

Clinical Laboratory COVID-19 Response Call

Monday, February 7, 2022, at 3:00 PM ET

- **Welcome**
 - Jasmine Chaitram, CDC Division of Laboratory Systems
- **How It Works: COVID-19 Sequencing From Patient Swab to Variant Classification**
 - Justin Lee, CDC Laboratory and Testing Task Force
- **Increasing Community Access to Testing (ICATT) Pharmacy Expansion Update**
 - Daniel Parker, CDC Expansion of Screening and Diagnostics Task Force
- **FDA Update**
 - Tim Stenzel, US Food and Drug Administration (FDA)



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



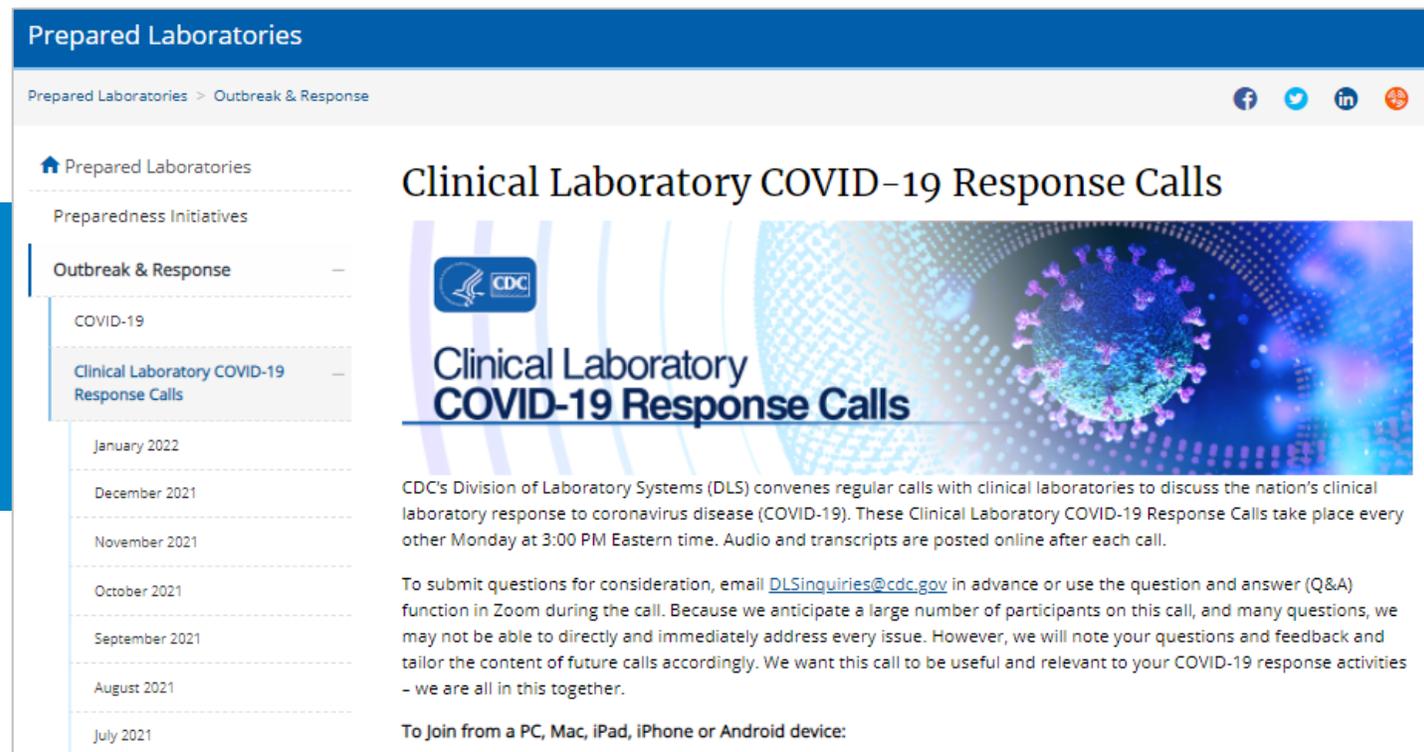
Accessible and Usable Laboratory Data

- 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 'Prepared Laboratories' section of the CDC website. The main heading is 'Clinical Laboratory COVID-19 Response Calls'. Below the heading is a list of call dates from July 2021 to January 2022. The 'Clinical Laboratory COVID-19 Response Calls' link is highlighted. To the right of the list is a detailed description of the calls, including the CDC logo and contact information for submitting questions.

Prepared Laboratories

Prepared Laboratories > Outbreak & Response

Prepared Laboratories

Preparedness Initiatives

Outbreak & Response

COVID-19

Clinical Laboratory COVID-19 Response Calls

January 2022

December 2021

November 2021

October 2021

September 2021

August 2021

July 2021

Clinical Laboratory COVID-19 Response Calls

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.

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.

To Join from a PC, Mac, iPad, iPhone or Android device:

Increasing Community Access to Testing (ICATT) for COVID-19

<https://www.cdc.gov/icatt/index.html>

CDC's ICATT program supports free COVID-19 laboratory testing in pharmacies and other locations in US communities that have been disproportionately affected by the pandemic

Increasing Community Access to Testing (ICATT) for COVID-19



Search for a free COVID-19 laboratory test provider

CDC and its partners can help you find where to get a free COVID-19 laboratory test.

CDC's Increasing Community Access to Testing (ICATT) program can help you find where to get a free COVID-19 laboratory test. These tests can tell if you have a current COVID-19 infection. You'll get a result usually within 24-72 hours after you get tested. To find free ICATT COVID-19 laboratory testing locations, visit our partner websites [CVS](#), [eTrueNorth](#), [Rite Aid](#), and [Walgreens](#) to search for where to get a test using a ZIP code, city, state, territory, or street address. [Visit this page](#) for CDC's description of the different kinds of tests for COVID-19 offered under the ICATT program and by other healthcare providers.

CDC's goal for ICATT is to provide free COVID-19 laboratory testing. More than 10,000 pharmacy sites participate in ICATT. These locations have performed more than 36 million COVID-19 tests since April 2021.

[Visit the U.S. Department of Health and Human Services website](#) to find other community-based testing sites for COVID-19. You can also visit your [state](#), [tribal](#), [local](#), or [territorial](#) health department's website to look for the latest local information on testing.

 Partners  About the Program

Next Scheduled CLCR Call

The next call will be on **Monday, March 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?

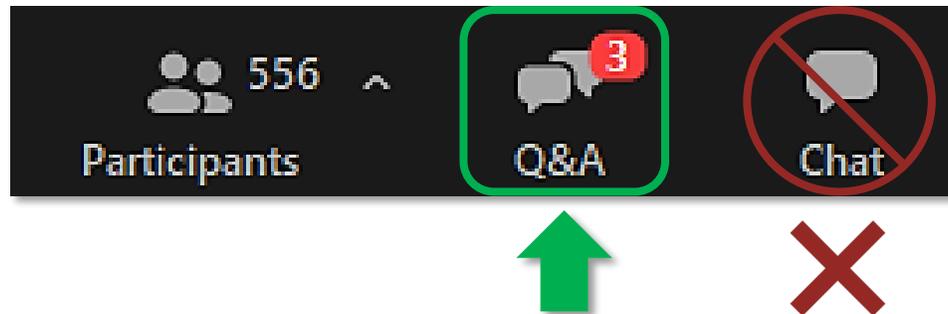
Contact LabTrainingNeeds@cdc.gov



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.



How it works:
COVID-19 sequencing
from patient swab to
variant classification

Justin Lee
CDC Genomic Sequencing Lab
psd8@cdc.gov

NGS Quality

- It's never been easier to generate sequence data.
- It's never been easier to analyze sequence data.
- Come on...everyone's doing it!

