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

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.

https://www.cdc.gov/icatt/index.html
The next call will be on **Monday, March 7** from **3:00 PM to 4:00 PM ET**
Training and Workforce Development

Questions about education and training?
Contact LabTrainingNeeds@cdc.gov
How to Ask a Question

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

- For media questions, please contact CDC Media Relations at [media@cdc.gov](mailto:media@cdc.gov)
- If you are a patient, please direct any questions to your healthcare provider
Slide decks may contain presentation material from panelists who are not affiliated with CDC. Presentation content from external panelists may not necessarily reflect CDC’s official position on the topic(s) covered.
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

**Samples**
- Specimen Accessioning, RNA Extraction
- cDNA synthesis, Library Preparation
- Next Generation Sequencing

**Data**
- LIMS
- Bioinformatics Pipeline
- NCBI/GISAID

Age, location, vax status, Ct value, etc. 
Sequence Data
Tiled amplicon enrichment of SARS-CoV-2
Tiled amplicon enrichment of SARS-CoV-2

Primer scheme we use currently at CDC:
~300 primer pairs
How does sequencing work?
Reference sequence
(SARS-CoV-2 Wuhan-1)

Primer binding locations
<table>
<thead>
<tr>
<th>Primer binding locations</th>
<th>Reference sequence (SARS-CoV-2 Wuhan-1)</th>
</tr>
</thead>
</table>

**NGS Data (‘NGS reads’)**

<table>
<thead>
<tr>
<th>SARS-CoV-2</th>
<th>covid19genome_201-2</th>
<th>covid19genome_202</th>
<th>covid19genome_203</th>
</tr>
</thead>
<tbody>
<tr>
<td>...</td>
<td>...</td>
<td>...</td>
<td>...</td>
</tr>
</tbody>
</table>

18
<table>
<thead>
<tr>
<th>Reference sequence (SARS-CoV-2 Wuhan-1)</th>
<th>Primer binding locations</th>
<th>Sequencing errors</th>
</tr>
</thead>
<tbody>
<tr>
<td>NGS Data ('NGS reads')</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Primer binding locations

Mutation
(base different from reference)

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

NGS Data
(‘NGS reads’)

Sequencing errors
<table>
<thead>
<tr>
<th>NGS Data ('NGS reads')</th>
<th>Consensus sequence (independent of reference)</th>
</tr>
</thead>
<tbody>
<tr>
<td>...TTT TTA... ...ATA GTA... ...GCT GTA...</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Nucleotide</th>
<th></th>
</tr>
</thead>
</table>

```
...GCT GTA...ATA GTA...
TTT TTA...
```
Consensus sequence (independent of reference)

<table>
<thead>
<tr>
<th>NGS Data ('NGS reads')</th>
<th>Nucleotide</th>
<th>Amino Acid</th>
</tr>
</thead>
<tbody>
<tr>
<td>TTT TTA... ATA GTA... GCT GTA... Phe Leu... Ile Val... Ala Val... (Val)</td>
<td>...GCT GTA...</td>
<td>...Phe Leu...</td>
</tr>
</tbody>
</table>
From consensus to lineage assignment...

Transcribed Consensus Sequence

_._TTT TTA ... ATA GTA ... GCT GTA...

...Phe Leu ... Ile Val ... Ala Val ...
(Val)
From consensus to lineage assignment...

Translated Consensus Sequence

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

...Phe Leu ... Ile Val ... Ala Val...
(Val)

Taxonomic Classification

WHO Designation for Variants of Concern

Alpha
Beta
Gamma
Delta
Omicron
Sequencing overview

Samples

- Specimen Accessioning, RNA Extraction
- cDNA synthesis, Library Preparation
- Next Generation Sequencing

Data

- Age, location, vax status, Ct value
- LIMS
- Bioinformatics Pipeline
- NCBI/GISAID

Sequence Data
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
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 reporting\(^1\), physician orders, reimbursement for each resulted test through subcontract with eTN

- Testing options include\(^2\)
  - Laboratory-based Nucleic Acid Amplification Tests (NAATs) with observed or unobserved self-collection
  - Point-of-care (POC) testing

- Testing models\(^2\) 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

Drive-through observed self-collection, POC test processed on site

Drive-through observed self-collection, transported to laboratory for testing

Unobserved self-collection, specimen drop off at store, & transported to laboratory for testing

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 sites\(^1\)

- 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
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.
COVID-19 Emergency Use Authorization (EUA) Information for Medical Devices
https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations

COVID-19 In Vitro Diagnostic EUAs

COVID-19 Frequently Asked Questions

COVID-19 Updates

FDA Townhall Meetings

Independent Evaluations of COVID-19 Serological Tests
https://open.fda.gov/apis/device/covid19serology/
COVID-19 Diagnostic Development
CDRH-EUA-Templates@fda.hhs.gov

Spot Shortages of Testing Supplies: 24-Hour Support Available
1. Call 1-888-INFO-FDA (1-888-463-6332)
2. Then press star (*)

FDA MedWatch
Thank You For Your Time!

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