Clinical Laboratory COVID-19 Response Call

Monday, February 22, 2021 at 3:00 PM ET

- **Welcome**
  - Jasmine Chaitram, Division of Laboratory Systems, CDC
- **K-12 Testing Guidance**

  - Greta Massetti, CDC Community Interventions and Critical Populations Task Force for the COVID- 19 Response
- **SARS-CoV-2 Variants Update**
  - Vivien Dugan, CDC Laboratory and Testing Task Force for the COVID-19 Response
- **Testing for the Travel Order**
  - Nicky Cohen, CDC Global Migration Task Force for the COVID-19 Response
  - Pam Diaz, CDC Global Migration Task Force for the COVID-19 Response
- **FDA Update**
  - Tim Stenzel, U.S. Food and Drug Administration (FDA)

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.

Opt-In to Receive Updates from the CDC Laboratory Outreach Communication System

https://tools.cdc.gov/campaignproxyservice/subscriptions.aspx?topic_id=USCDC_2146

Once you opt-in, you will receive an email at the address you submitted and will need to confirm your subscription.

The link will be available in the chat box!

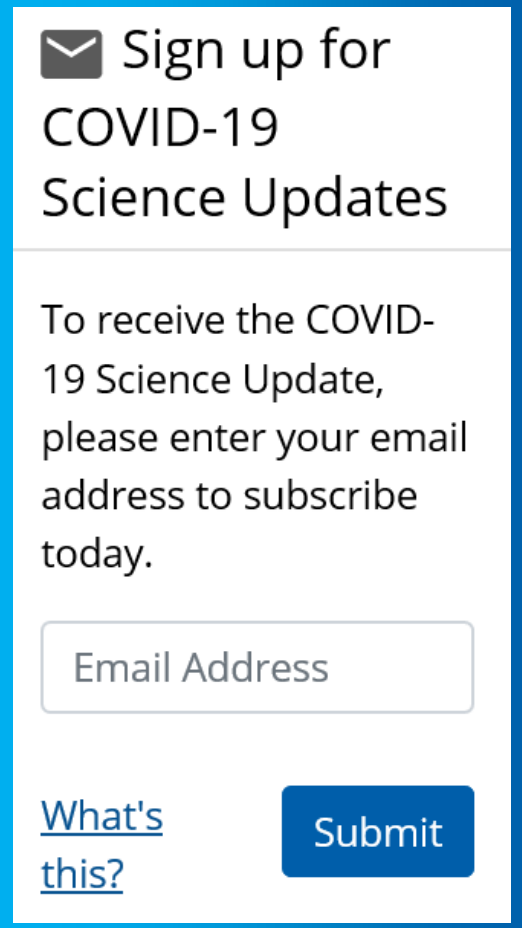
LOCS
Laboratory Outreach Communication System

COVID-19 Science Updates

These are weekly summaries of new COVID-19 related studies on topics like epidemiology, clinical treatment and management, laboratory science, and modeling.

To receive updates, visit this page (https://www.cdc.gov/library/covid19/scienceupdates.html?Sort=Date%3A%3Adesc) and enter your email in the "Sign up for COVID-19 Science Updates" box at the lower left-hand side of the page.

The link will also be available in the chat.



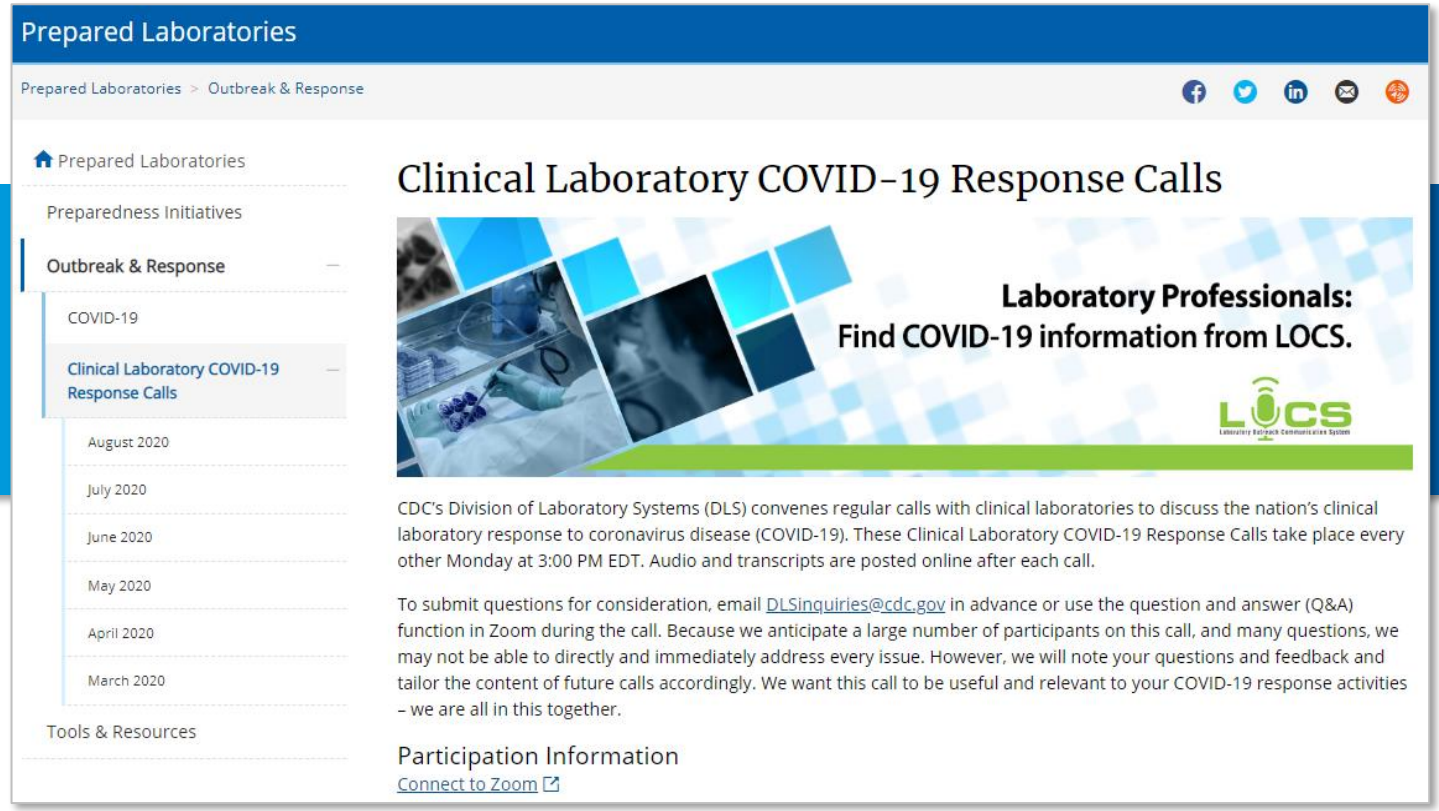
COVID-19 Resources for Laboratories

- **LOINC In-Vitro Diagnostic (LIVD) Test Code Mapping for SARS-CoV-2 Tests**
  https://www.cdc.gov/csels/dls/sars-cov-2-livd-codes.html
- **IVD Industry Connectivity Consortium**
  https://ivdconnectivity.org/livd/
- **Antigen Testing Guidance**
  https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html
- **Frequently Asked Questions about COVID-19 for Laboratories**
  https://www.cdc.gov/coronavirus/2019-ncov/lab/faqs.html
- **Interim Guidance for Collecting, Handling, and Testing Clinical Specimens**
  https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html
- **Diagnostic Tools and Virus**
  https://www.cdc.gov/coronavirus/2019-ncov/lab/tool-virus-requests.html
- **Emergency Preparedness for Laboratory Personnel**
  https://emergency.cdc.gov/labissues/index.asp
- **CDC Laboratory Outreach Communication System (LOCS)**
  https://www.cdc.gov/csels/dls/locs/

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, March 8** from

3:00 PM to 4:00 PM ET

We Want to Hear From You!

