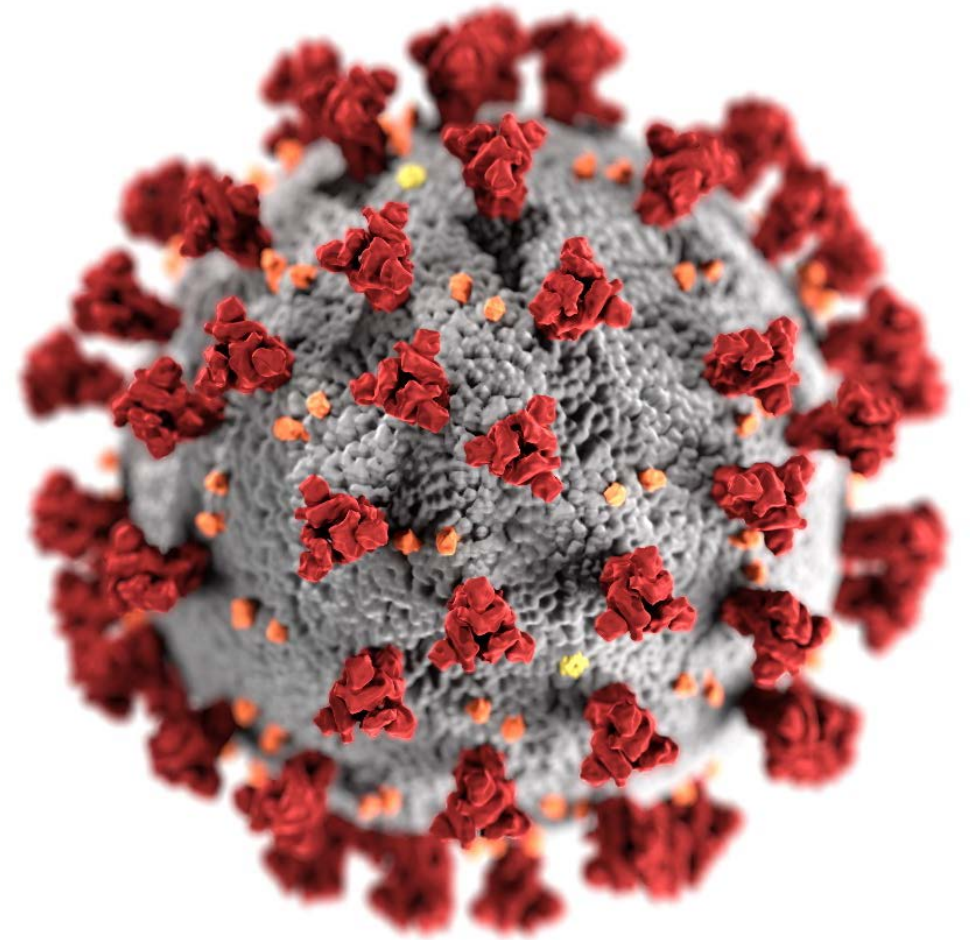


*Slide decks may contain presentation material from panelists who are not affiliated with CDC. Presentation content from external panelists may not necessarily reflect CDC's official position on the topic(s) covered.*

# Variants Update

**Jessica Chen, PhD**

**7/12/2021**



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

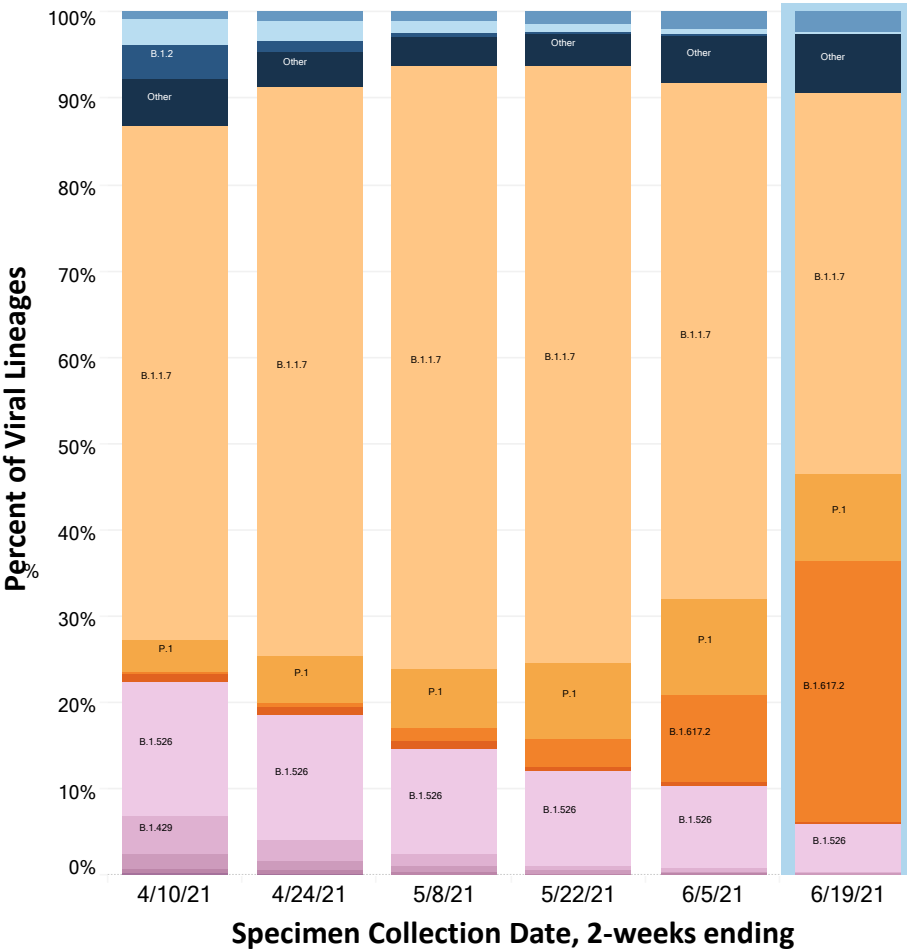


# National Prevalence of SARS-CoV-2 Variants



## U.S. 3/28/2021 – 06/19/2021

## U.S. 6/6/2021 – 06/19/2021



	Lineage	Type	%Total	95%CI		
Most common lineages #	B.1.1.7	Alpha	VOC	44.2%	39.8-48.8%	
	B.1.617.2	Delta	VOC	30.4%	24.1-37.7%	
	P.1	Gamma	VOC	9.9%	7.6-13.0%	
	B.1.526	Iota	VOI	5.5%	4.3-6.9%	
	B.1			2.2%	1.4-3.5%	
Additional VOI/VOC lineages #	B.1.1.1.519			0.2%	0.1-0.4%	
	B.1.2		†	0.0%	0.0-0.1%	
	B.1.351	Beta	VOC	0.2%	0.1-0.5%	
	B.1.429	Epsilon	VOI	0.1%	0.0-0.4%	
	B.1.525	Eta	† VOI	0.1%	0.0-0.4%	
	B.1.427	Epsilon	VOI	0.1%	0.0-0.3%	
	B.1.617.1	Kappa	† VOI	0.0%	0.0-0.1%	
	B.1.617.3		† VOI	0.0%	NA	
	P.2	Zeta	† VOI	0.0%	NA	
	Other*	Other		6.9%	5.3-8.9%	