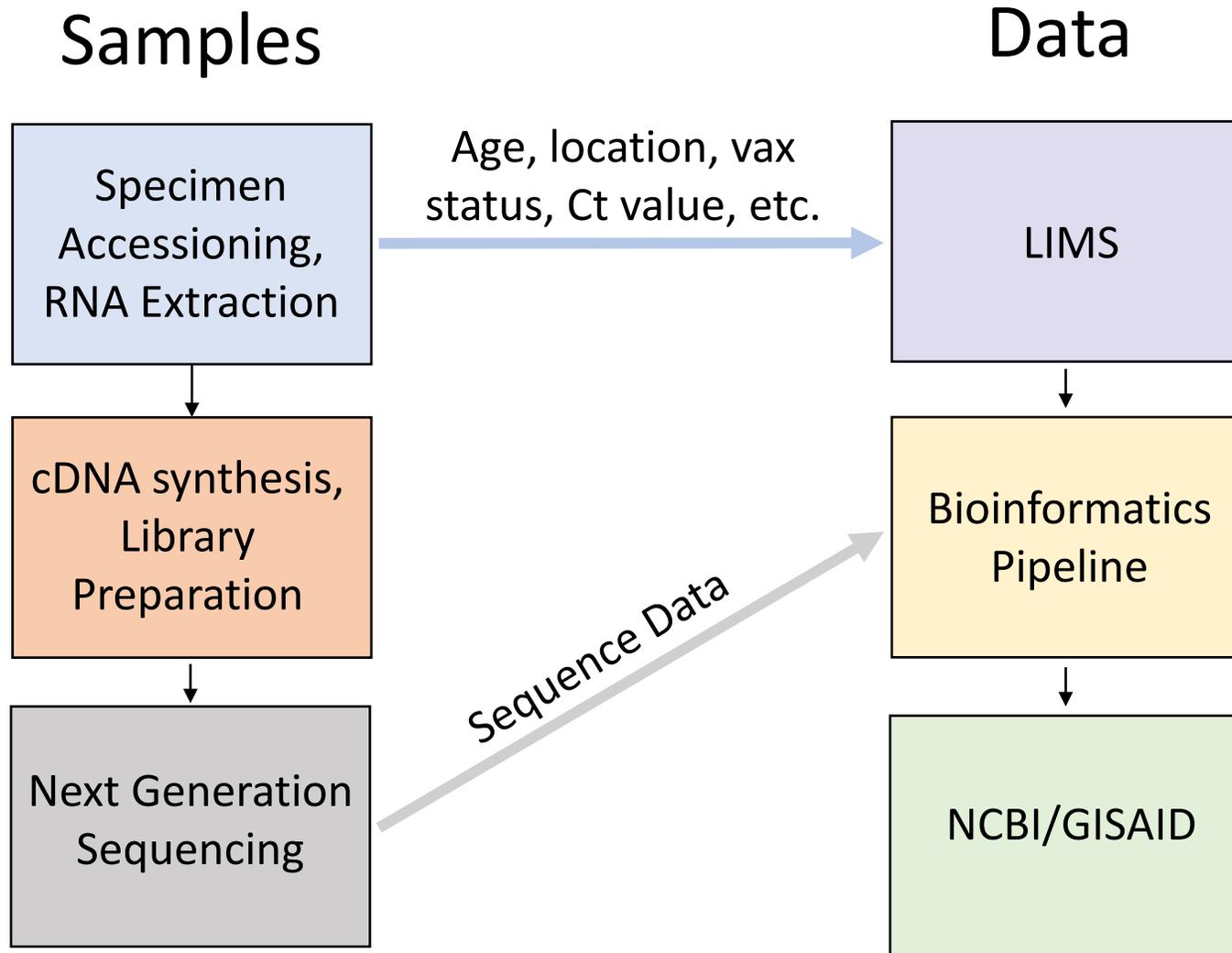
NGS Quality

- It's never been easier to generate sequence data.
- It's never been easier to analyze sequence data.

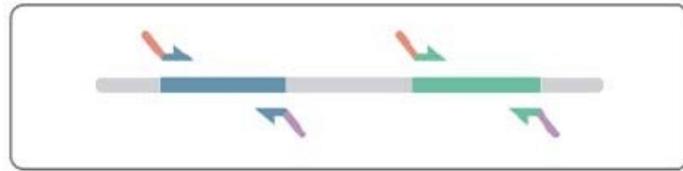
- But it is still difficult to generate & analyze GOOD sequence data!