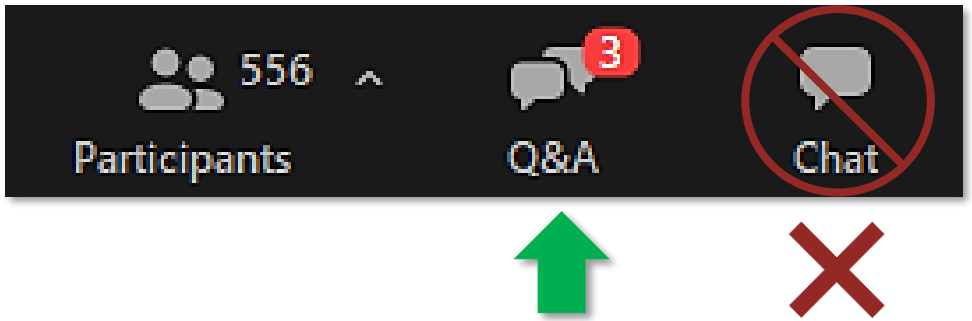
Training and Workforce Development

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

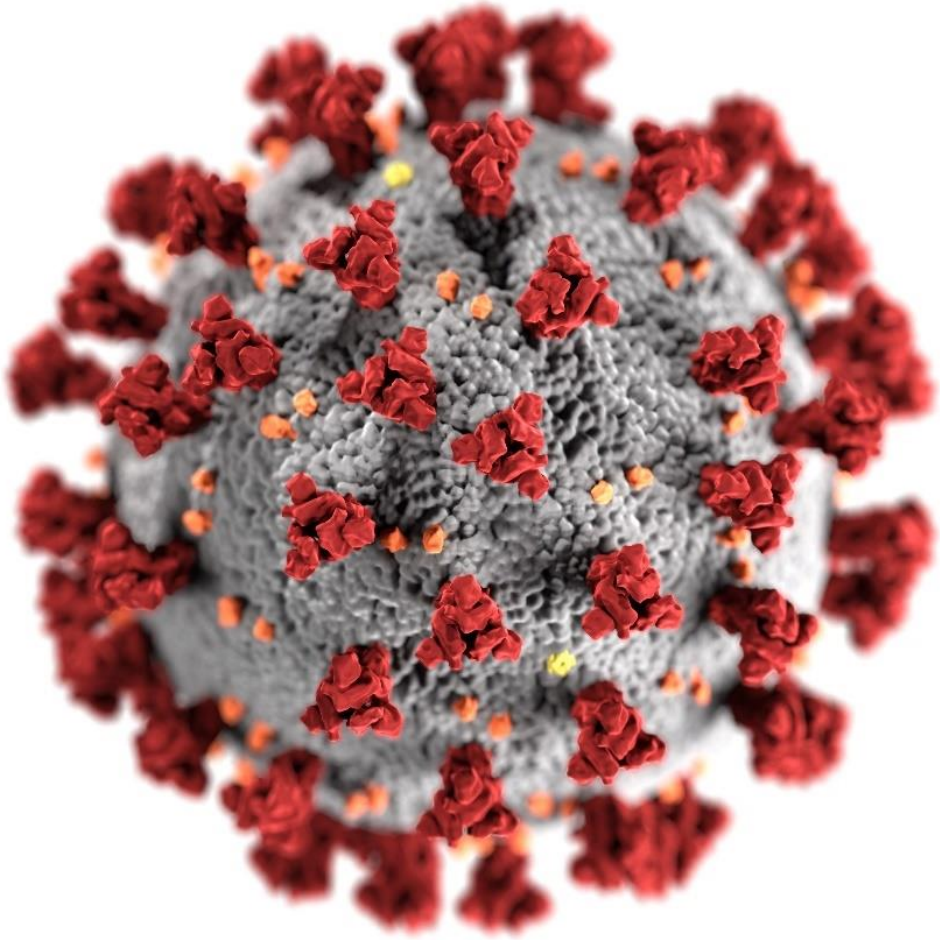


- For media questions, please contact CDC Media Relations at media@cdc.gov
- If you are a patient, please direct any questions to your healthcare provider

Operational Strategy for K-12 Schools through Phased Mitigation

Greta Massetti, PhD

CDC Community Interventions and Critical Populations Task Force



Essential Elements of Safe In-person Learning

1. Consistent implementation of **layered mitigation strategies** to reduce transmission of SARS-CoV-2 in schools
2. **Indicators of community transmission** to reflect level of risk
3. **Phased mitigation** and learning modes based on levels of community transmission

Additional layers of COVID-19 prevention

- **Testing** to identify individuals with SARS-CoV-2 infection
- **Vaccination for teachers and school staff**

Levels of Community Transmission

Indicator[1]	Low Transmission Blue	Moderate Transmission Yellow	Substantial Transmission Orange	High Transmission Red
Total new cases per 100,000 persons in the past 7 days[2]	0-9	10-49	50-99	≥100
Percentage of NAATs that are positive during the past 7 days[3]	<5.0%	5.0%-7.9%	8.0%-9.9%	≥10.0%

[1]If the two indicators suggest different levels, the actions corresponding to the higher threshold should be chosen. County-level data on total new cases in the past 7 days and test percent positivity are available on the County View tab in CDC's COVID Data Tracker.

[2]Total number of new cases per 100,000 persons within the last 7 days is calculated by adding the number of new cases in the county/community in the last 7 days divided by the population in the county and multiplying by 100,000.

[3]Percentage of positive diagnostic and screening nucleic acid amplification tests (NAATs) during the last 7 days is calculated by dividing the number of positive tests in the county during the last 7 days by the total number of tests resulted over the last 7 days. Additional information can be found on the Calculating Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Laboratory Test Percent Positivity: CDC Methods and Considerations for Comparisons and Interpretation webpage.