\* "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

- 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%

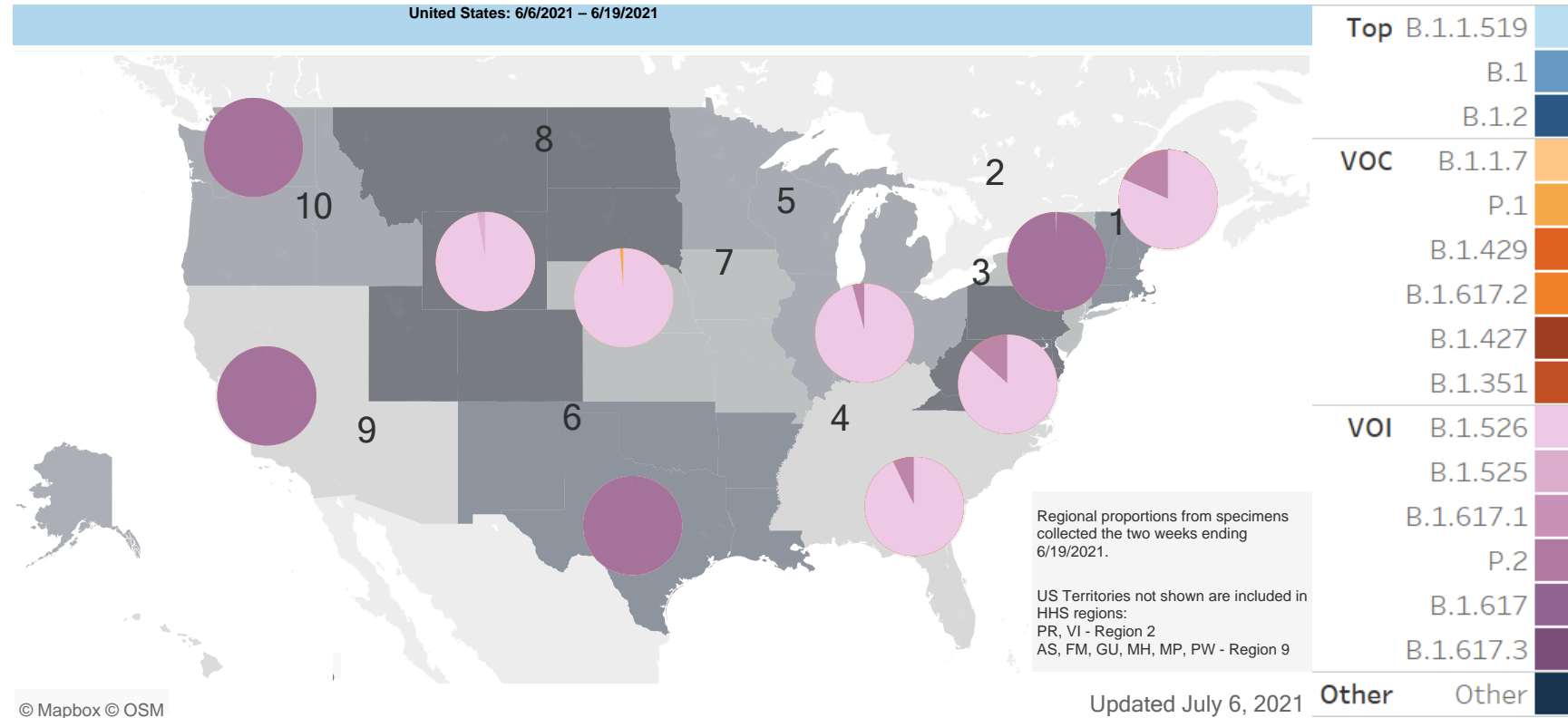
**Variant of Concern:** Evidence of increased transmissibility, more severe disease (hospitalizations or mortality), reduced therapeutic effectiveness, significant reduction in neutralization (convalescent or vaccinee sera), diagnostic impact, assessed to be VOC by WHO/WHO SARS-CoV-2 Virus Evolution 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