Sequencing overview



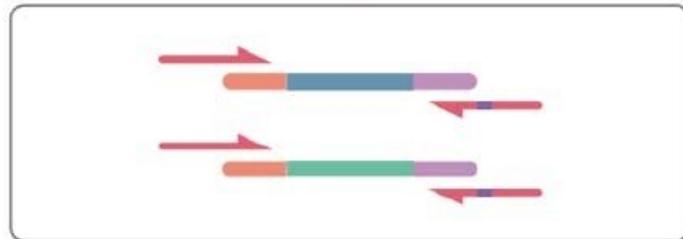
Tiled amplicon enrichment of SARS-CoV-2



1. Multiplex PCR



2. Background Cleaning

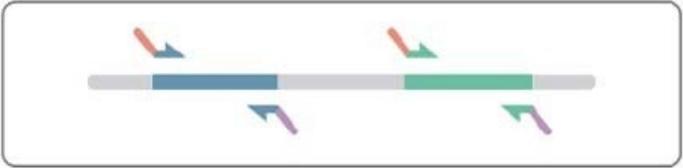


3. Indexing PCR



Ready libraries

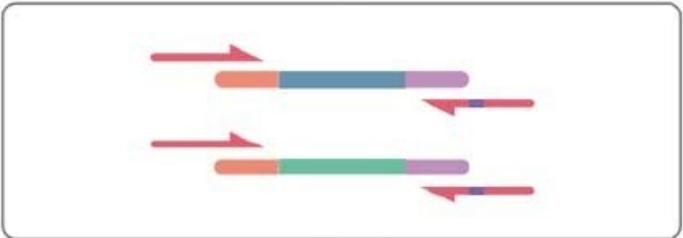
Tiled amplicon enrichment of SARS-CoV-2



1. Multiplex PCR



2. Background Cleaning

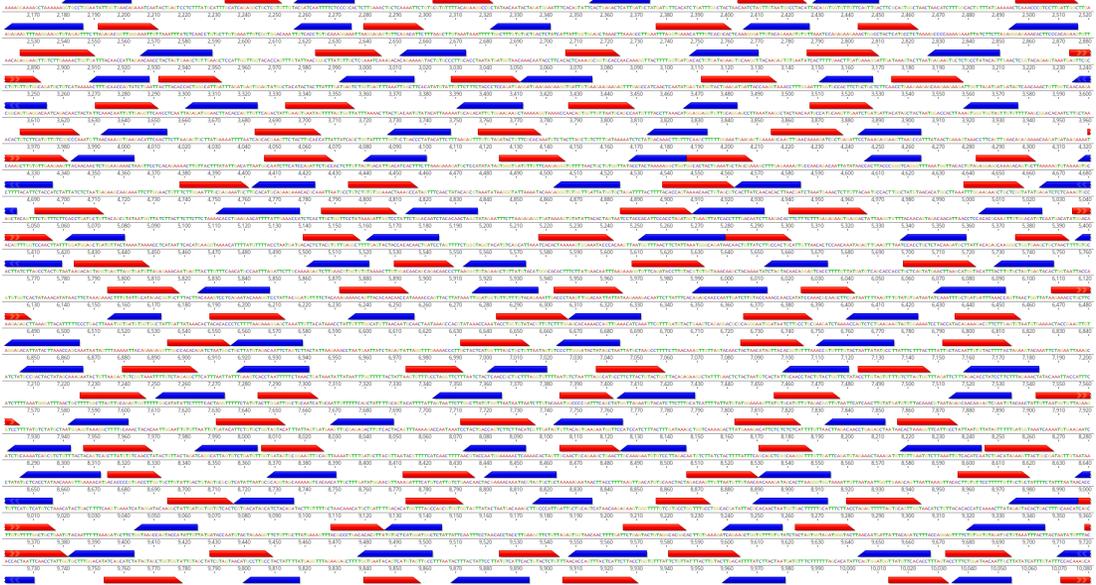


3. Indexing PCR



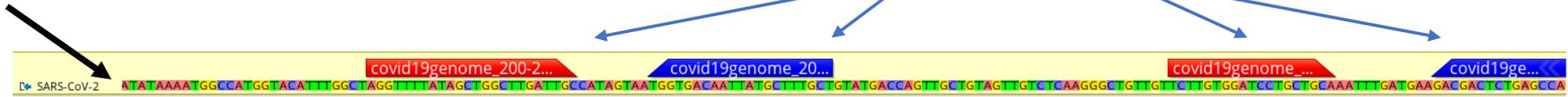
Ready libraries

Primer scheme we use currently at CDC:
~300 primer pairs



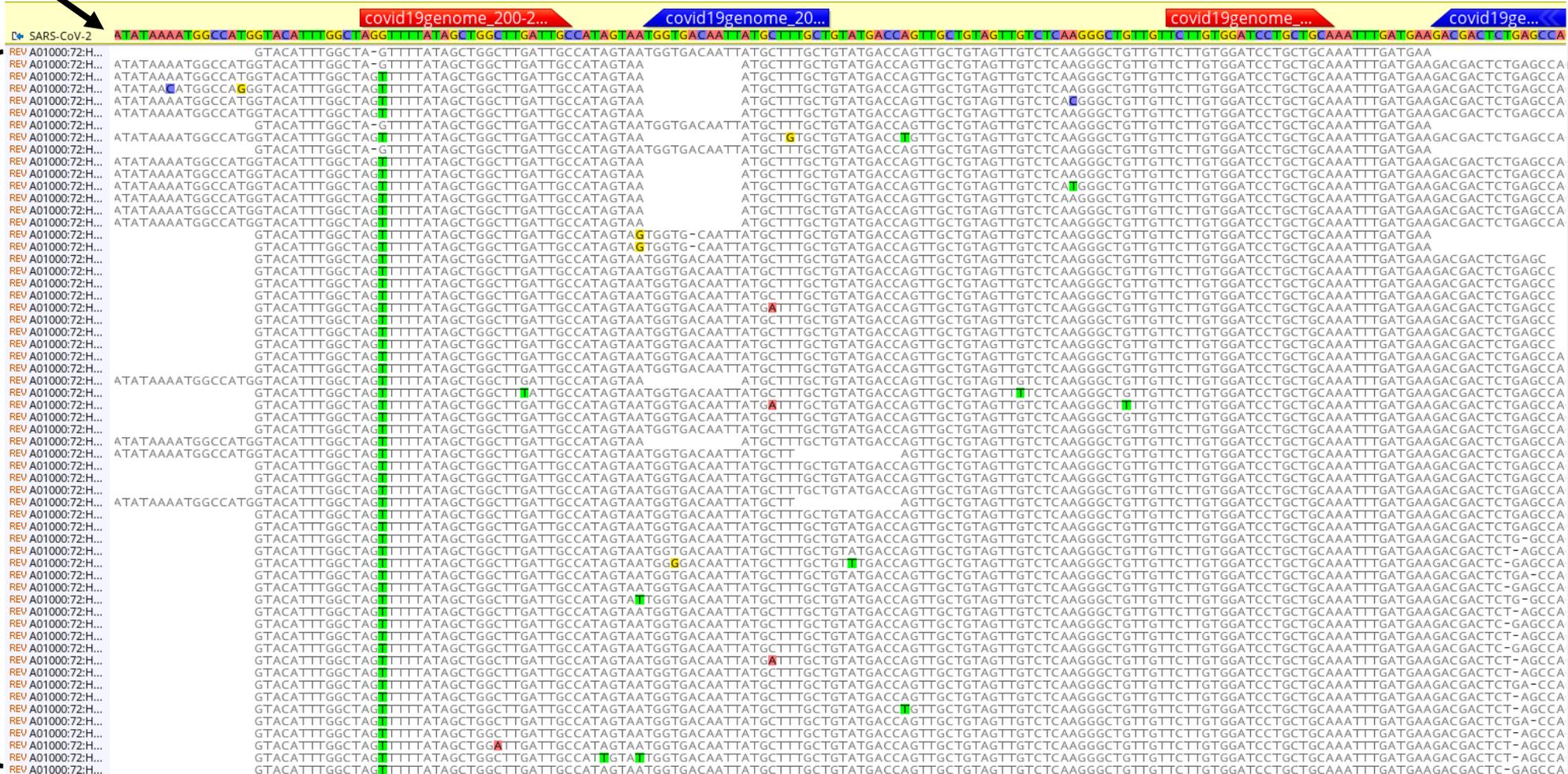
Reference sequence (SARS-CoV-2 Wuhan-1)

Primer binding locations



Reference sequence (SARS-CoV-2 Wuhan-1)

Primer binding locations

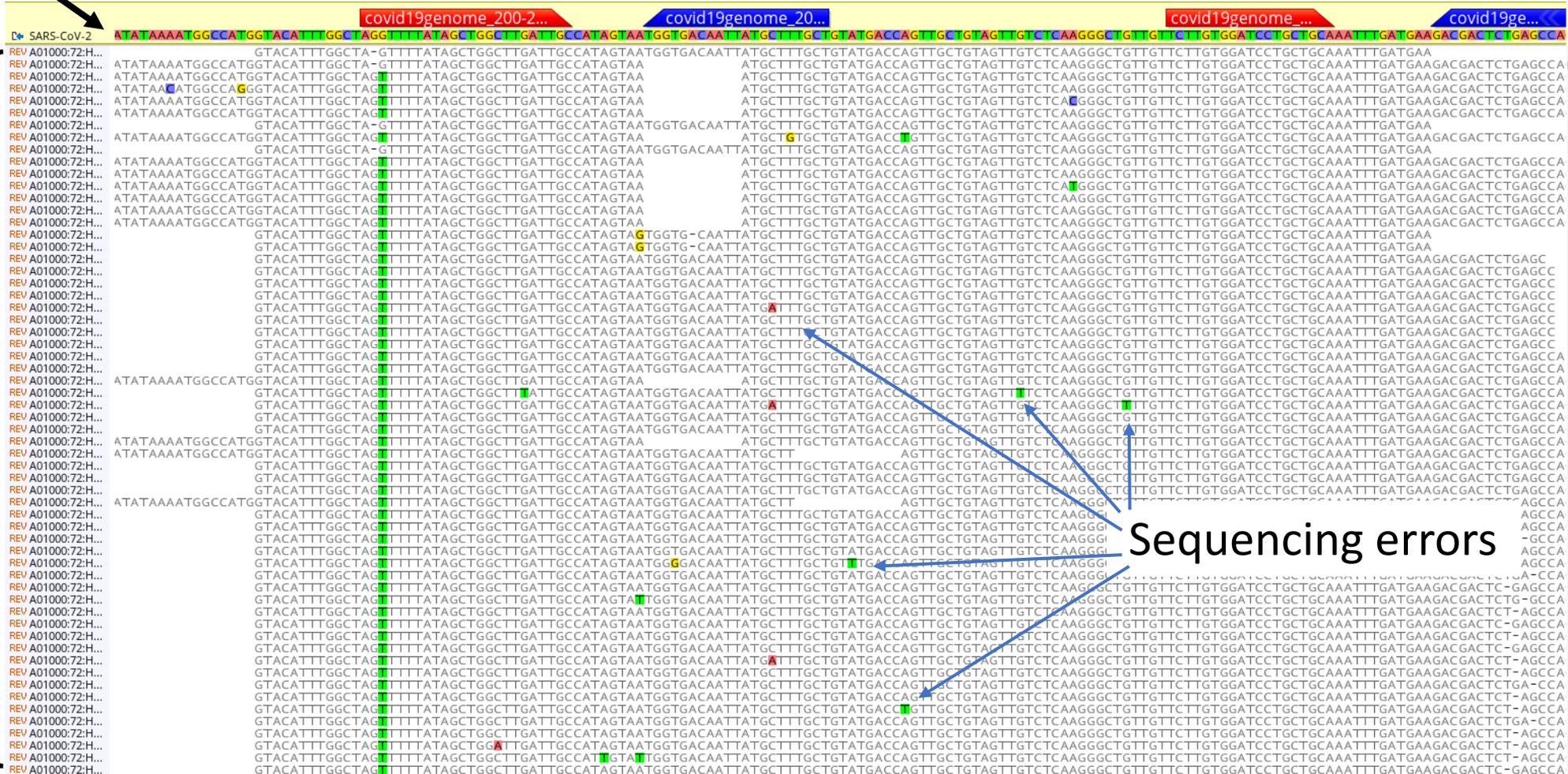


NGS Data
(‘NGS reads’)