Testing to Identify Individuals with SARS-CoV-2 Infection and Limit Outbreaks

- In the K-12 Operational Strategy, testing is framed as additional COVID-19 prevention in schools, along with vaccination.
- Diagnostic testing: **all schools** should offer referrals to any student, teacher, staff member who has symptoms at school and those who were exposed.
- Screening testing: **some schools** may elect to use screening testing as a strategy to identify cases and prevent secondary transmission
  - Added layer of mitigation—it doesn't replace other mitigation strategies
  - At schools that offer screening testing: weekly testing recommended for teachers (all levels), students (moderate, substantial, high levels)

Phased Mitigation by Level of Community Transmission for Schools that Implement Screening Testing

<table>
<tr><th>Low Transmission[1]
Blue</th><th>Moderate Transmission
Yellow</th><th>Substantial Transmission
Orange</th><th>High Transmission
Red</th></tr>
<tr><td colspan="4">All schools implement 5 key mitigation strategies: universal and correct use of masks required; physical distancing; handwashing and respiratory etiquette; cleaning and maintaining healthy facilities; contact tracing in combination with quarantine and isolation
Diagnostic testing[2]: symptomatic students, teachers, and staff and close contacts referred for diagnostic testing</td></tr>
<tr><td colspan="4">Screening testing[3]</td></tr>
<tr><td colspan="4">Routine screening testing of teachers and staff offered at least once per week</td></tr>
<tr><td>No screening testing for students</td><td colspan="3">Routine screening testing of teachers and staff offered once per week[4]</td></tr>
<tr><td colspan="2">K-12 schools open for full in-person instruction; physical distancing of 6 feet or more to the greatest extent possible[5]</td><td colspan="2">K-12 schools in hybrid learning mode or reduced attendance[6]; physical distancing of 6 feet or more required</td></tr>
<tr><td>Sports and extracurricular activities occur with masks required, physical distancing of 6 feet or more to the greatest extent possible[7]</td><td>Sports and extracurricular activities occur with masks and physical distancing of 6 feet or more required</td><td>Sports and extracurricular activities occur only if they can be held outdoors, with masks and physical distancing of 6 feet or more</td><td>Sports and extracurricular activities virtual only</td></tr>
</table>

[4]Schools may consider testing a random sample of at least 10% of students or may conduct pooled testing of cohorts/pods for screening testing in areas of moderate and substantial community transmission.

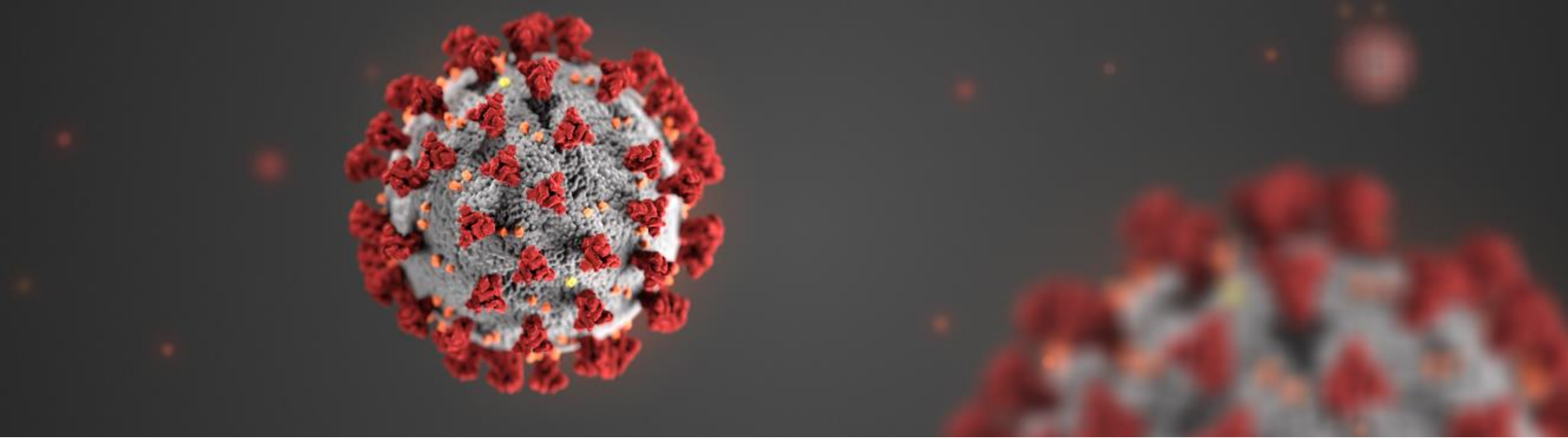
5If physical distancing of at least 6 feet among all students, teachers, and staff within a class, cohort, or pod is not possible at all times, schools should ensure physical distancing between classes, cohorts, and pods. [6]Hybrid learning or reduced attendance is intended to maximize physical distance between students. Schools may consider hybrid learning models or instructional modes where substantial percentages of students are in virtual only instruction. At all levels of community transmission, schools should provide families the option to participate in virtual learning if a student or family member is at risk of severe illness from COVID-19.[7]School officials should implement limits on spectators and attendees for sports, extracurricular activities, and school events as consistent with recommendations for masking and physical distancing for each phase.

Considerations in Implementing Screening Testing in K-12 Schools

- Priorities for testing:
  - Teachers and staff
  - High school students, then middle school stu
  - Elementary school students
- Prioritize access to testing in **schools that serve populations experiencing a disproportionate burden of COVID-19 cases or severe disease**.
  - Communities with moderate or large proportions of groups that experienced disproportionately high rates of COVID-19
  - Geographic areas with limited access to testing

Elements Needed for Screening Testing in K-12 Schools

- Dedicated infrastructure, staffing, and resources to support school-based testing
- CLIA certificate of waiver
- Mechanism to report all testing results
- Timely reporting of results (<24 hours) is key
- Ways to obtain parental consent for minors and informed consent for adults
- Physical space to conduct testing safely and privately, protocols to maintain confidentiality of results
- Plans to confirm result of antigen testing need to be established



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.