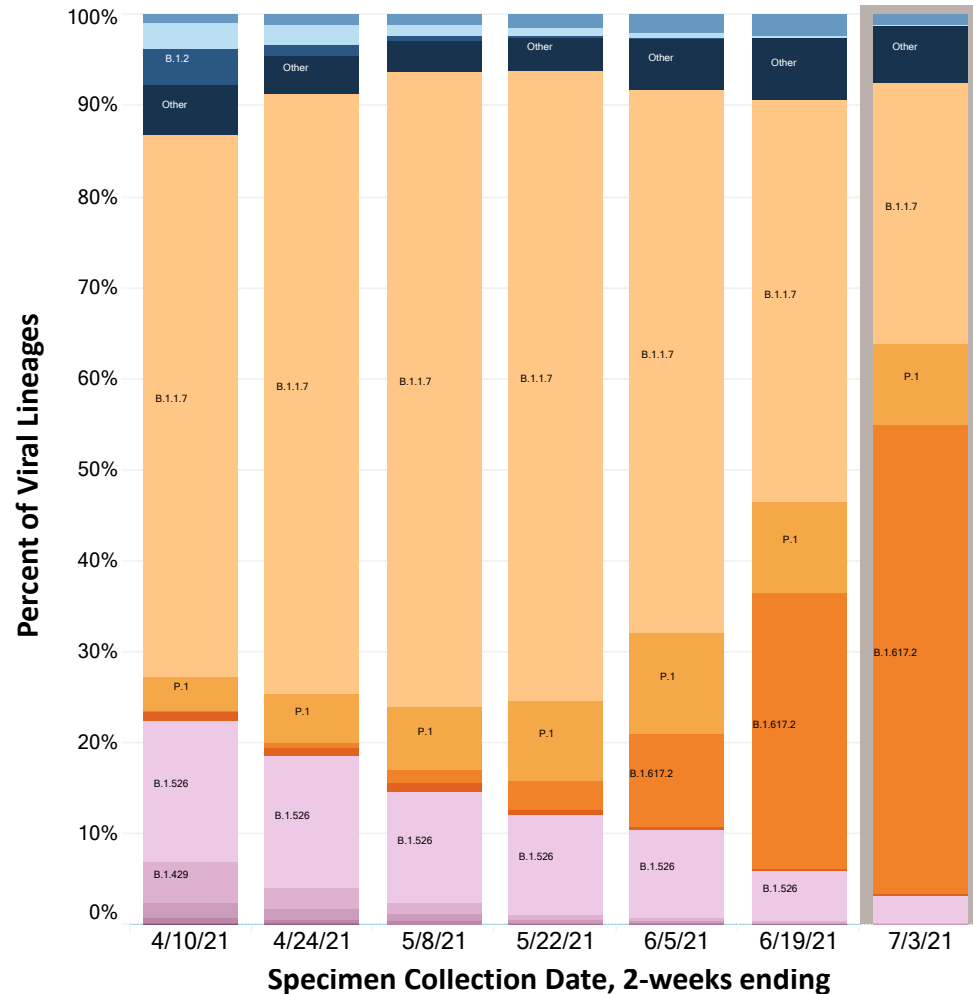


# National Nowcast Estimates SARS-CoV-2 Lineages



U.S. 3/28/2021 – 7/3/2021

NOWCAST U.S. 6/20/2021 – 7/3/2021



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

- **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

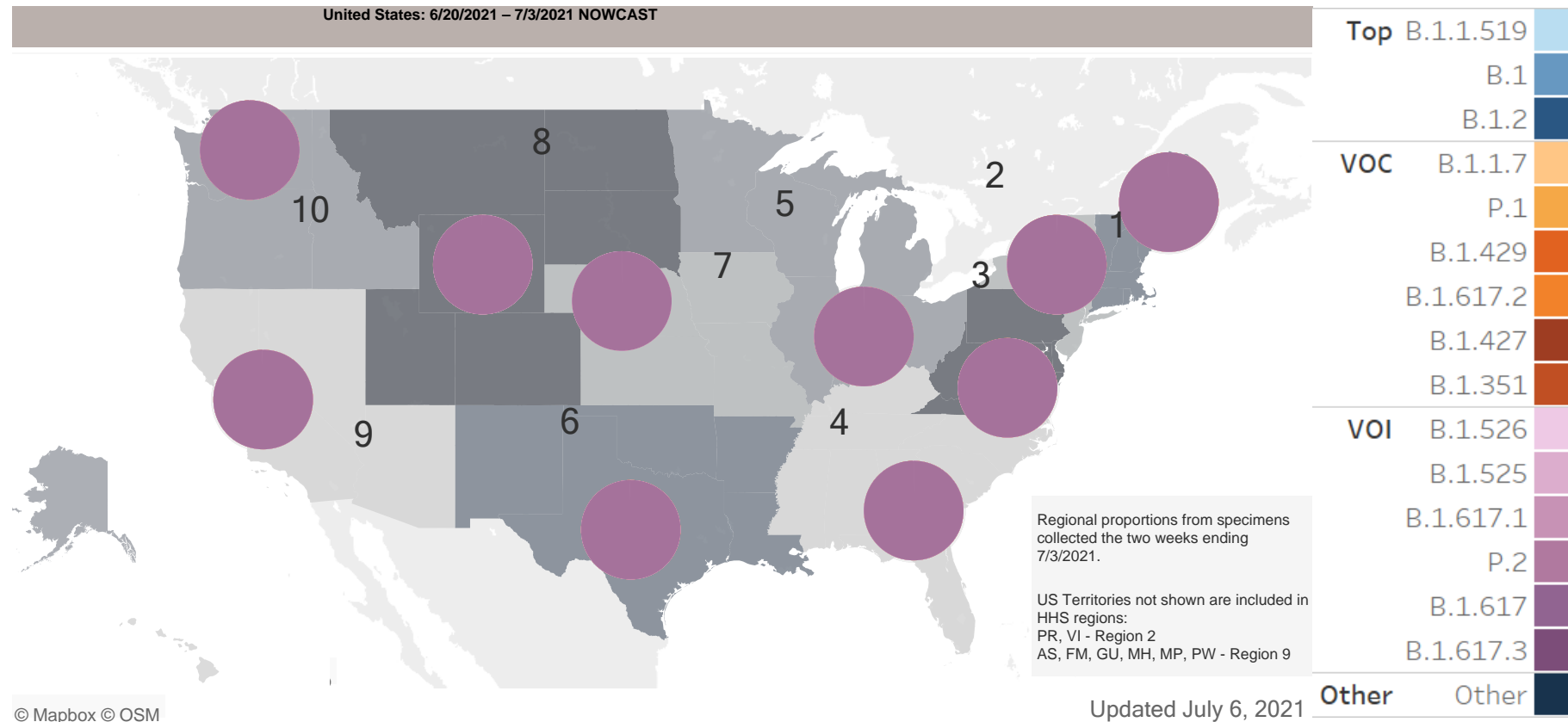
\*\* These data include Nowcast estimates, which are modeled projections that may differ from weighted estimates generated at later dates

# 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



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

# ASU COVID-19 Diagnostics Commons



**ASU**  
**COVID-19**  
DIAGNOSTICS COMMONS

[ASUcovidcommons.com](https://ASUcovidcommons.com)



**ASU** College of  
**Health Solutions**  
Arizona State University

**Master Degree in  
Biomedical Diagnostics**



**COVID-19**  
TESTING COMMONS



**COVID-19**  
WORKPLACE COMMONS



**COVID-19**  
EVIDENCE COMMONS



**CONNECT**  
TO TEST



**TESTING**  
TECHNOLOGY  
TRENDS



TAKING BACK  
CONTROL  
**WEBINARS**

**COVID-19**  
TESTING COMMONS

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.



**COVID-19**  
EVIDENCE COMMONS

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



**COVID-19**  
WORKPLACE COMMONS

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.

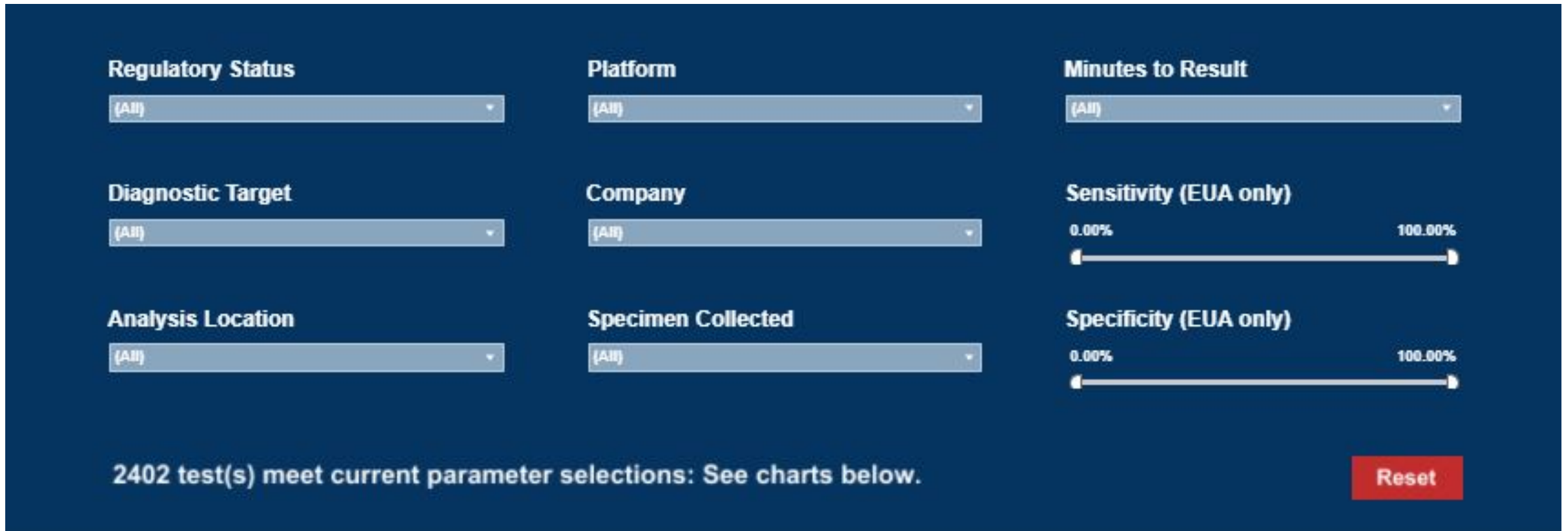


**CONNECT**  
TO TEST

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.



# TestingCommons.com

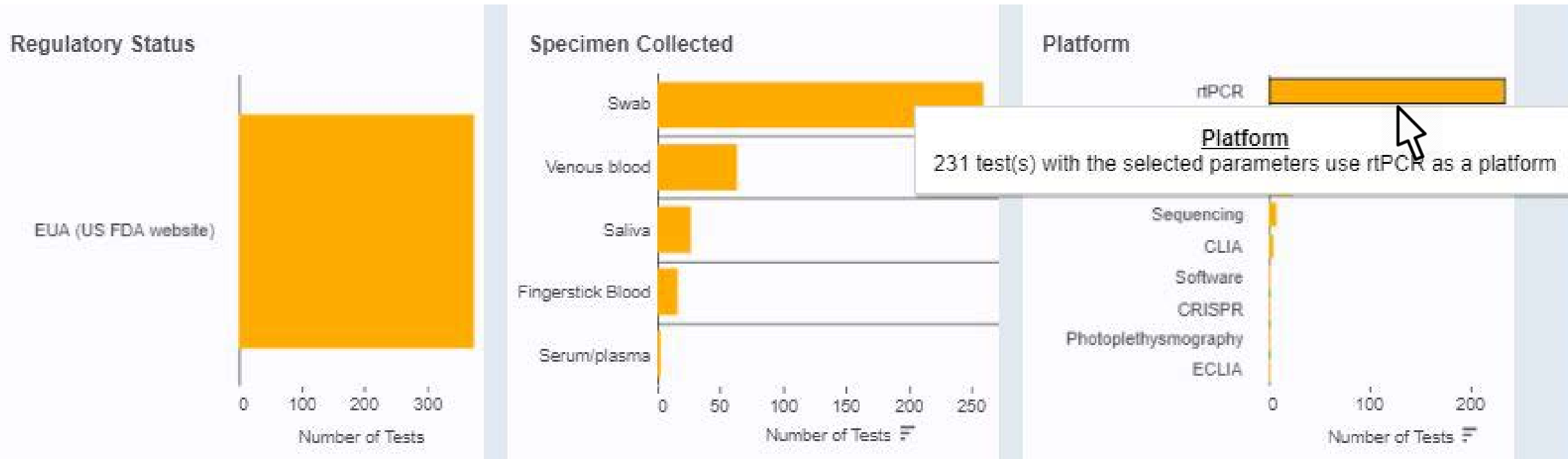


The screenshot shows a search interface with the following elements:

