

Clinical Laboratory COVID-19 Response Call

Monday, January 24, 2022, at 3:00 PM EDT

- **Welcome**

- Jasmine Chaitram, CDC Division of Laboratory Systems (DLS)

- **COVID-19 Data Tracker for Testing**

- Jason Hall, CDC Data, Analytics, and Visualization Task Force

- **FDA Update**

- Tim Stenzel, US Food and Drug Administration (FDA)

- **SARS-CoV-2 Variants Update**

- Natalie Thornburg, CDC Laboratory and Testing Task Force



Division of Laboratory Systems (DLS)

Vision

Exemplary laboratory science and practice advance clinical care, public health, and health equity.

Mission

Improve public health, patient outcomes, and health equity by advancing clinical and public health laboratory quality and safety, data and biorepository science, and workforce competency.



Four Goal Areas



Quality Laboratory Science

- Improve the quality and value of laboratory medicine and biorepository science for better health outcomes and public health surveillance



Highly Competent Laboratory Workforce

- Strengthen the laboratory workforce to support clinical and public health laboratory practice



Safe and Prepared Laboratories

- Enhance the safety and response capabilities of clinical and public health laboratories



Accessible and Usable Laboratory Data

- Increase access and use of laboratory data to support response, surveillance, and patient care

CDC Preparedness Portal

<https://www.cdc.gov/csels/dls/preparedlabs/covid-19-clinical-calls.html>

Find CLCR call information, transcripts, and audio recordings on this page



The screenshot shows the CDC Preparedness Portal website. At the top, the CDC logo and name are visible, along with the tagline "CDC 24/7: Saving Lives. Protecting People™". A search bar and "Advanced Search" link are in the top right. The main navigation bar includes "Prepared Laboratories" and "Outbreak & Response". The left sidebar lists "Preparedness Initiatives" and "Outbreak & Response", with "Clinical Laboratory COVID-19 Response Calls" selected. The main content area features a large banner for "Clinical Laboratory COVID-19 Response Calls" with a CDC logo and a graphic of a virus particle. Below the banner, the text states: "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 Eastern time. Audio and transcripts are posted online after each call." It also provides instructions for submitting questions: "To submit questions for consideration, email 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."



Updated Storage and Shipping Guidance for Submission to CDC Infectious Disease Laboratories

Learn about the changes regarding
specimen submission to CDC!

Upcoming Event!

January 28, 2022
1:30-2:30 PM EST

Speaker:
Dr. Atis Muehlenbachs,
MD PHD

[Register Now](#)



Next Scheduled CLCR Call

The next call will be on **Monday, February 7**
from **3:00 PM to 4:00 PM ET**



We Want to Hear from You!

Training and Workforce Development

Questions about education and training?