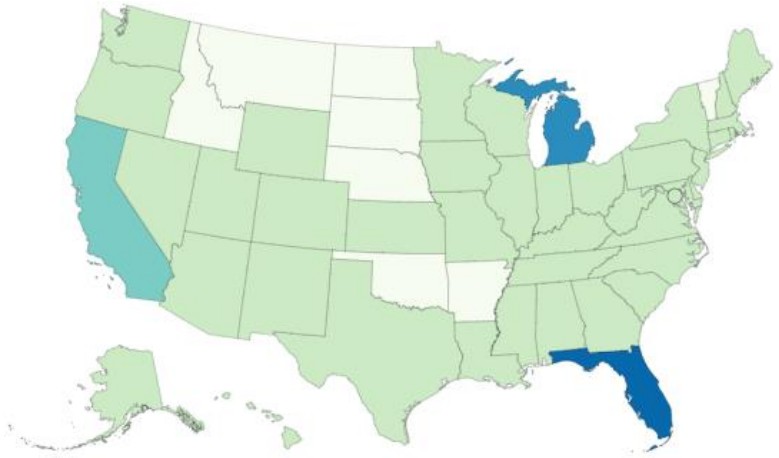
SARS-CoV-2 Variants Update

Vivien Dugan
CDC Laboratory and Testing Task Force for the COVID-19 Response

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

Emerging Variant Cases in the United States

B.1.1.7 variant



B.1.351 variant

P.1 variant

Territories AS GU MH FM MP PW PR VI

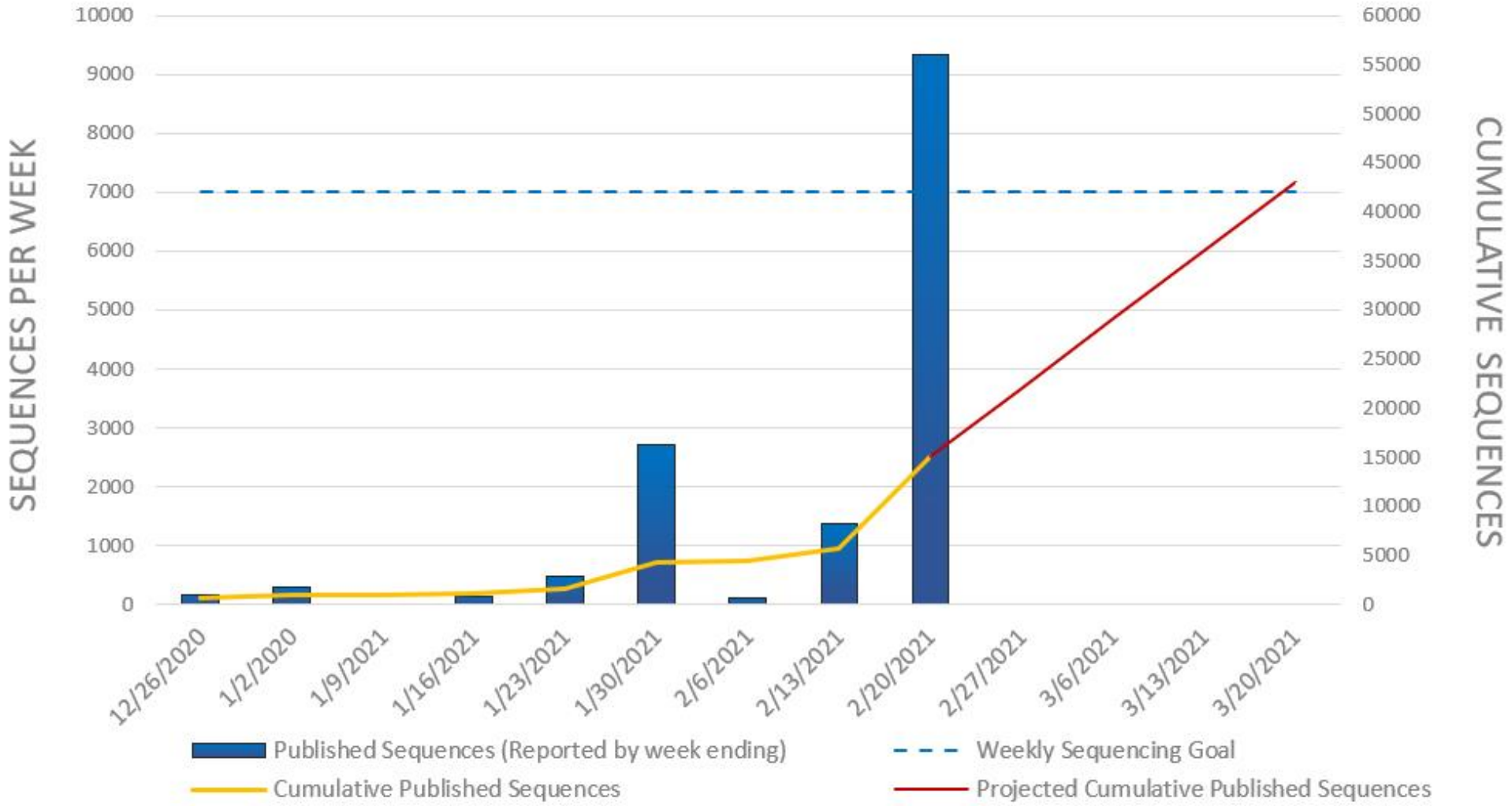
Total US Variant Cases	B.1.1.7		B.1.351		P.1	
	Total B.1.1.7	US Jurisdictions	Total B.1.351	US Jurisdictions	Total P.1	US Jurisdictions
1688	1661	44	22	10	5	4

Number of Cases

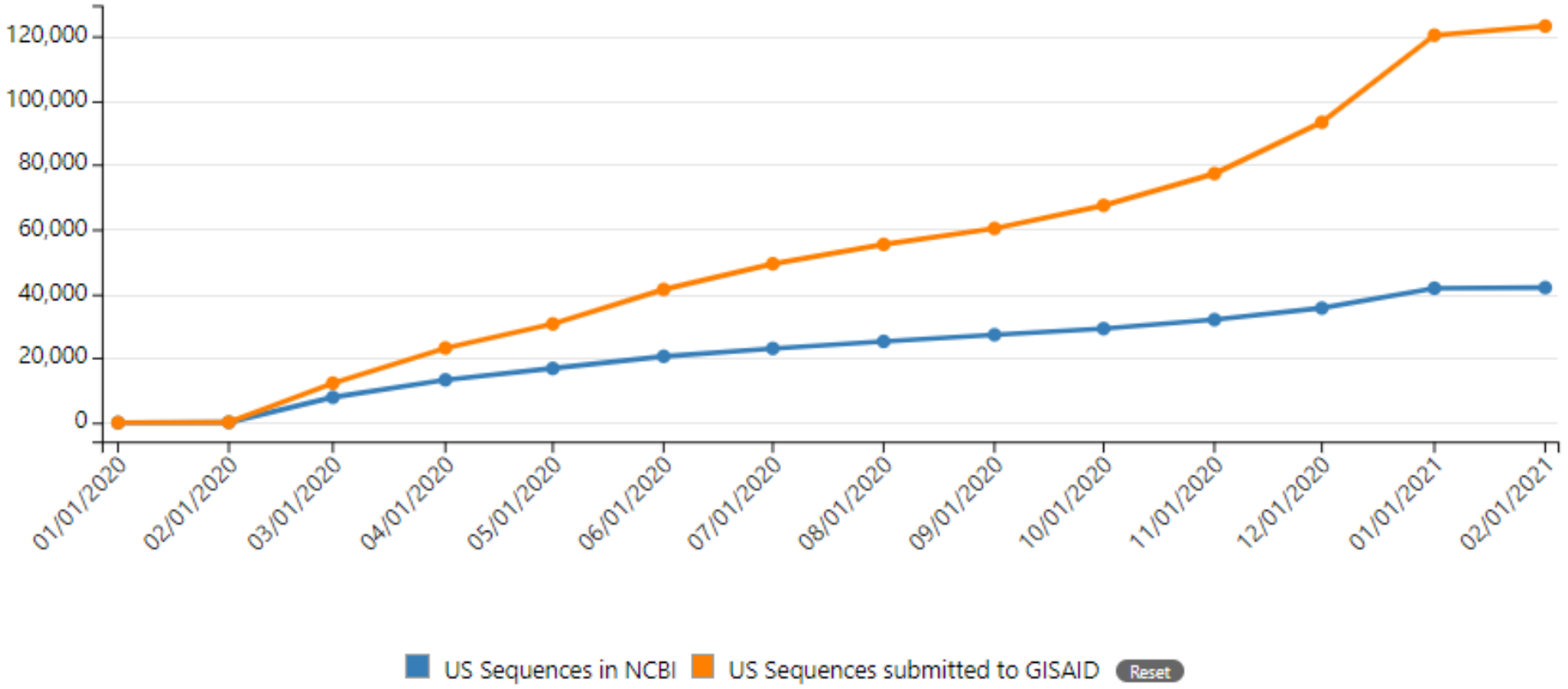
0 to 0
1 to 100
101 to 200
201 to 300
401 to 500

Numbers reflect the number of jurisdictions with > 1 case that have been reported to CDC as of February 21, 2021 and may be higher than what is shown on the US COVID-19 Cases Caused by Variants webpage. Numbers will be updated on Sunday, Tuesday and Thursday by 7pm and final case counts may be higher.
US COVID-19 Cases Caused by Variants | CDC