Reference sequence (SARS-CoV-2 Wuhan-1)

Primer binding locations

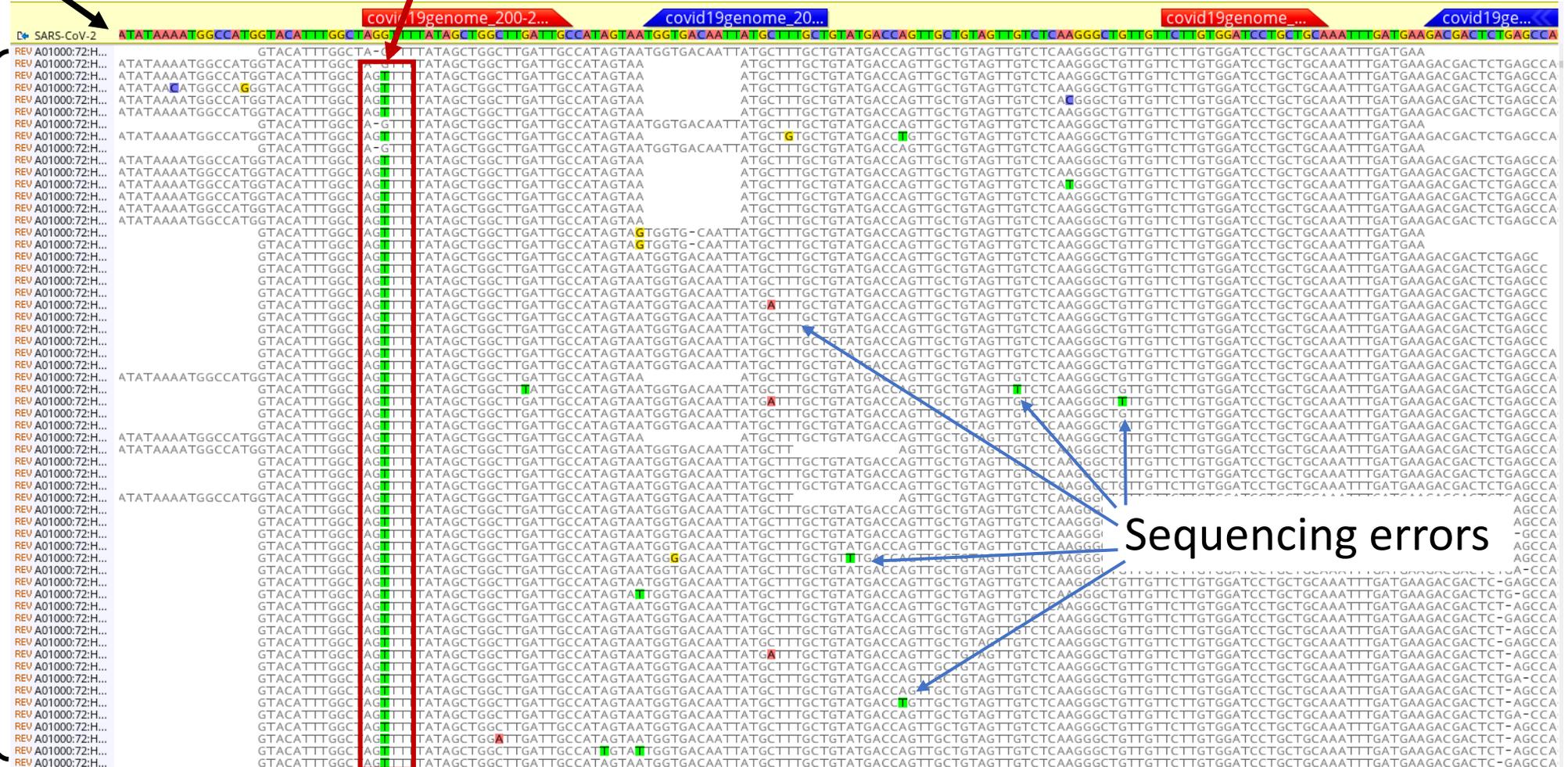


Reference sequence
(SARS-CoV-2 Wuhan-1)

Mutation
(base different from reference)

Primer binding locations

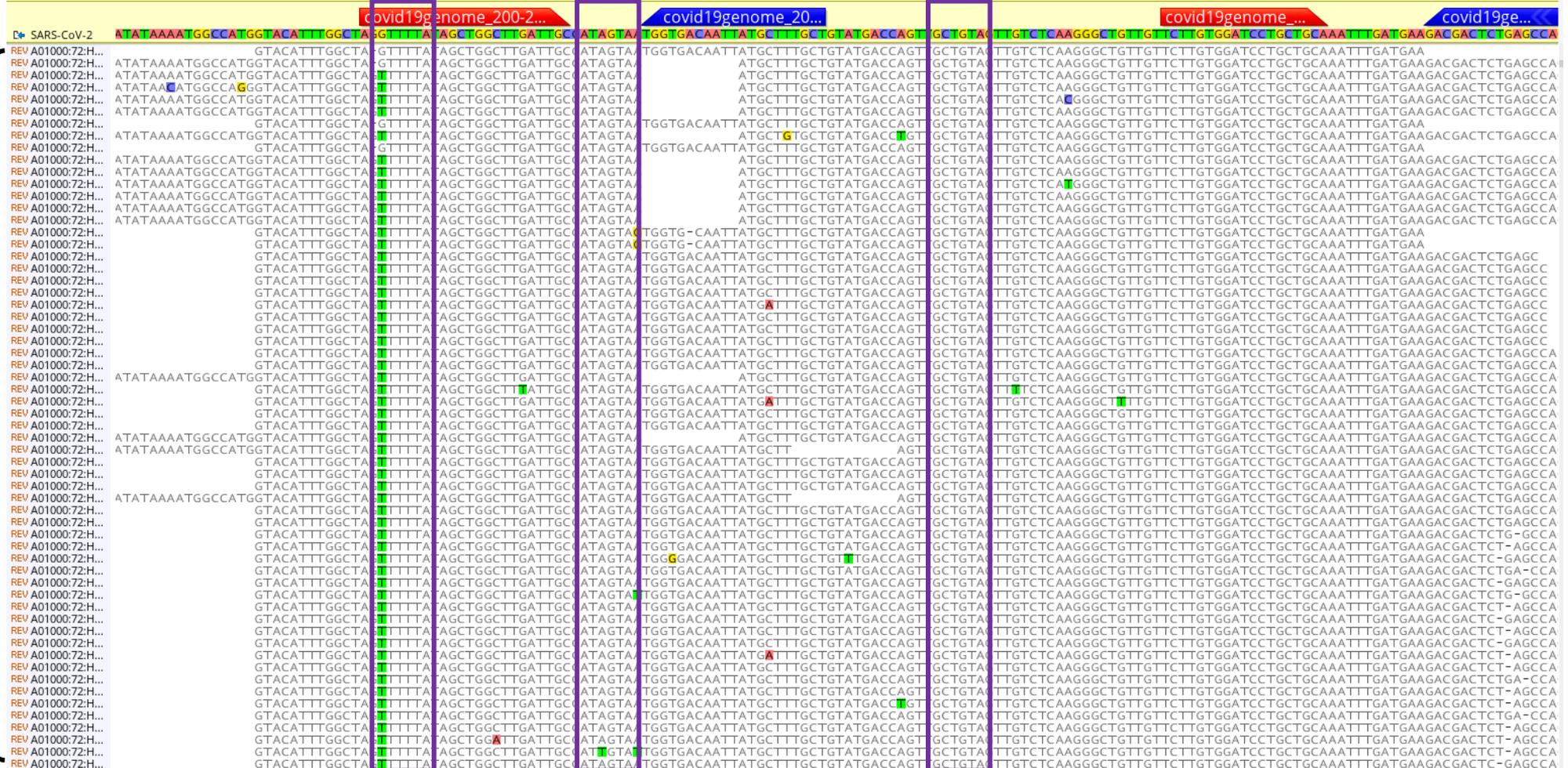
NGS Data
(‘NGS reads’)