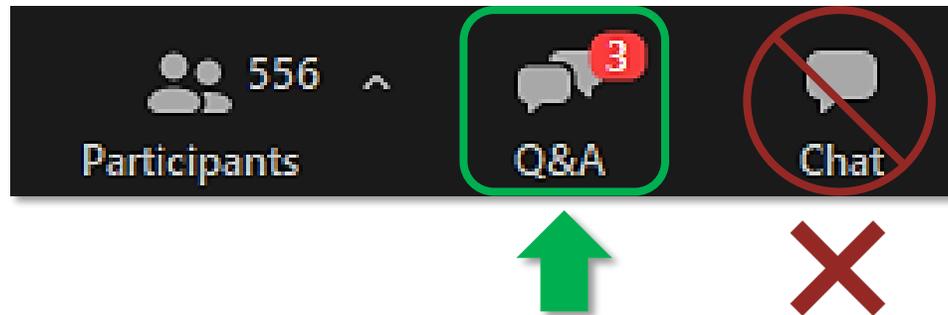
Contact LabTrainingNeeds@cdc.gov



How to Ask a Question

- **Using the Zoom Webinar System**

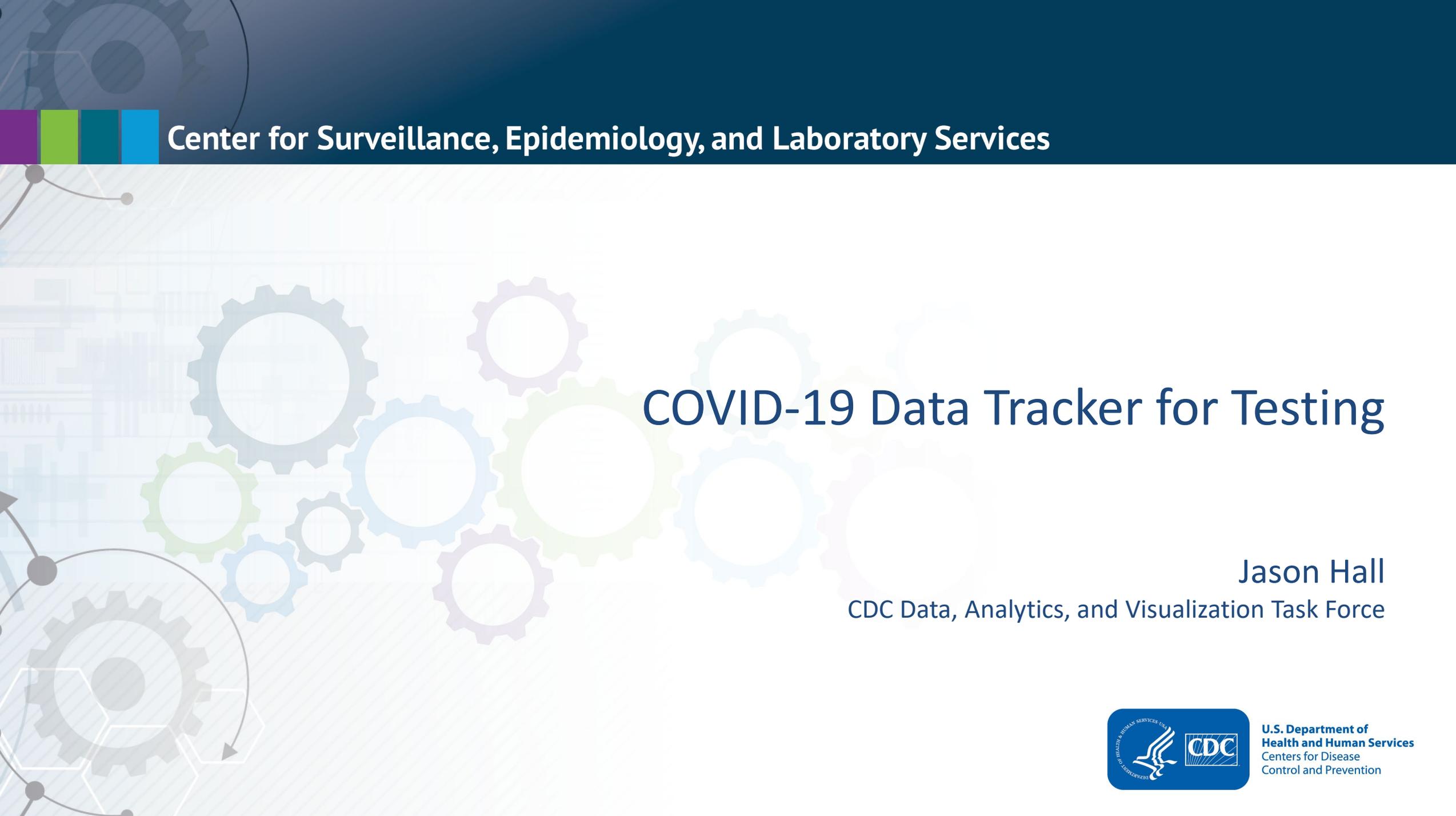
- Click the **Q&A** button in the Zoom webinar system
- Type your question in the **Q&A** box and submit it
- **Please do not submit a question using the chat button**



- 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



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.