NS3 and Sequencing Contracts through CDC

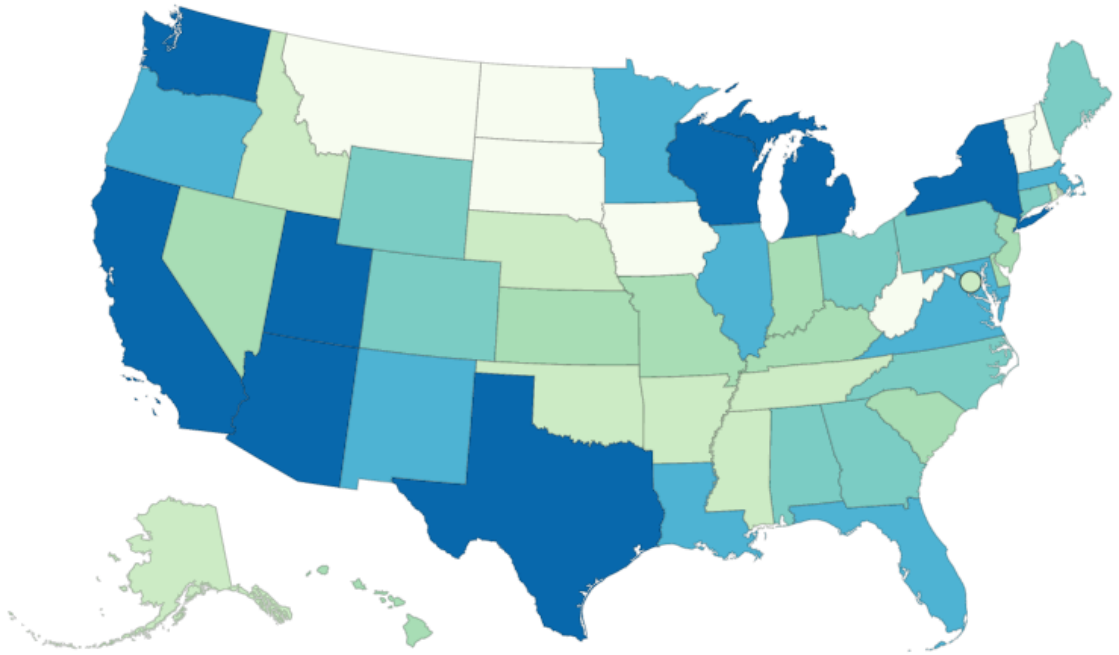


U.S. Sequences Available in Public Repositories



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.

Total Sequences Submitted (GISAID)

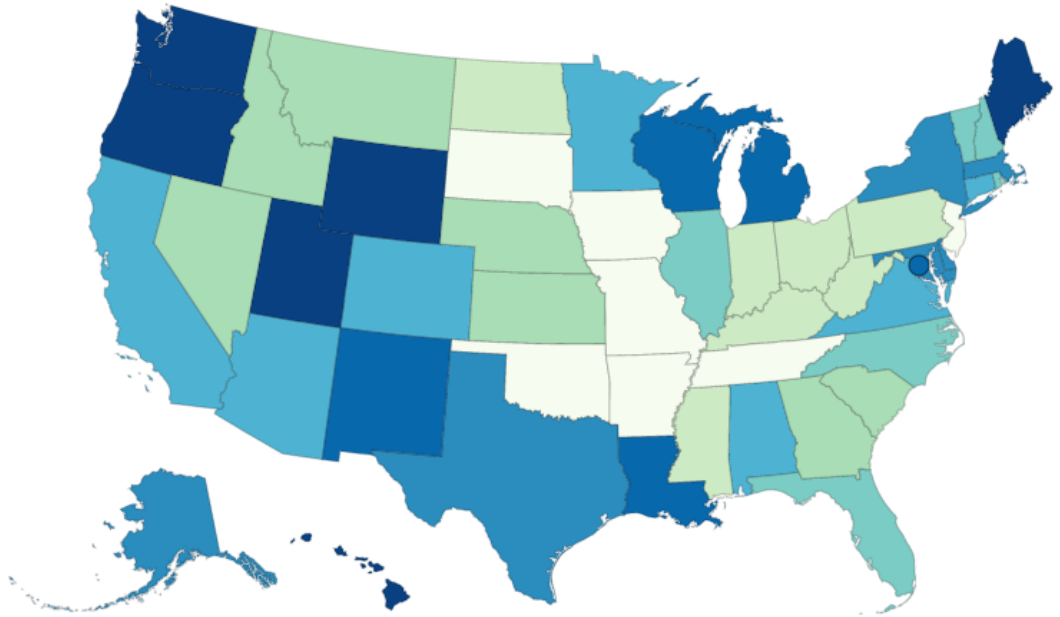


Territories VI PR

22 - 246	250 - 376
377 - 916	1014 - 1778
2168 - 4745	5021 - 18976

The map shows the percentage of SARS-CoV-2-positive cases by state that have been sequenced and published in public repositories from Jan 2020 to the present.

Percentage of Cumulative Cases Sequenced (%)



Territories PR VI

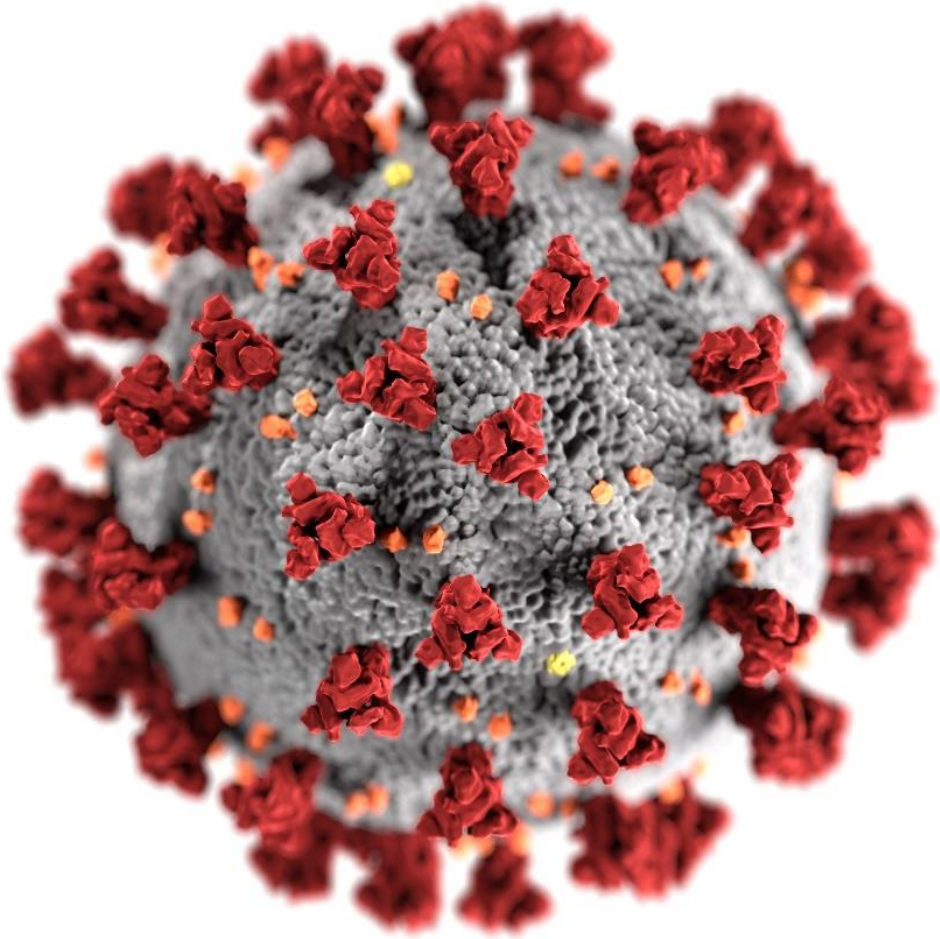
0.044% - 0.086%	0.089% - 0.144%
0.144% - 0.169%	0.177% - 0.274%
0.35% - 0.624%	0.626% - 0.71%
0.745% - 1.191%	1.582% - 3.49%

The map shows the cumulative number of SARS-CoV-2 sequences by state that have been published in public repositories from January 2020 to the present.