- Regulatory Status:** A dropdown menu with "[All]" selected.
- Platform:** A dropdown menu with "[All]" selected.
- Minutes to Result:** A dropdown menu with "[All]" selected.
- Diagnostic Target:** A dropdown menu with "[All]" selected.
- Company:** A dropdown menu with "[All]" selected.
- Sensitivity (EUA only):** A horizontal slider ranging from 0.00% to 100.00%.
- Specificity (EUA only):** A horizontal slider ranging from 0.00% to 100.00%.
- Analysis Location:** A dropdown menu with "[All]" selected.
- Specimen Collected:** A dropdown menu with "[All]" selected.
- Summary:** "2402 test(s) meet current parameter selections: See charts below."
- Reset:** A red button to clear the filters.

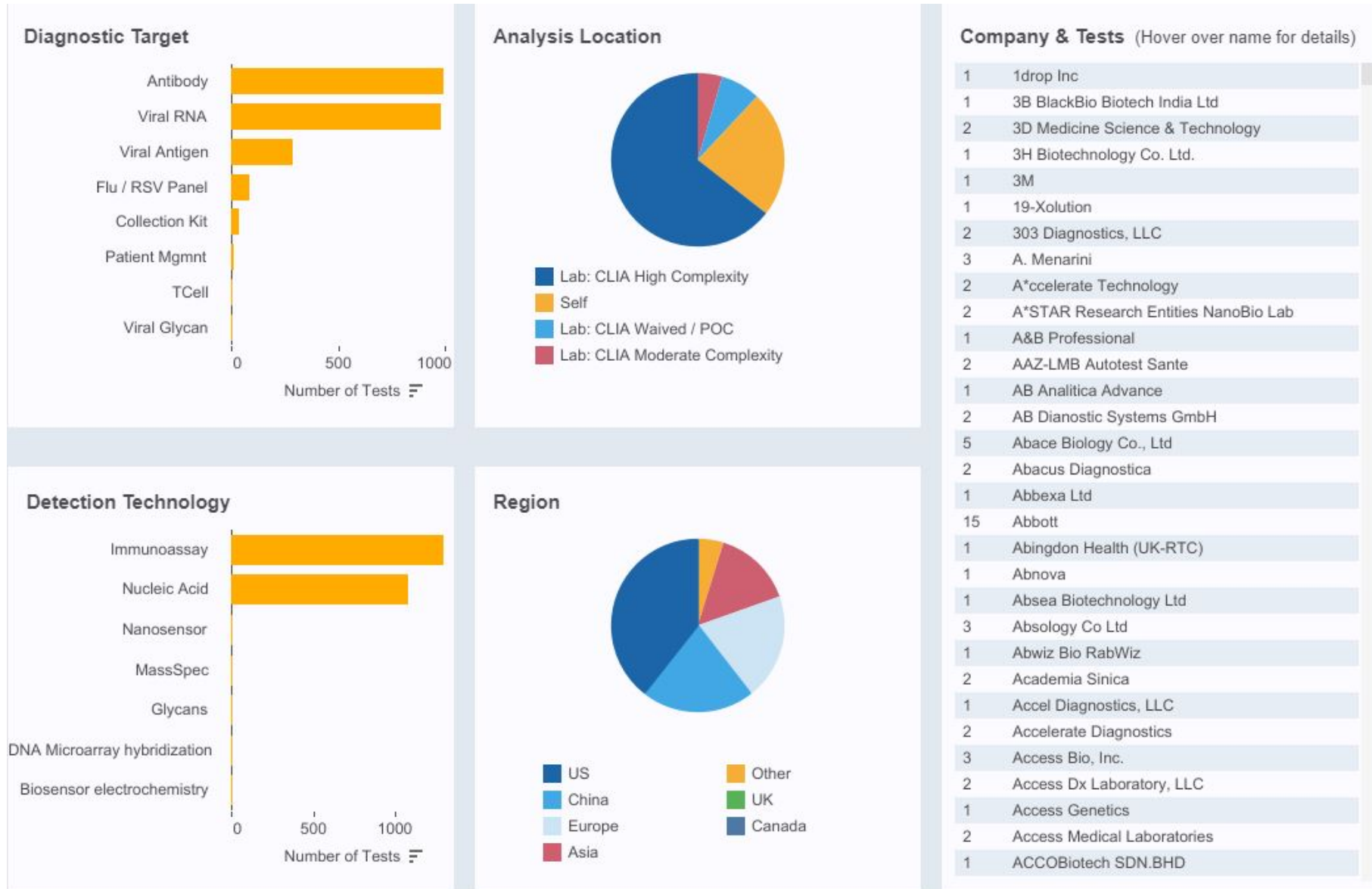
Upon entering the site, you will be greeted with these interactive parameters which can be easily adjusted to fit your company's area(s) of interest regarding COVID-19 testing. Each of the above options has its own drop-down menu to allow for customized data.

# TestingCommons.com



From there, you can hover over any parameter for more detailed information on the number of tests that fit your criteria.





## Company & Tests (Hover over name for details)

Count	Company Name
1	BGI Genomics Co. Ltd
1	BillionToOne
1	binx Health
4	Bio-Rad Laboratories Inc.
1	Biocan Diagnostics Inc.
3	BioCheck, Inc.
1	BioCore Co., Ltd
1	Bioekser R&D Technologies
1	Biofire Defense
2	Biofire Diagnostics
1	BioHIT HealthCare (Hefei) Co., Ltd
1	Biomeme
3	bioMérieux