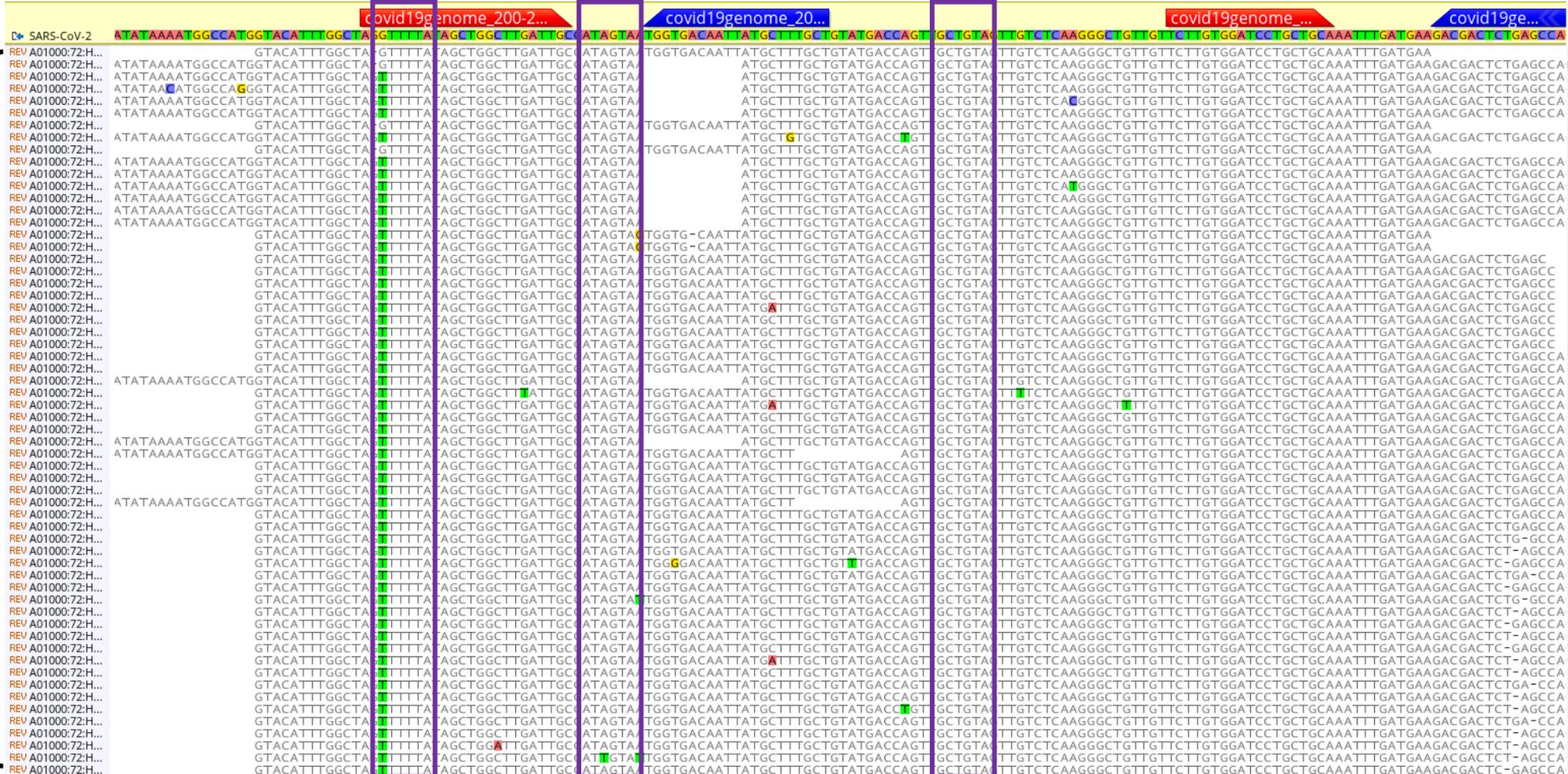
Consensus sequence
(independent of reference)

...TTT TTA... ...ATA GTA... ...GCT GTA...

Nucleotide



Consensus sequence (independent of reference) ...TTT TTA... ..ATA GTA... ..GCT GTA... Nucleotide
 ...Phe Leu... ..Ile Val... ..Ala Val... Amino Acid
 (Val)



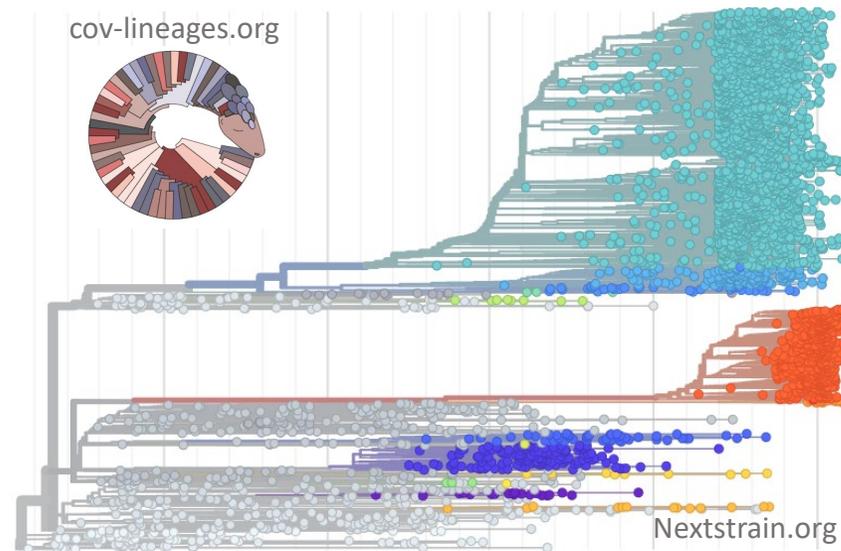
NGS Data
 ('NGS reads')

From consensus to lineage assignment...

Translated Consensus Sequence

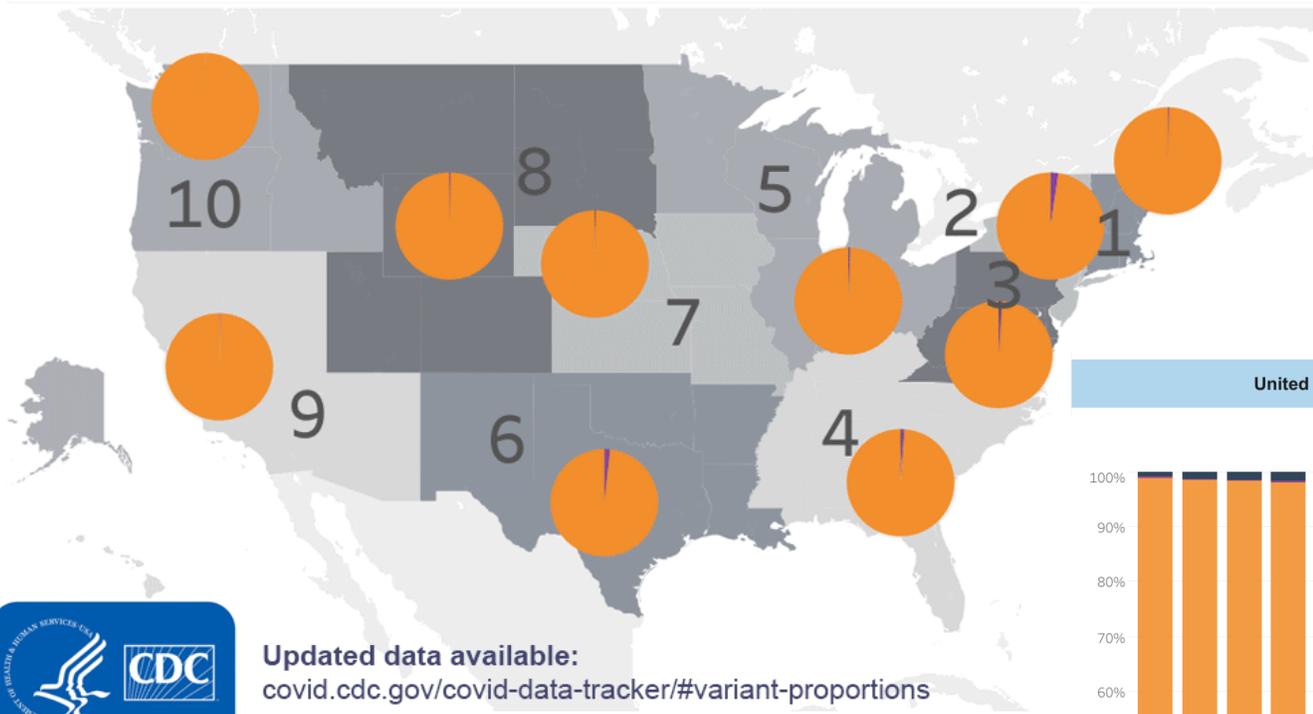
...TTT TTA ... ATA GTA ... GCT GTA...
...Phe Leu ... Ile Val ... Ala Val...
(Val)