CDC Testing Order for Air Passengers

Nicky Cohen and Pam Diaz

Global Migration Task Force
CDC COVID-19 Response



cdc.gov/coronavirus

CDC Regulatory Authorities

- Quarantine Regulations
  - 42 CFR § 71 - Foreign Quarantine
  - 42 CFR § 70 - Interstate Quarantine
- Allow CDC Director to take measures to prevent introduction and spread of communicable diseases into and within the United States
- Testing Order issued under:
  - 42 CFR § 71.20 - Public health prevention measures to detect communicable disease
  - 42 CFR § 71.32 - Persons, carriers, and things

Rationale for Testing Requirement

- Continued introduction of SARS-CoV-2 through international air travel
  - Transmission during travel
  - Translocation of virus to destination communities
- New variants in United Kingdom, South Africa, Brazil, and other countries raise concerns about:
  - Increased transmissibility
  - Potential for greater severity of illness
  - Decreased susceptibility to therapeutics
  - Ability to evade natural or vaccine-induced immunity

Requirements of Testing Order

- Before boarding, all air passengers 2 years and older must present to aircraft operator:
  - Negative result of a viral test (NAAT or antigen) performed no more than 3 days before flight departs, OR
  - Documentation of having recovered from COVID-19 in the past 3 months:
    - Positive viral test result
    - Letter from licensed healthcare provider or public health official indicating clearance to travel
- Limited exemptions: crew members, federal law enforcement, humanitarian purposes (health/safety), DOD personnel on official orders, people with COVID-19 if transported in accordance with CDC guidance

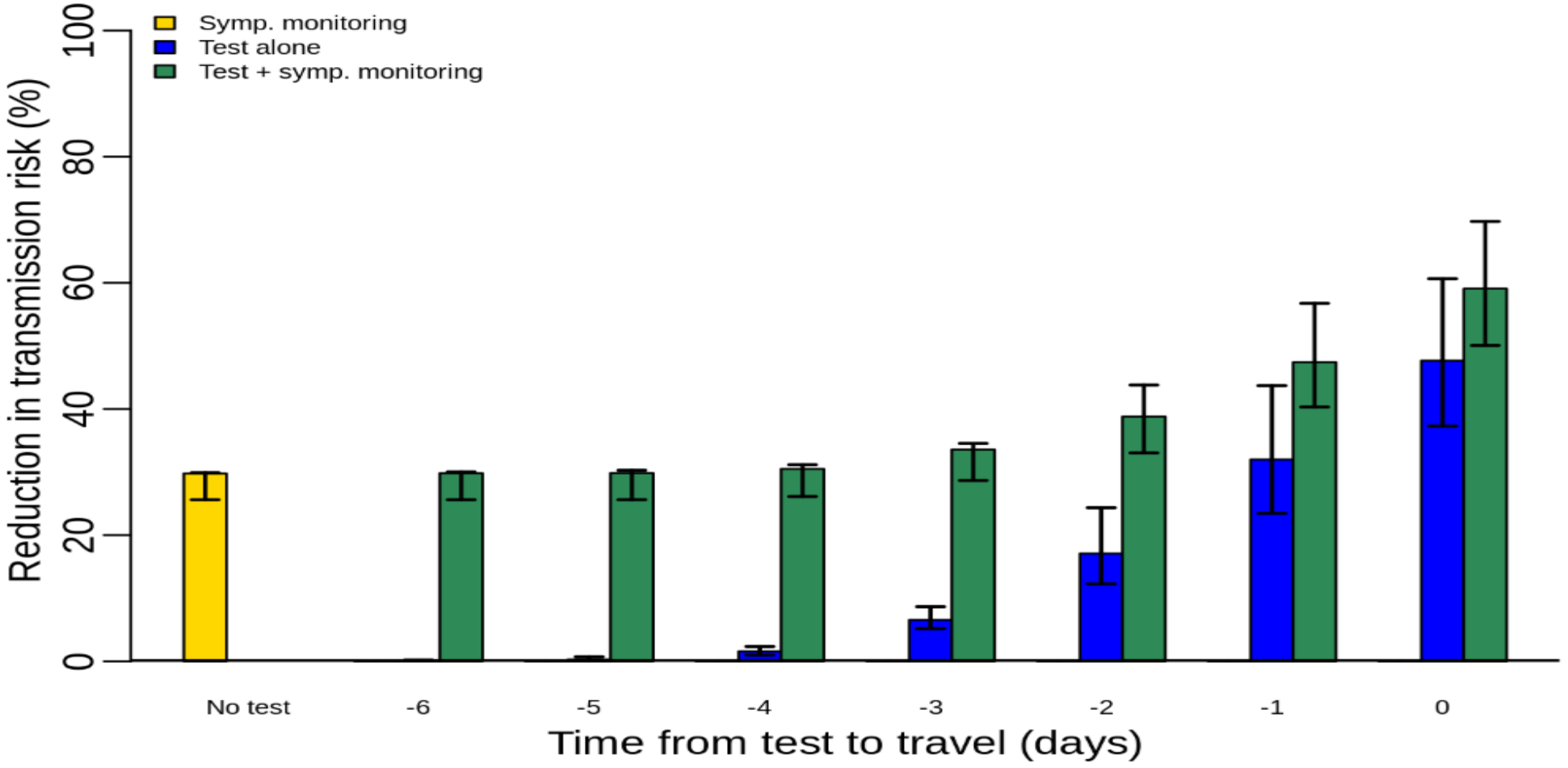
https://www.cdc.gov/coronavirus/2019-ncov/travelers/testing-international-air-travelers.html

Post-travel Recommendations

- Get tested with a viral test 3-5 days after travel **AND stay home and self-quarantine** for 7 days after travel, even if test is negative
  - If test is positive, isolate to protect others from getting infected
- If not tested, stay home and self-quarantine for 10 days after travel
- Avoid being around people who are at increased risk for severe illness for 14 days, whether tested or not
- Follow all state and local recommendations or requirements after travel