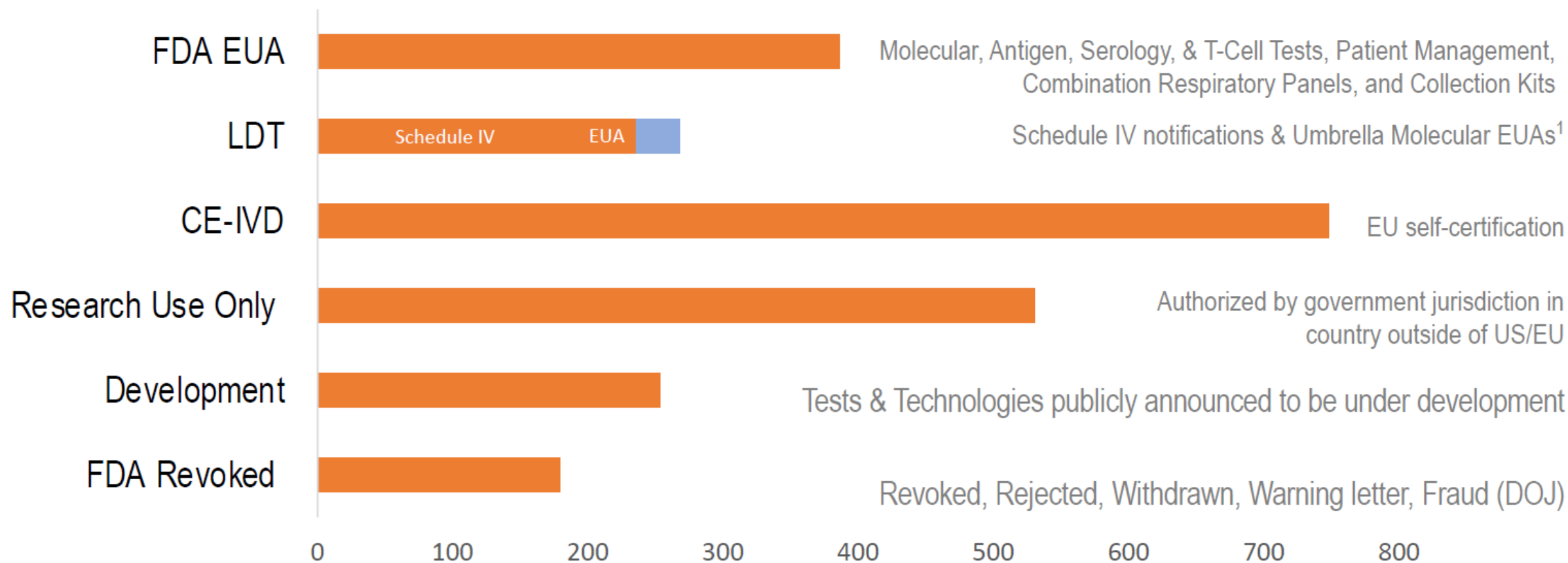
**Bio-Rad Laboratories Inc.**  
 Test Name: Bio-Rad Reliance SARS-CoV-2/FluA/FluB RT-PCR Assay Kit  
 Company HQ: CA  
 Regulatory Status: EUA (FDA website)  
 Platform: rPCR  
 Sample Type: Swab  
 Specimen Collected by: HC Prof  
 Specimen Collection Sub-type: MT,NASAL,NP,OP  
 Diagnostic Target: Flu / RSV Panel  
 Detection Technology: NAT  
 Analysis Location: Lab: CLIA High Complexity  
 Total Sensitivity: 97.60%  
 Total Specificity: 100.00%  
 Time to Result (minutes): 217  
 EUA listed LoD: 0.949

**Bio-Rad SARS-CoV-2 ddPCR Test**  
 Company HQ: CA  
 Regulatory Status: EUA (FDA website)  
 Platform: rPCR  
 Sample Type: Swab  
 Specimen Collected by: HC Prof  
 Specimen Collection Sub-type: NASAL,NP  
 Diagnostic Target: VirRNA  
 Detection Technology: NAT  
 Analysis Location: Lab: CLIA High Complexity  
 Total Sensitivity: 94.87%  
 Total Specificity: 94.87%  
 Time to Result (minutes): 170  
 EUA listed LoD: 0.149  
 FDA Panel LoD: 0.599

**BioRad Reliance SARS-CoV-2 RT-PCR Assay Kit**  
 Company HQ: CA  
 Regulatory Status: EUA (FDA website)  
 Platform: rPCR  
 Sample Type: Swab  
 Specimen Collected by: HC Prof  
 Specimen Collection Sub-type: MT,NASAL,NP,OP  
 Diagnostic Target: VirRNA  
 Detection Technology: NAT  
 Analysis Location: Lab: CLIA High Complexity  
 Total Sensitivity: 100.00%  
 Total Specificity: 100.00%  
 Time to Result (minutes): 217  
 EUA listed LoD: 0.25

**Platelia SARS-CoV-2 Total Ab assay**  
 Company HQ: CA  
 Regulatory Status: EUA (FDA website)  
 Add'l Regulatory Status: Australia TGA - Singapore HAS  
 Platform: ELISA  
 Sample Type: Venous blood  
 Specimen Collected by: HC Prof  
 Diagnostic Target: Antibody  
 Detection Technology: IA  
 Analysis Location: Lab: CLIA High Complexity  
 Total Sensitivity: 98.00%  
 Total Specificity: 99.30%  
 Time to Result (minutes): 105

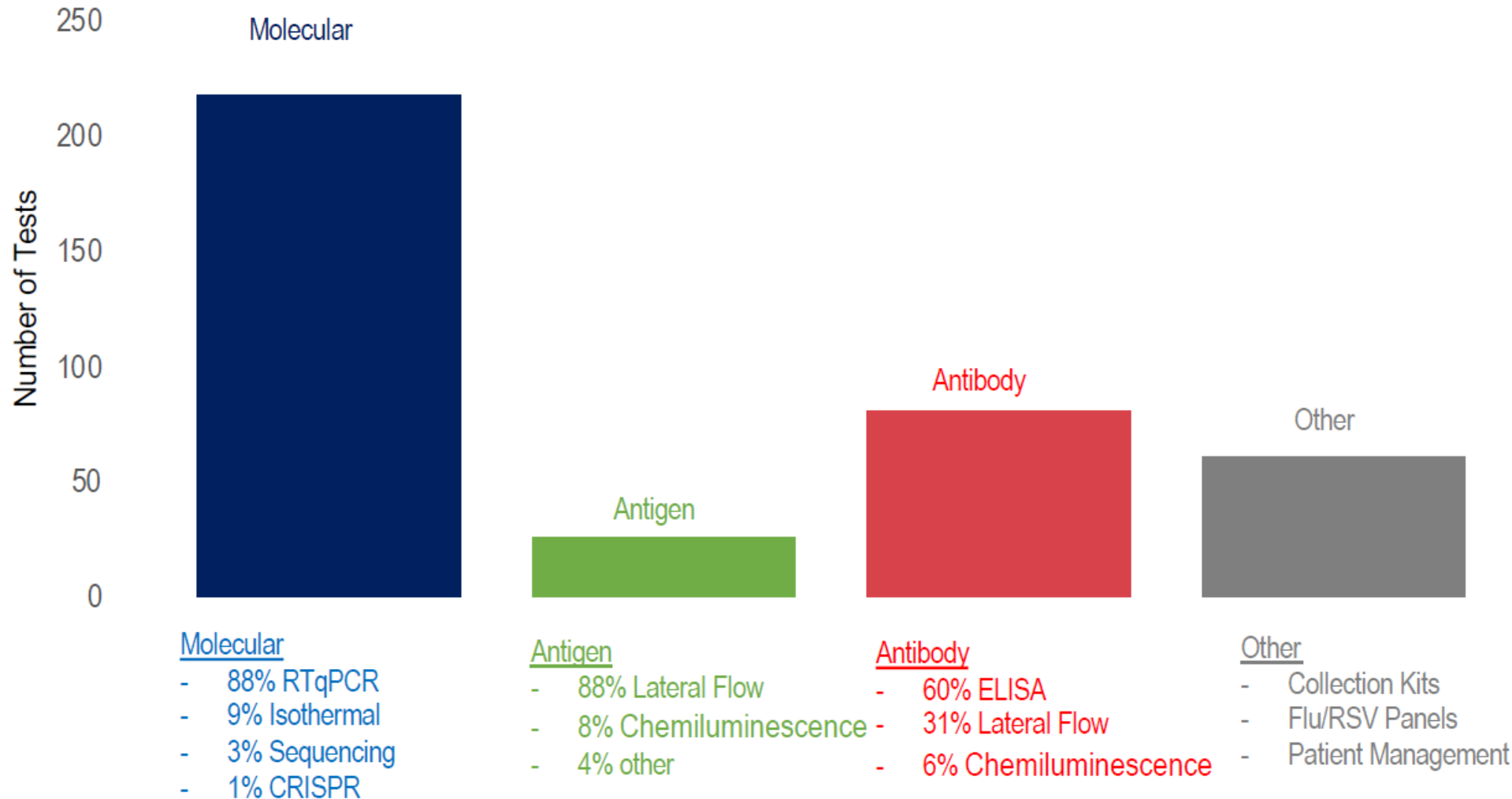
# TestingCommons.com Pandemic Review



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

# US FDA Emergency Use Authorizations



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



**COVID-19**  
WORKPLACE COMMONS

FSU Florida State University  
with support from  
HOSPITALITY FOUNDATION

# Survey Overview

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



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

# Top 10 Insights



## Vaccination Strong Support by Employers

- 88% of employers plan to require or encourage their employees to be vaccinated against COVID-19
- 59% of employers plan to incentivize their employees to be vaccinated against COVID-19
- 60% 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
- 58% 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