Center for Surveillance, Epidemiology, and Laboratory Services

COVID-19 Data Tracker for Testing

Jason Hall

CDC Data, Analytics, and Visualization Task Force



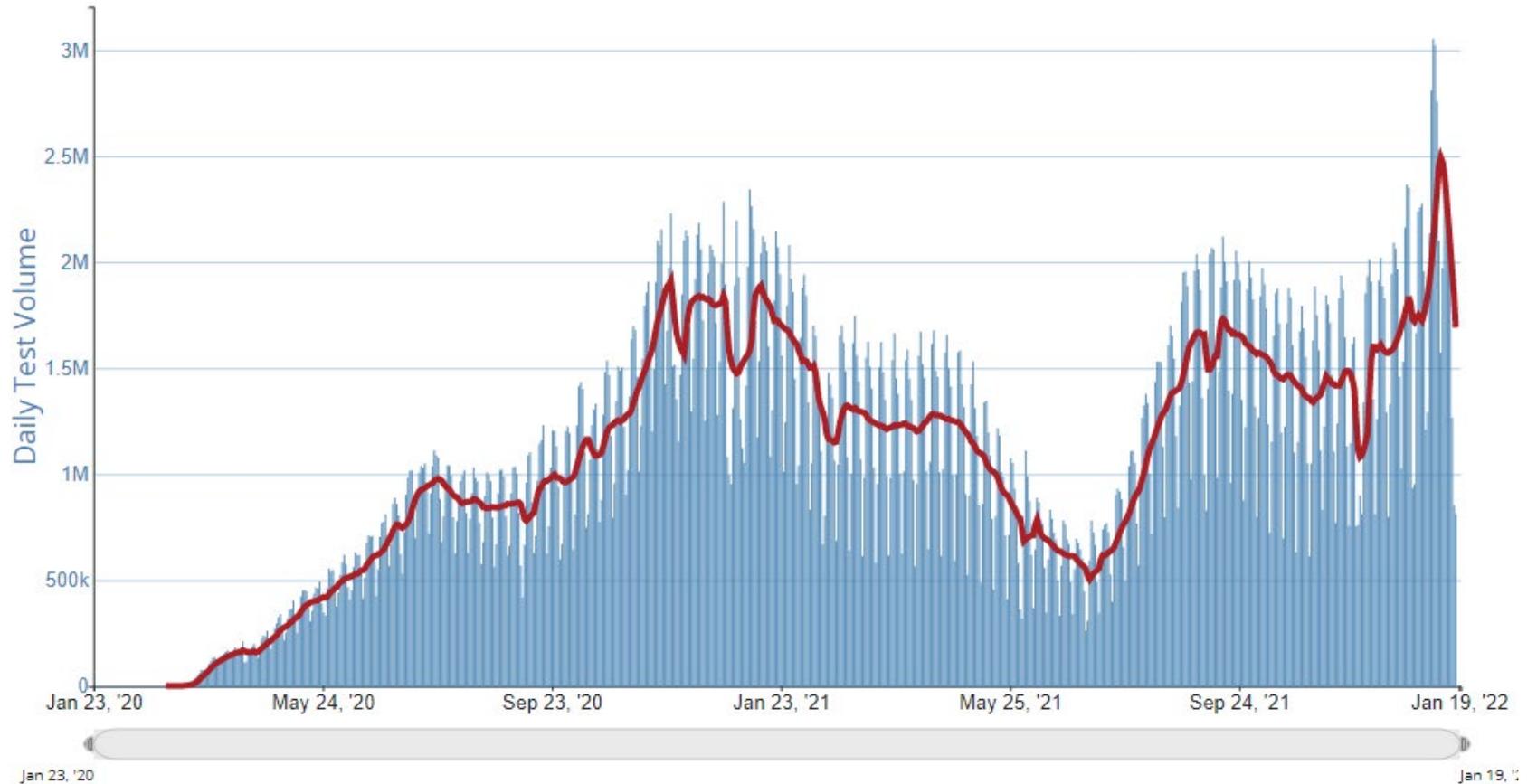
U.S. Department of
Health and Human Services
Centers for Disease
Control and Prevention

COVID-19 Electronic Laboratory Reporting (CELR) Updates and Progress: NAAT Results



- Over **761M** NAAT test results reported to CDC since March 1, 2020
- Single day peaks over **3M** in January 2022

Daily COVID-19 Nucleic Acid Amplification Tests (NAATs) Performed in The United States Reported to CDC