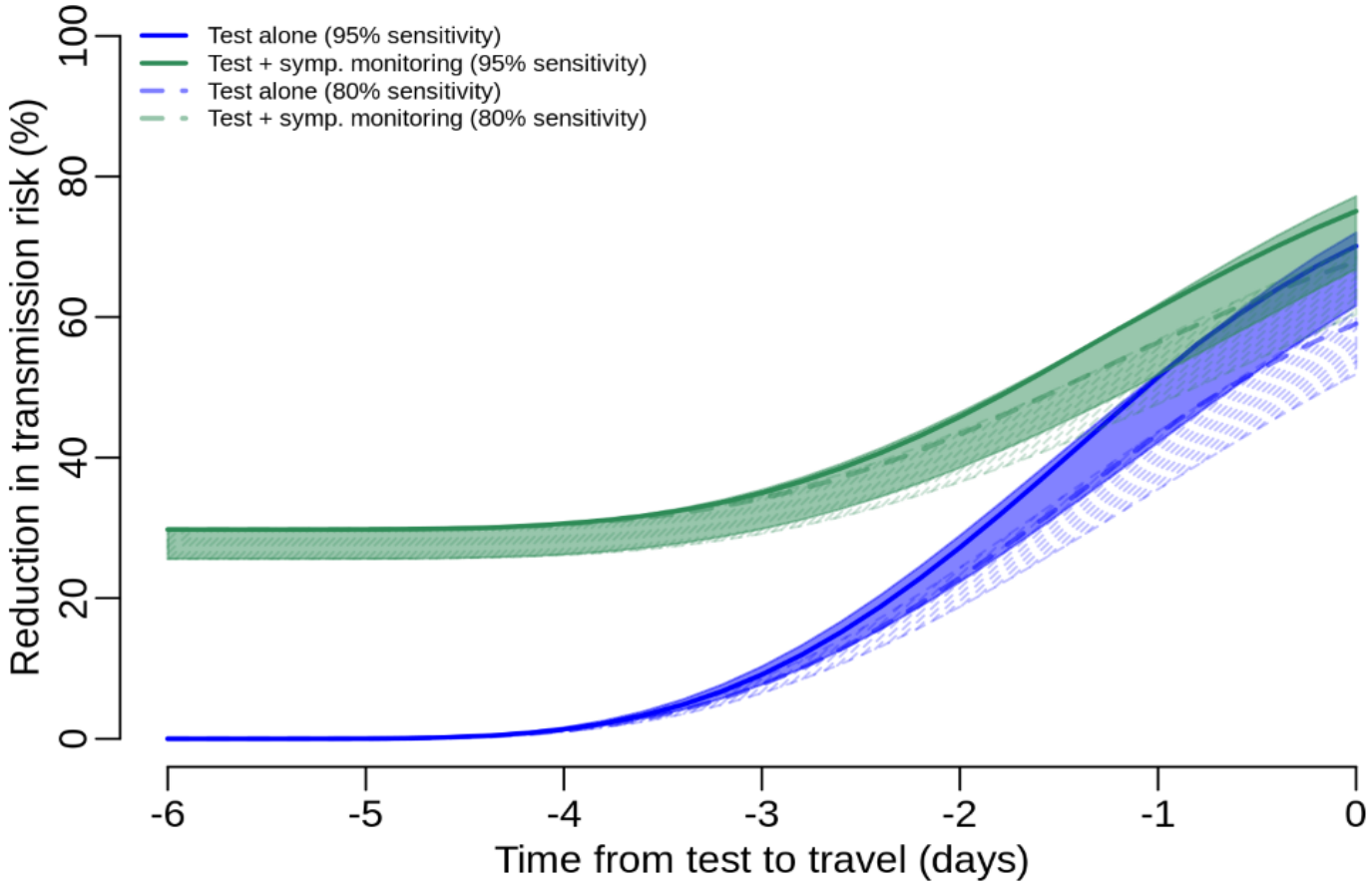
https://www.cdc.gov/coronavirus/2019-ncov/travelers/after-travel-precautions.html

Reductions in transmission risk during a 1-day trip assuming a 7-day exposure window prior to travel, stratified by method of risk reduction



From: Johansson MS, Wolford H, Paul P, et al. Reducing travel-related SARS-CoV-2 transmission with layered mitigation measures: symptom monitoring, quarantine, and testing *medRxiv.* 2020

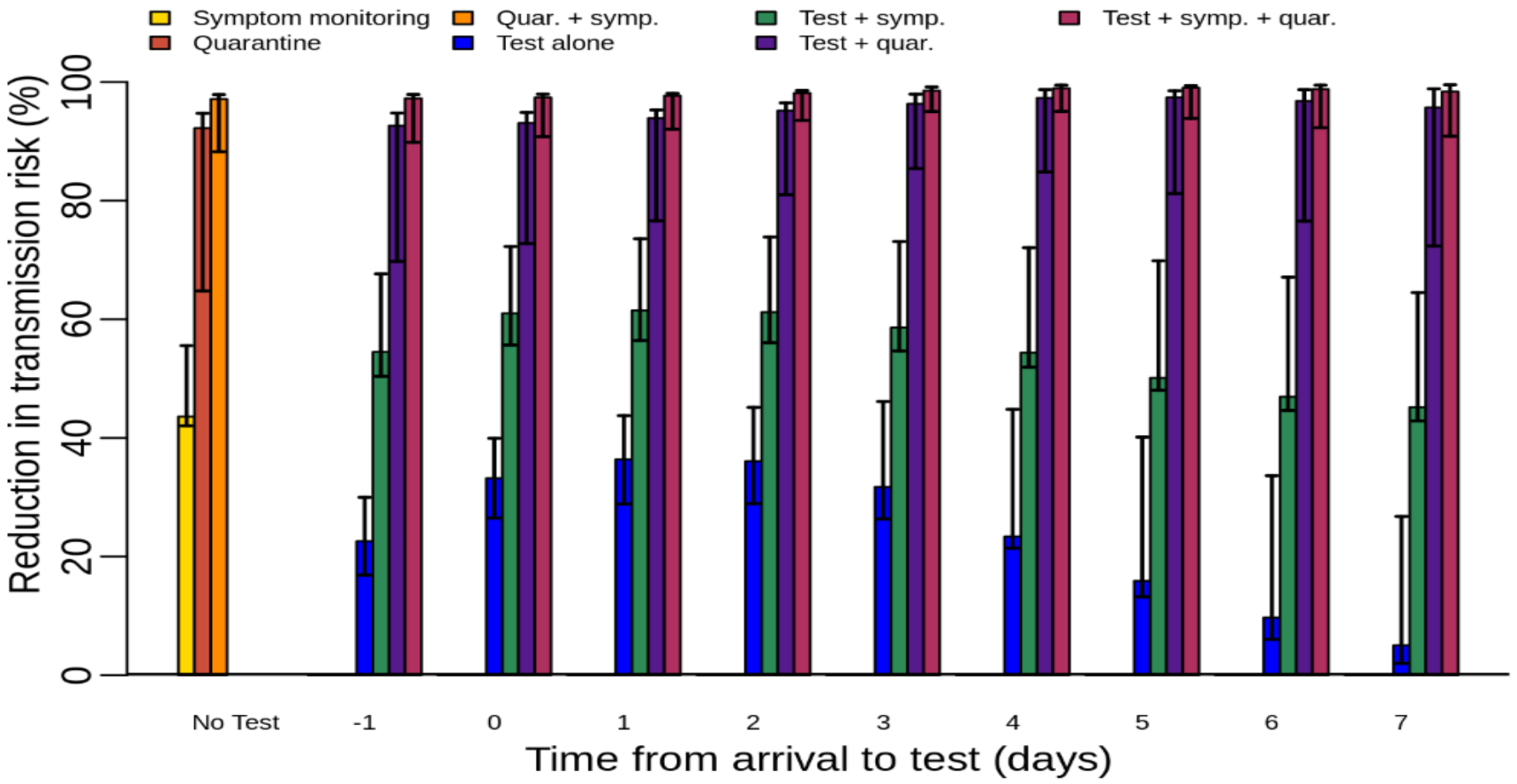
Reductions in transmission risk during a 1-day trip