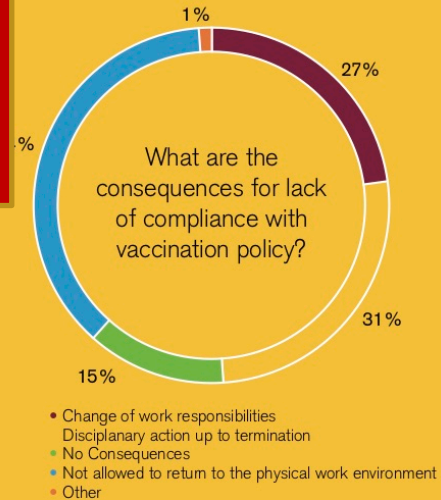
**40%** Require all employees to be vaccinated against COVID-19

**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



# 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.

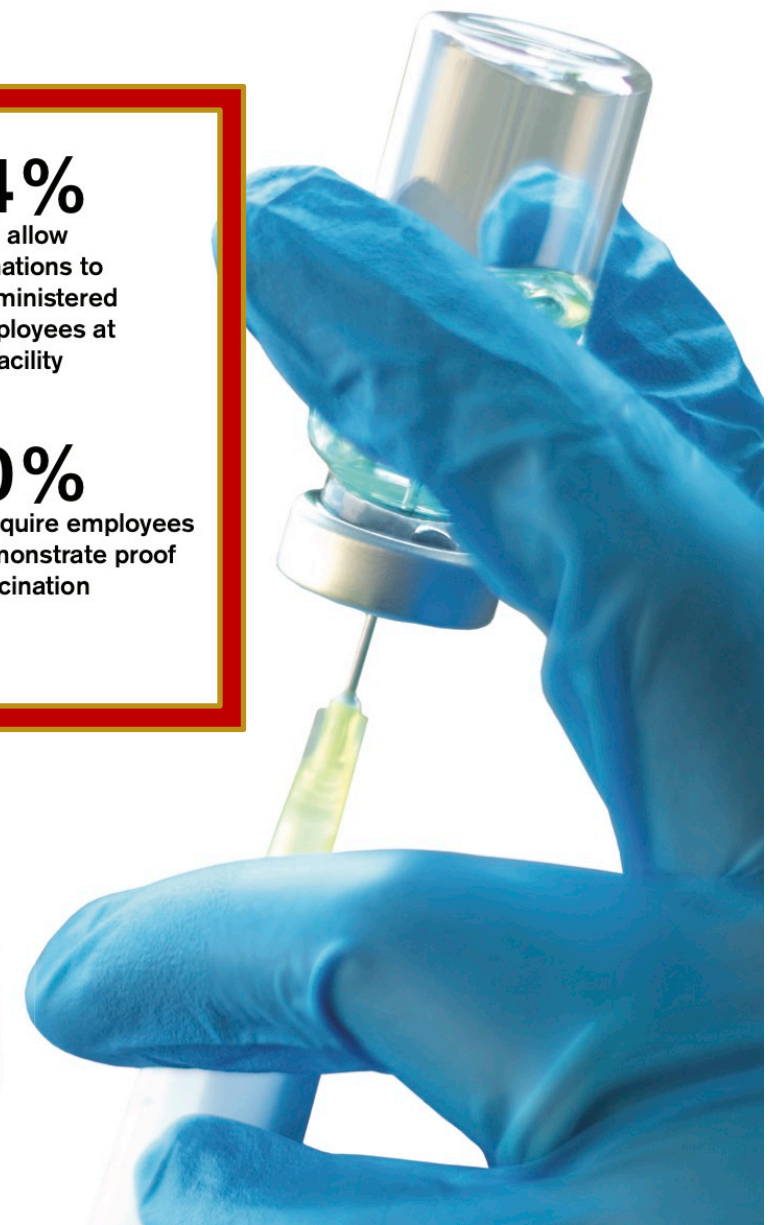
Our survey showed surprisingly high support for vaccination with almost 90% of employers planning to require or at least encourage their employees to get vaccinated. Our survey asked employers their stance on a variety of other issues related to COVID-19 vaccination and their employees, and their responses 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



**COVID-19 Vaccination Record Card**

Please keep this record card, which includes medical information about the vaccines you have received.

Por favor, guarde esta tarjeta de registro, que incluye información médica sobre las vacunas que ha recibido.

Last Name \_\_\_\_\_ First Name \_\_\_\_\_ MI \_\_\_\_\_

Patient number (medical record IIS record number) \_\_\_\_\_

Date of birth \_\_\_\_\_

Vaccine	Product Name/ Manufacturer Lot Number	Date	Healthcare Professional or Clinic Site
1 <sup>st</sup> Dose COVID-19	.....	mm / dd / yy	
2 <sup>nd</sup> Dose COVID-19	.....	mm / dd / yy	
Other	.....	mm / dd / yy	
Other	.....	mm / dd / yy	

# Testing & Contact Tracing

**68%** Test their workers

**29%**  
Daily Testing

**43%**  
Weekly Testing

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 EUA's 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

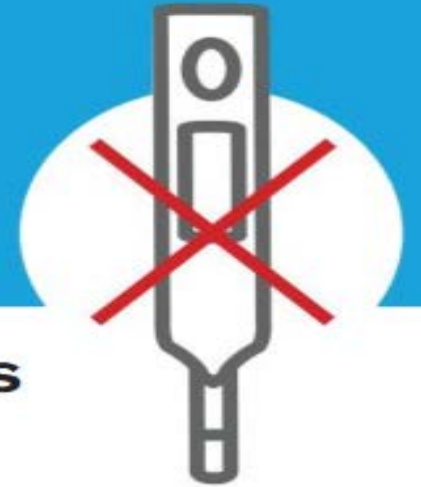
**17%** Test availability

**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

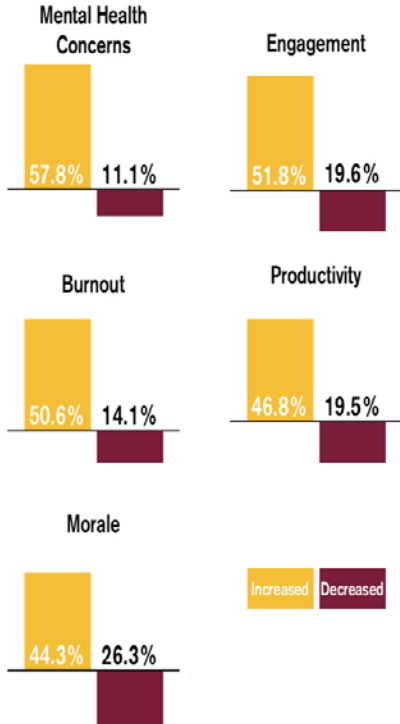
It is almost too obvious to say that everyone's health and wellbeing has been impacted by the pandemic. While physical health has taken the center stage, mental health is now being acknowledged as every bit a crisis as well. Loneliness, depression and anxiety are present in every demographic. Work has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

Our survey focused on five key areas of employee well-being: mental health, burnout, productivity, morale and engagement. The goal was to understand employers' 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, employers reported employee engagement and morale increased by over 40%.