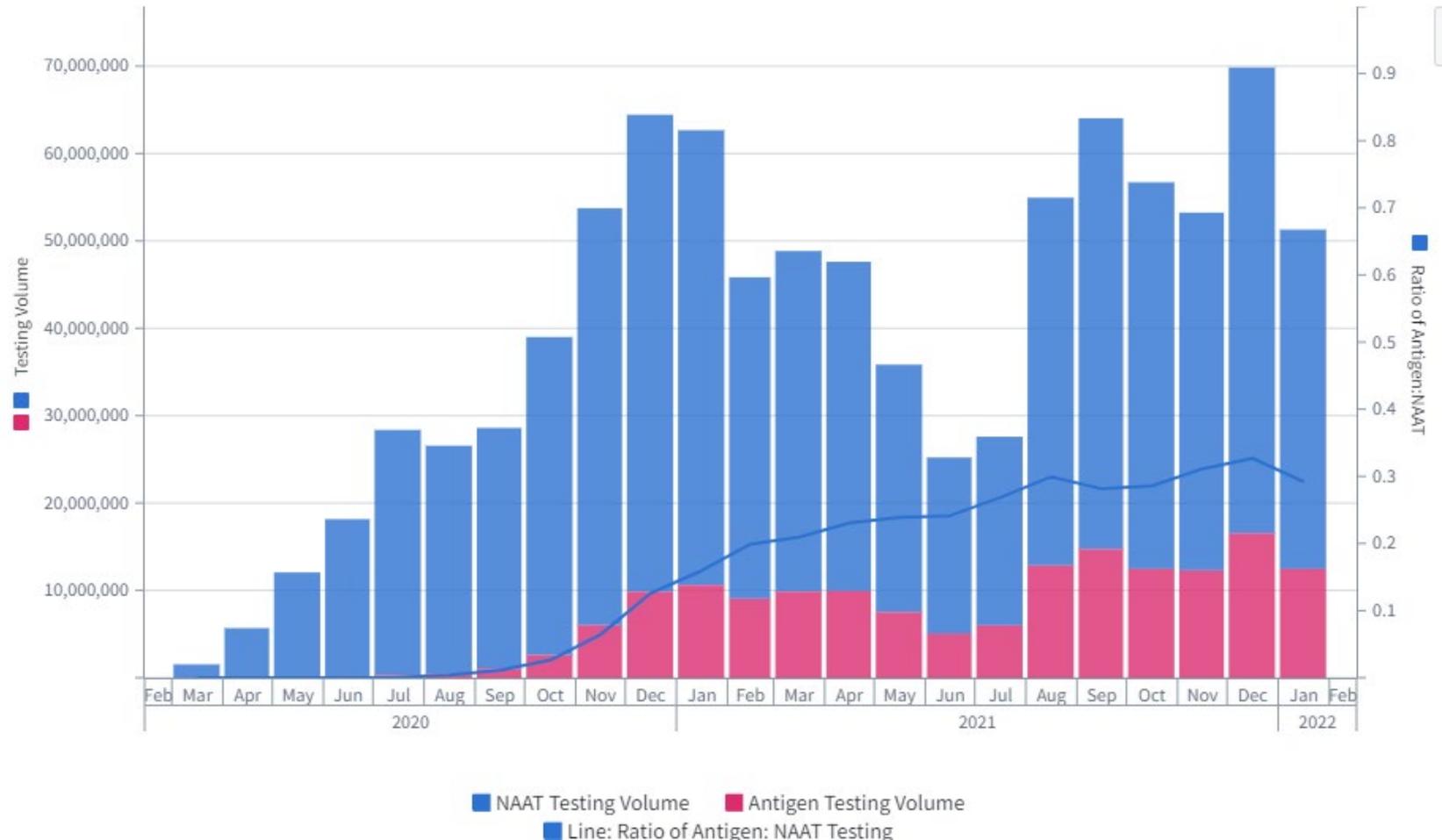
*NAAT data available publicly on <https://covid.cdc.gov/covid-data-tracker>

Data are Provisional Until Officially Released by the CDC - For Internal Use Only (FIUO) - For Official Use Only (FOUO) - Sensitive But Unclassified (SBU) - Not for Further Distribution



COVID-19 Electronic Laboratory Reporting (CELR) Updates and Progress: Antigen & Sequencing Results

- Over **160M** antigen test results reported
- Over **756K** sequencing results reported
- Completeness of reporting varies by state so these data are not used for national statistics



COVID-19 Electronic Laboratory Reporting (CELR) Updates and Progress: On the Radar



- Updates to reporting guidance
- Processing issues due to high volumes
- Self-administered tests

FDA Update

Tim Stenzel

US 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

- **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>

SARS-CoV-2 Variants Update

Natalie Thornburg
CDC Laboratory and Testing Task Force



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!