Taxonomic Classification



Weighted Estimates of Proportions of SARS-CoV-2 Lineages

United States: 11/28/2021 – 12/4/2021

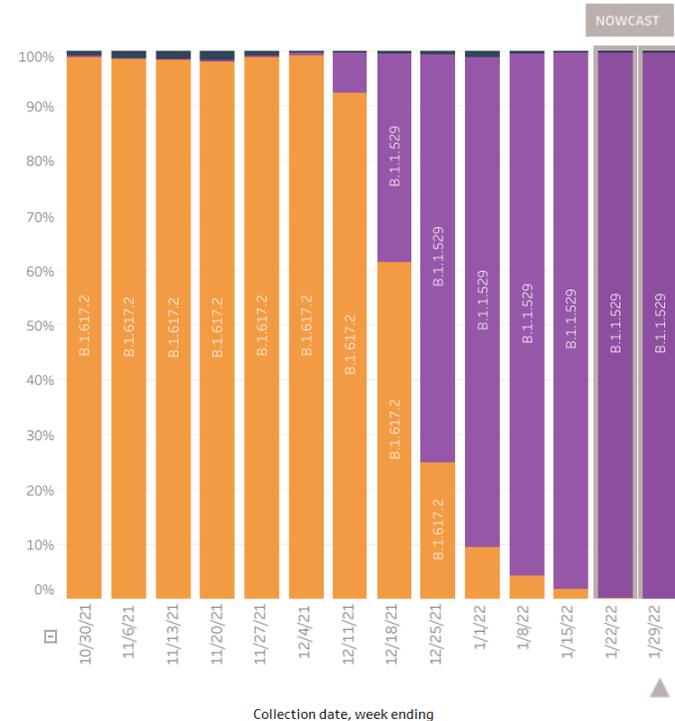


Updated data available:
covid.cdc.gov/covid-data-tracker/#variant-proportions

National Surveillance

United States: 10/24/2021 – 1/29/2022

United States: 1/23/2022 – 1/29/2022 NOWCAST

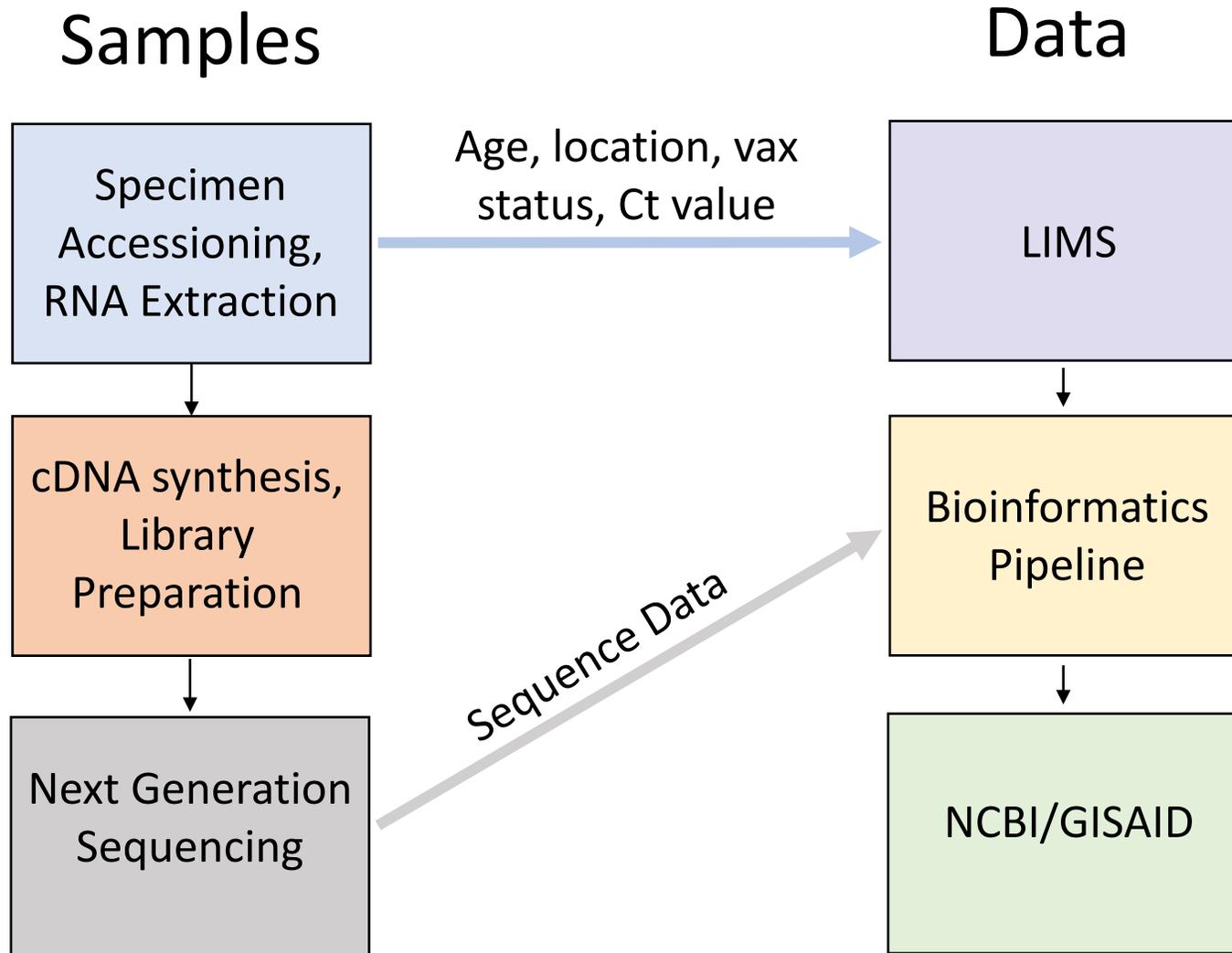


USA				
WHO label	Lineage #	US Class	%Total	95%PI
Omicron	B.1.1.529	VOC	99.9%	99.9-100.0%
Delta	B.1.617.2	VOC	0.1%	0.0-0.1%
Other	Other*		0.0%	0.0-0.0%

* Enumerated lineages are US VOC and lineages circulating above 1% nationally in at least one week ending. "Other" represents the aggregation of lineages which are circulating <1% nationally during all weeks displayed.
 ** These data include Nowcast estimates, which are modeled projections that may differ from weighted estimates generated at later dates
 # AY.1-AY.133 and their sublineages are aggregated with B.1.617.2. BA.1, BA.2 and BA.3 are aggregated with B.1.1.529.