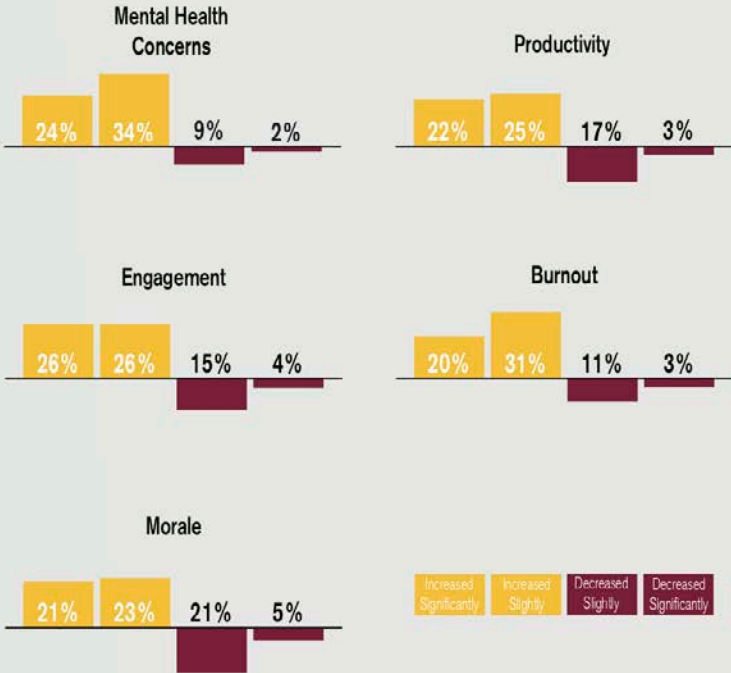
The bottom line for us is that so many are working so hard to keep it all together – to balance work, family, friends and even some fun. For the most part, it has worked, but we are not sure how much longer that balancing act can last.

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



**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



# 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 57% 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.



Spring 21 | Fall 20

About Survey & Case Studies | Testing & Contact Tracing | Vaccination | Employee Wellbeing | Future of Work | Pandemic Response & Preparedness | Financial Impact

Filter by continent | Filter by industry | Number of Employees

**Testing** | Overview | **Viral** | Antibodies | Contact Tracing

Test their workers 68%	Test only for viral infection 31%	Test only for antibodies 5%	Test for both 59%
---------------------------	--------------------------------------	--------------------------------	----------------------

Below distribution represents 68% of companies that test their workers

Reasons why companies choose not to test \*

Too costly	30%
Too complicated to implement	29%
Worried about employee privacy	22%
Concern about test accuracy	19%
Worried about liability	18%
Test availability	17%
Other	15%
Time to obtain test results	13%
Lack of knowledge or information	11%

Spring 21 | Fall 20

About Survey & Case Studies | Testing & Contact Tracing | **Vaccination** | Employee Wellbeing | Future of Work | Pandemic Response & Preparedness | Financial Impact

Filter by continent | Filter by industry | Number of Employees

**Vaccination**

Plan to incentivize employees to be vaccinated 59%	Would allow vaccinations to be administered to employees at their facility 84%	Plan to change safety mitigation measures once broad vaccination is achieved 61%	Will require employees to demonstrate proof of vaccination 60%
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Companies' policies for employees regarding COVID-19 vaccination

Require all employees to be vaccinated against COVID-19	40%
Encourage but not require employees to be vaccinated against COVID-19	32%
Require some employees to be vaccinated against COVID-19	16%
We don't have a policy developed at this time	
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?

Other	44%
Change of Work Responsibilities	27%
Disciplinary action up to termination	31%
No consequences	15%
Not allowed to return to the physical	

Users hover over each option at the top to see real survey answers regarding each question or topic.

A male scientist with dark hair, wearing a white lab coat and blue nitrile gloves, is focused on his work in a laboratory. He is using a blue pipette to transfer liquid into a clear plastic multi-well plate. The background shows a typical laboratory environment with shelves of supplies and other equipment. A yellow banner with black text is overlaid on the bottom half of the image.

# MS Biomedical Diagnostics



# MS Biomedical Diagnostics Program Overview

30 Credits

1 year to 1.5 year

100% Online

Part-Time & Full-Time

Two starts: Aug & Jan

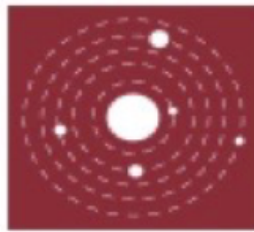
- Unique graduate program focusing on biomedical diagnostics
- Graduates of the program will have a broad understanding of the business and practices of diagnostics
- Program includes Applied Project – Field work for every student
- Work opportunities for graduates are wide and varied

# ASU Biomedical Diagnostics Mission

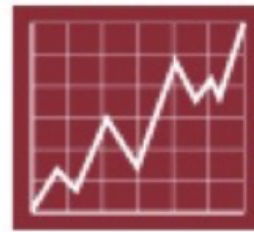
- *Educate next generation of healthcare executives to understand and appreciate Diagnostics in clinical medicine and scientific research*
- *Educate students to be active and impactful members of the healthcare and life science communities through coursework and exposure to industry*
- *Shape Diagnostic 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*



Science  
of Diagnostics



Technology  
of Diagnostics



Business  
of Diagnostics



Application  
of Diagnostics

First and only interactive national repository of research on COVID-19 tests & testing.

Research Dashboard

Hide Filters

Visualization Table

Search

Studies in repository: 75 This component of the Evidence Commons is in Beta Version.

ID	Study Status	Study Title/ Name	Study Category	Location	Study Description
1	Completed	University of California, San Francisco - Study on Effectiveness of Rapid Tests	Test Comparison	California (United States of America)	The objective of this study is to test the effectiveness of rapid antigen tests which have lower sensitivity compared to PCRs in a community test setting to identify infectious individuals. The initiative tested 87 over three days. Twenty-six individuals tested positive on PCR tests and were connected to care and isolation through the community "test to care" model that Unidos end Salud has pioneered and deliver partnership with the San Francisco Department of Public Health.
2	Completed	Supervised Self-collected SARS-CoV-2 Testing in Indoor Summer Camps to Inform School Reopening	Test Protocols	California (United States of America)	Testing strategies for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection in schools are needed to assess the efficacy of infection mitigation strategies and inform school reopening policies hypothesized that supervised serial self-collected non-nasopharyngeal testing in summer camp setting acceptable and feasible.
3	Completed	Rapid Serological Tests Have a Role in Asymptomatic Health Workers COVID-19 Screening	Test Comparison	Italy	In this original study on health workers, the Viva-Diag Rapid was able to identify subjects positive for a CoV-2 IgM. However, discordant results with respect to r-PCR and CLIA assays clearly refer to further optimize the utilization of the serological test in asymptomatic and in at risk subjects.
4	Completed	A Clinical Performance Evaluation of the SARS-COV-2 Direct Antigen Rapid Test "DART"	Test Validation/Evaluation	Florida (United States of America)	A rapid assay that does not require the sophisticated laboratory equipment and techniques could provide significant advantage to the way practitioners screen and ultimately treat patients. Moreover, the collection samples from the nasal nares should prove useful and less invasive. The study aims to validate the use of swabs and also to validate the antigen test, BIOCREDT COVID-19 Ag test, using nasal swabs.

Submit Entry Evidence Commons

COVID-19 EVIDENCE COMMONS

ASU UNIVERSITY OF ARIZONA WITH SUPPORT FROM RWJ FOUNDATION

Research Dashboard

Hide Filters

Visualization Table

Search

Studies in repository: 75 This component of the Evidence Commons is in Beta Version.