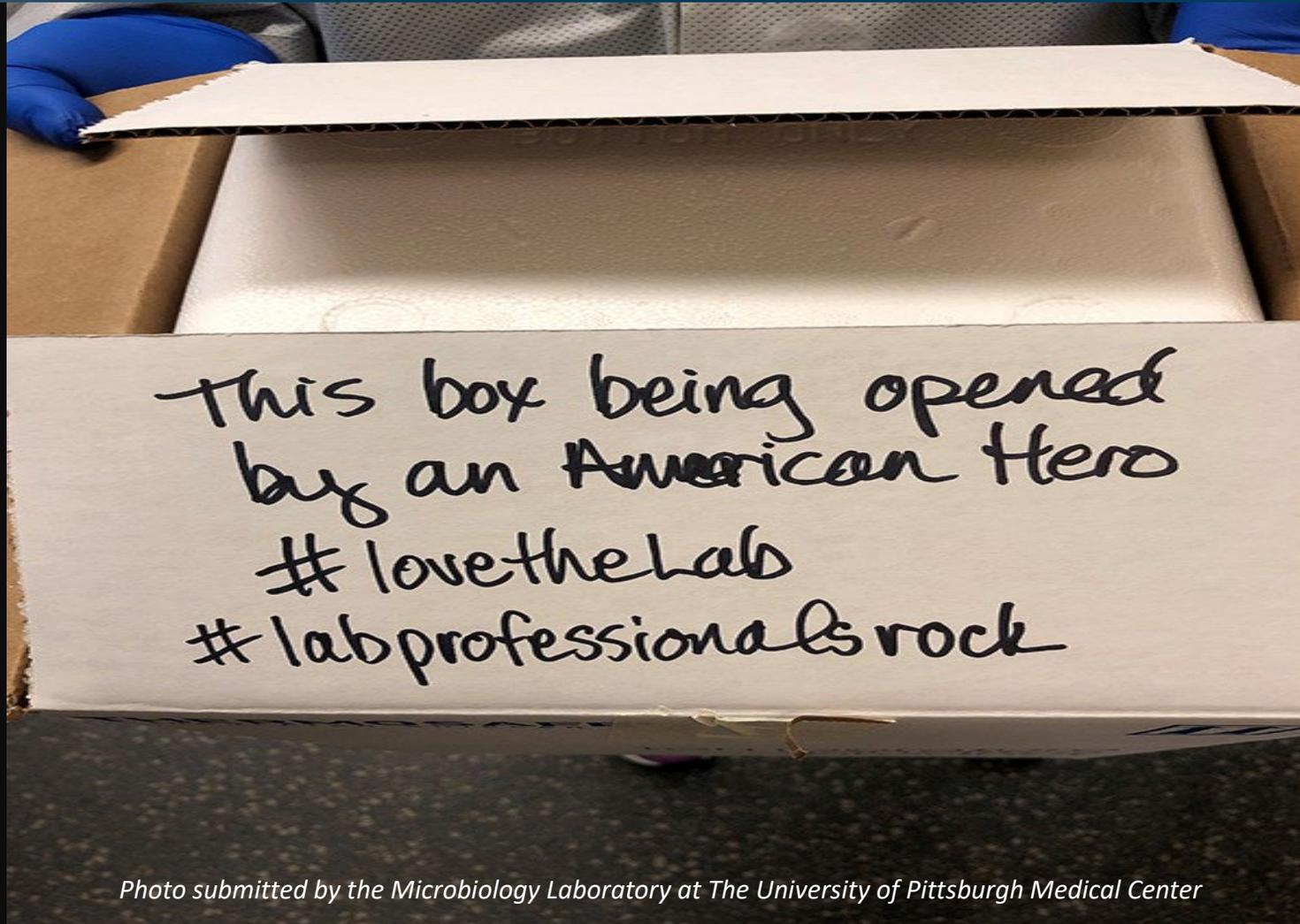


Photo submitted by the Microbiology Laboratory at The University of Pittsburgh Medical Center