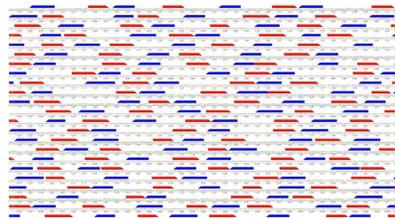
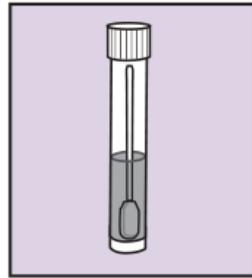
Collection date, week ending

Sequencing overview

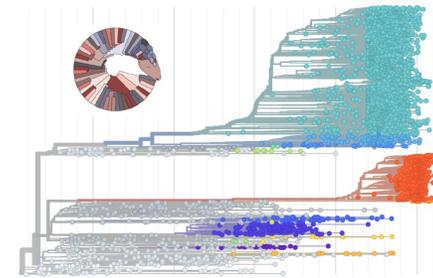
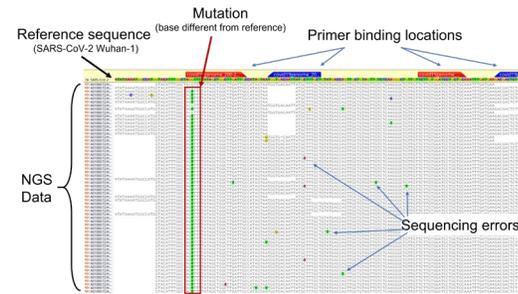


Summary: patient swab to variant classification

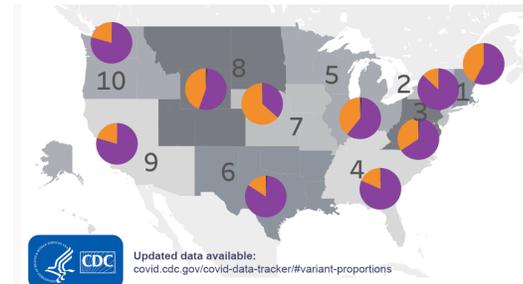
Samples



Data



Sequence Data



Acknowledgements

- National SARS-CoV-2 Strain Surveillance Program Contributors
- Sample processing
 - Accessioning: CDC STATT Lab
 - RNA extraction: CDC COORS Lab
- Sequencing: Genomic Sequencing Lab
- Analysis: Strain Surveillance and Emerging Variants Bioinformaticians
- CDC COVID-19 Laboratory and Testing Task Force
- CDC COVID-19 Epidemiology Task Force

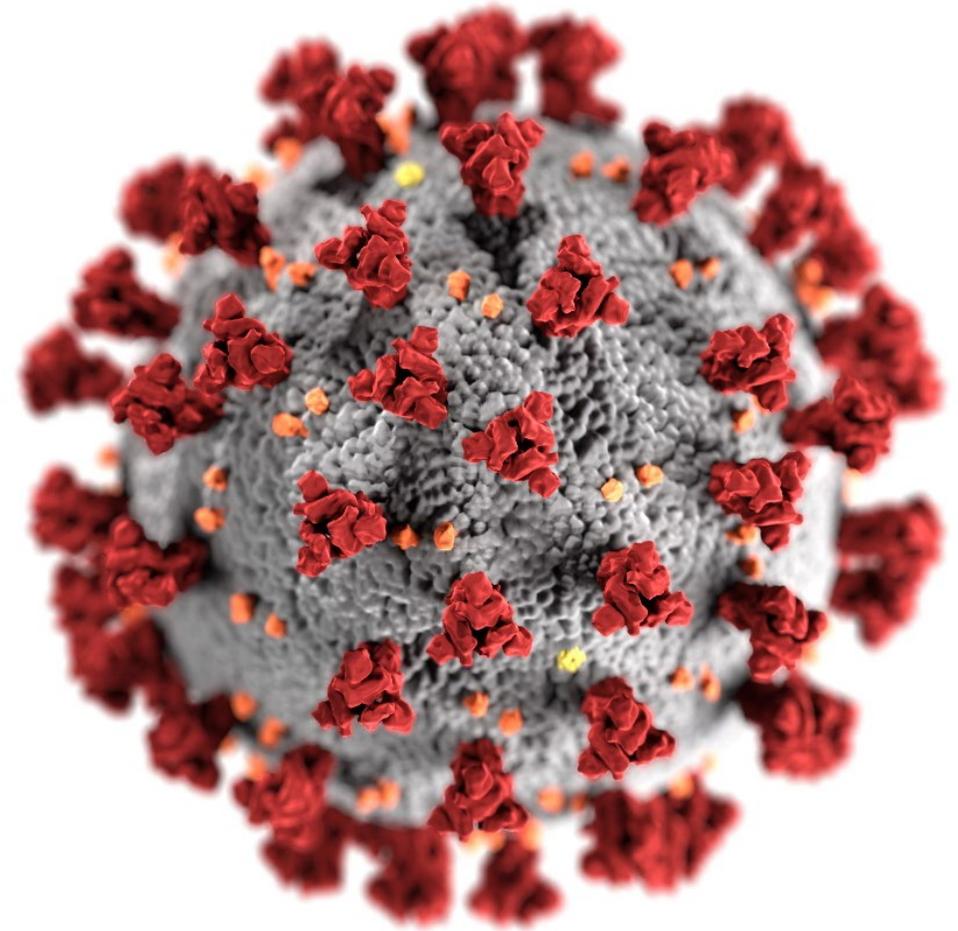
Increasing Community Access to Testing (ICATT) Pharmacy Expansion Update

Daniel Parker, MBA

ICATT Pharmacy Program Lead

Centers for Disease Control and Prevention (CDC)

February 2, 2022



cdc.gov/coronavirus



Background

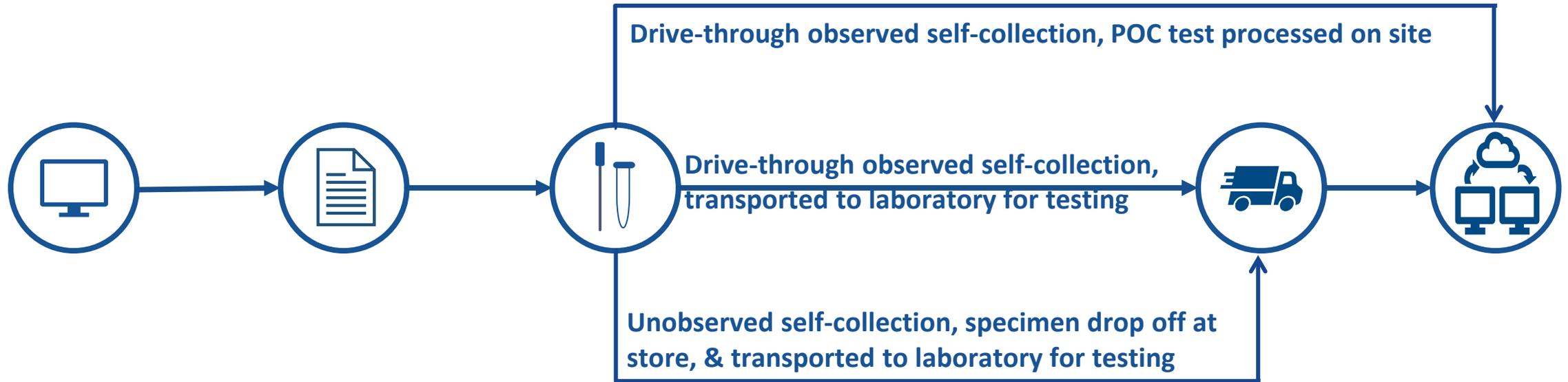
- ICATT partners with pharmacies to provide no-cost testing to communities that have been disproportionately affected by the pandemic
 - ~32.1M pharmacy tests to date
 - 10,230 pharmacy sites in all 50 states, DC, and PR
 - 40% of tests performed for racial/ethnic minorities
 - 53% of current facilities are in high SVI census tracts
- ICATT's Expansion Goal: Expand **to 20,000 pharmacy testing sites** across the nation by the end of March 2022, making free testing available to these communities.
- Independent pharmacies will be added to the ICATT program by subcontracting to eTrueNorth (eTN), an ICATT testing partner.
- State governments interested in expanding their independent pharmacy testing base can encourage independent pharmacy groups to apply to the ICATT program.