Assuming a 7-day exposure window prior to travel comparing the Gamma function version of the assays with 80% and 95% sensitivity.
Ranges indicate uncertainty from the different infectiousness models

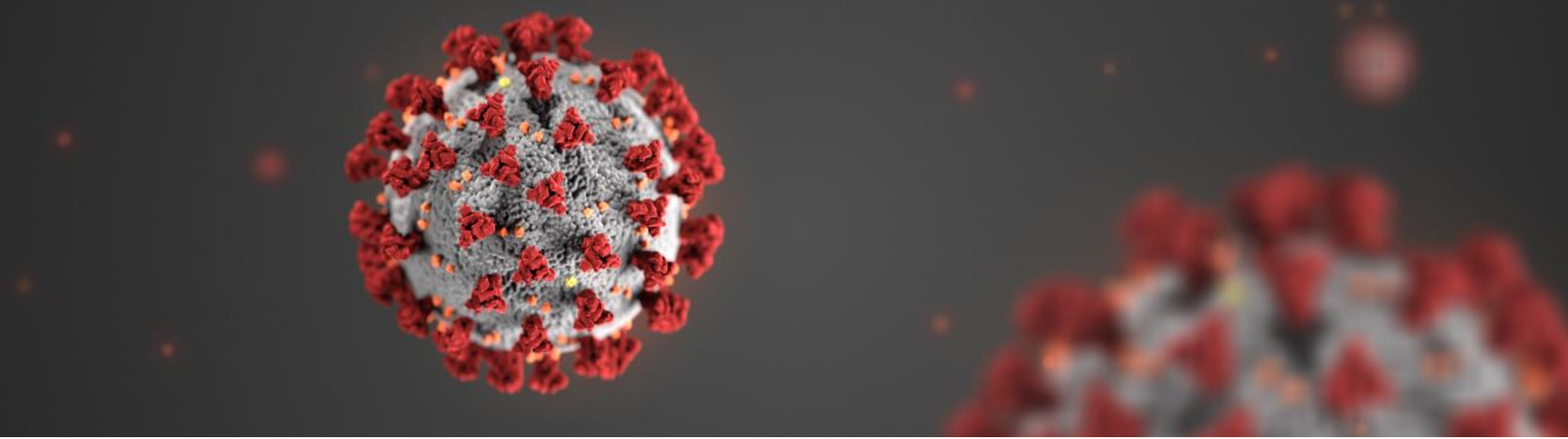
From: Johansson MS, Wolford H, Paul P, et al. Reducing travel-related SARS-CoV-2 transmission with layered mitigation measures: symptom monitoring, quarantine, and testing *medRxiv.* 2020

Reductions in transmission risk post-arrival



Assuming a 7-day exposure window prior to arrival, stratified by day of test and symptom monitoring, with and without a 7-day quarantine

From: Johansson MS, Wolford H, Paul P, et al. Reducing travel-related SARS-CoV-2 transmission with layered mitigation measures: symptom monitoring, quarantine, and testing *medRxiv.* 2020



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FDA Update

Tim Stenzel
U.S. Food and Drug Administration (FDA)

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/

FDA U.S. FOOD & DRUG ADMINISTRATION

U.S. Food and Drug Administration (FDA)

- **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**
  https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program

U.S. FOOD & DRUG ADMINISTRATION

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Thank You For Your Time!

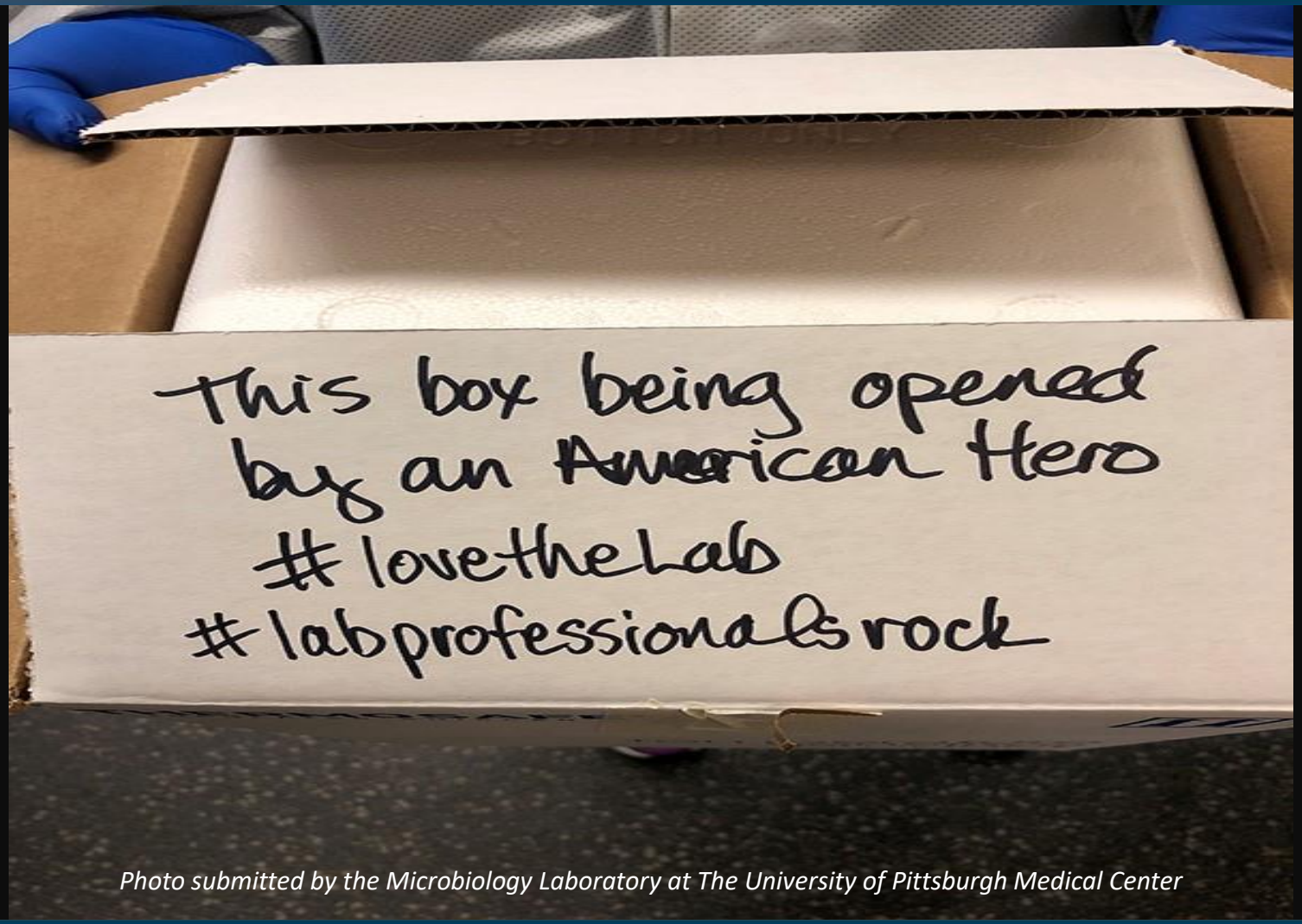

Photo submitted by the Microbiology Laboratory at The University of Pittsburgh Medical Center