Location (Global view) Switch to U.S. View

Study Status

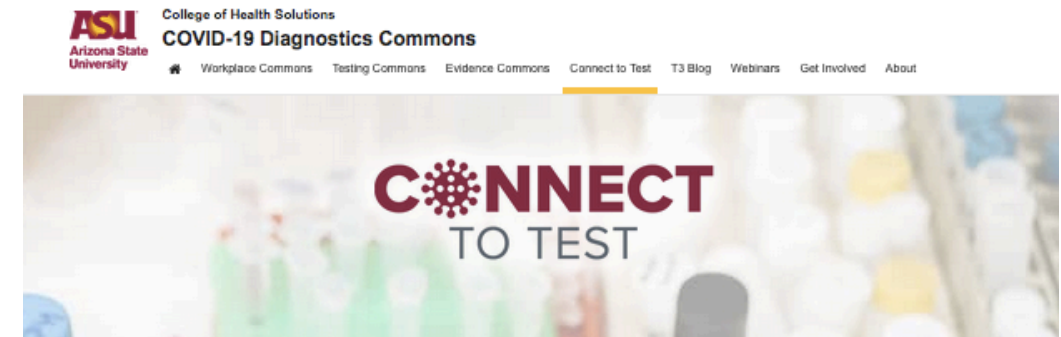
Study Type

Study Category

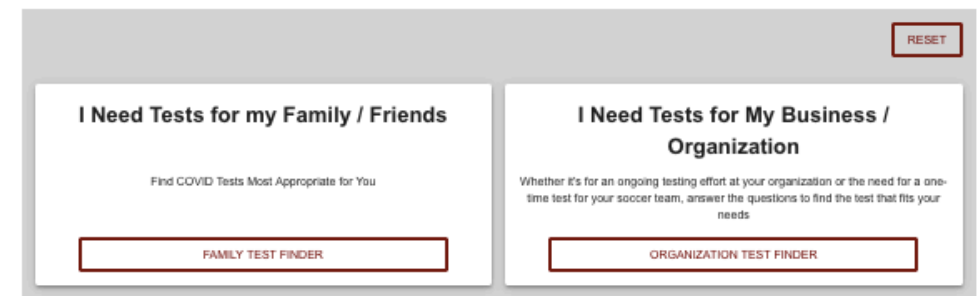
Note: Table may not sum as expected because studies in the evidence commons may have more than one tag.

# 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.



Connect to Test is a new tool that helps organizations and individuals find the right COVID-19 tests for their unique needs. Developed in collaboration with When To Test and Project N95, Connect to Test will allow users to make informed and speedy COVID-19 testing decisions.



# 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 16, 2021 | Mara G. Aspinall

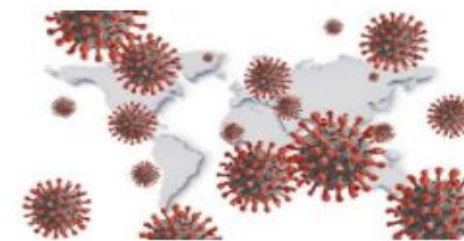
Viral load impacts disease severity, and most COVID-19 testing identifies it, but this data rarely gets reported. This blog explains why and looks at some challenges in sharing viral load test results with clinicians and epidemiologists.



## [COVID-19 testing: Going to the dogs?](#)

April 2, 2021 | Genie Joseph, Mara G. Aspinall

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 | L. Gayani Tillekeratne

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. Aspinall

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. 25, 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](#)



**Larry Gadea**  
Envoy



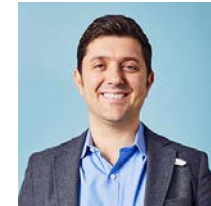
**Dr. Rajiv Shah**  
The Rockefeller Foundation



**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



**Mike Magee**  
Chiefs for Change



**Mara G. Aspinall**  
Arizona State University



**Alan Tennenberg**  
World Economic Forum



**Dr. Michael Crow**  
Arizona State University



**Roger Steen**  
Yara International ASA

# ASU COVID-19 Diagnostics Commons



[ASUcovidcommons.com](https://chscovidcommons.asu.edu)



<https://chs.asu.edu/diagnostics-commons/blog>



[testingcommons.com](https://testingcommons.asu.edu)



<https://chs.asu.edu/diagnostics-commons/evidence-commons>



[ASUworkplacecommons.com](https://asuworkplacecommons.com)



[ConnectToTest.com](https://connecttotest.com)



<https://chs.asu.edu/diagnostics-commons/webinars>

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# Partners



## 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>

# CDC Social Media

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



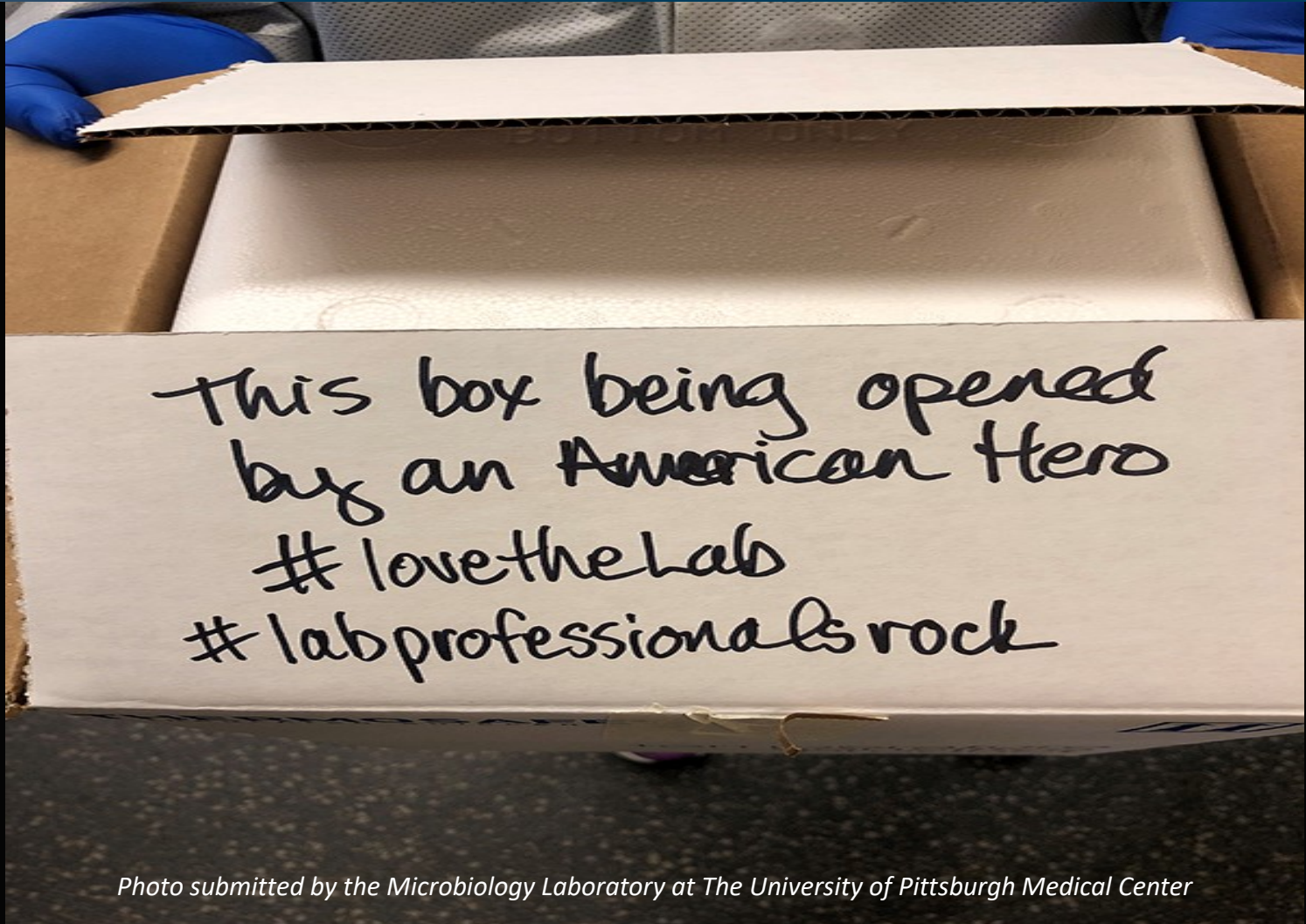
<https://twitter.com/cdcgov>

<https://www.instagram.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*