eTrueNorth End-to-End Testing Services

- eTN partners with independent pharmacies and provides:
 - Staff training, patient registration and scheduling, testing and specimen shipping supplies, results reporting¹, physician orders, reimbursement for each resulted test through subcontract with eTN
- Testing options include²
 - Laboratory-based Nucleic Acid Amplification Tests (NAATs) with observed or unobserved self-collection
 - Point-of-care (POC) testing
- Testing models² are optimized for use:
 - In drive through pharmacies, non-drive through pharmacies, and non-pharmacy retail locations
 - With technical and non-technical staff

1. Results reported according to all state and federal laws. 2. Not all testing models will be available to every site.

eTN Testing Models



Registration and Scheduling¹

- Patient registers on the eTN platform, completes COVID-19 assessment, and selects appointment time

Store arrival

- Patient arrives at store and presents voucher number for testing
- Drive-through or walk in to obtain self-collection kit OR customer service walks self-collection kit to the car

Self-Collection

- Patient self-collects specimen, observed or unobserved
- POC tests are processed on site³

Transportation²

- Store packages observed self-collection specimens and prepares for FedEx/UPS daily pickup
- Patient packages unobserved self-collection specimens for and drops in FedEx pickup box
- Laboratory performs NAAT testing

Results Reporting

- Patient receives email notification of result, and also has access to a 1-800 number
- eTN reports all test results to public health according to state and federal laws

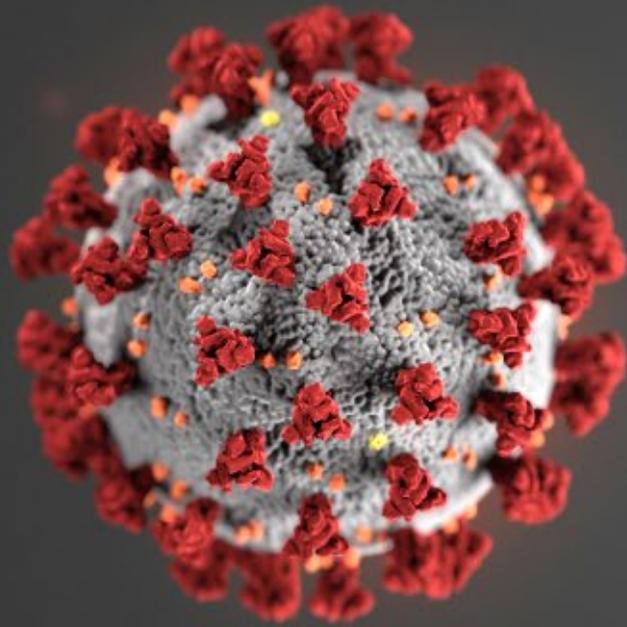


1. Available testing options will depend on the pharmacy
2. Excludes POC tests that are processed onsite at the pharmacy
3. POC test type and manufacturer may vary by location

Expansion Efforts: How to Help

- Encourage independent pharmacy chains in your state to apply to the ICATT Program online: eocevent586@cdc.gov
 - ICATT will distribute an informational one-pager to assist with promotion
 - Associations/pharmacy entities should have a minimum of 10 pharmacy sites¹
- In prioritizing this effort, states should account for testing needs especially within communities disproportionately affected by COVID-19 and consider factors such as:
 - Areas with intermediate to high SVI (> 0.5)
 - Areas with high testing demand
 - Areas with high community transmission levels
 - Areas with low vaccine coverage
 - Areas in communities that have very few or no community testing sites
- ICATT will continue to provide monthly pharmacy reports so states can track progress
- For questions contact ICATT at eocevent586@cdc.gov

1. Independent pharmacies with less than 10 members will be recruited after meeting the President's goal of 20,000 total ICATT pharmacy sites



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.



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

- **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>



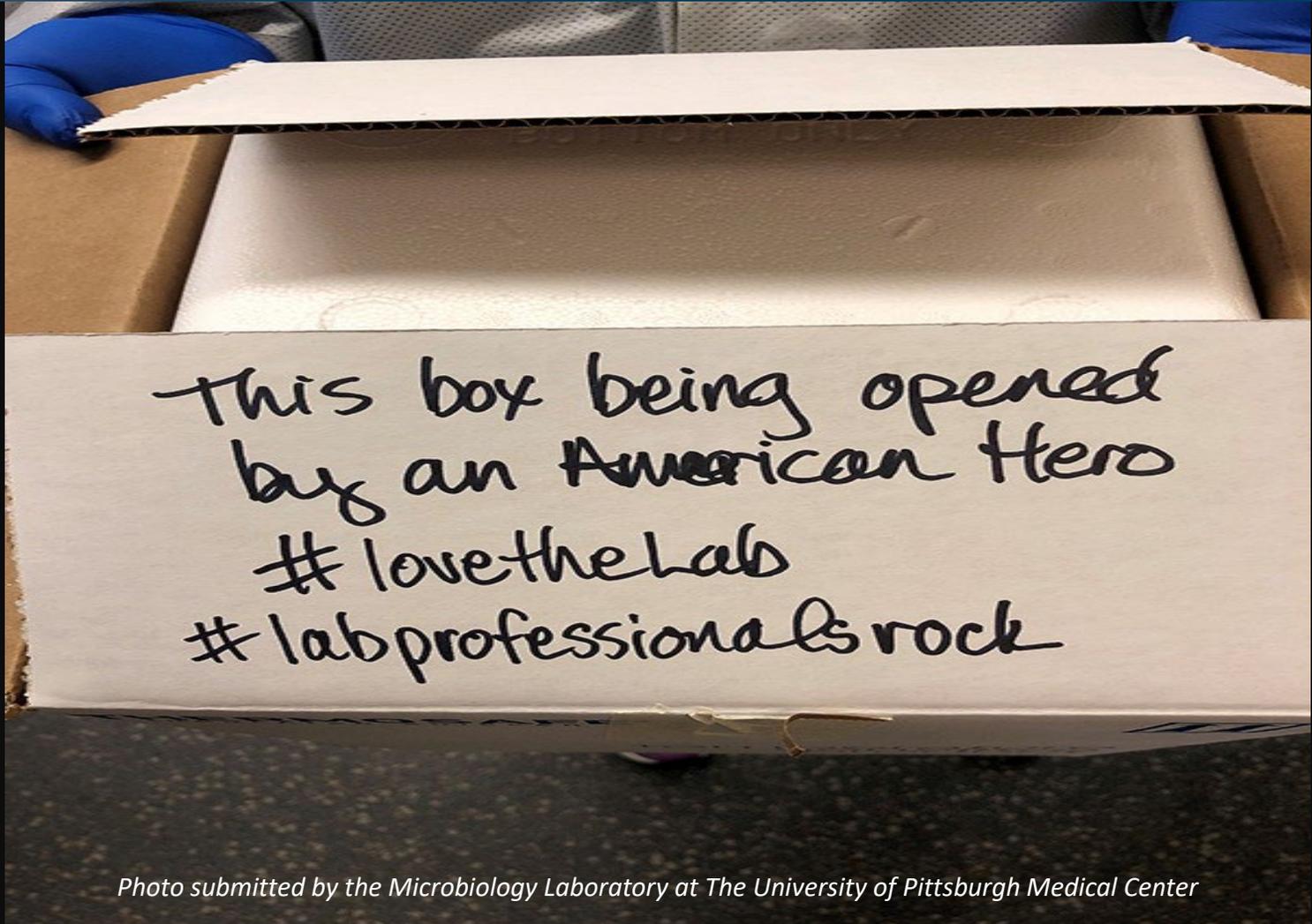
<https://twitter.com/cdcgov>

<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