Clinical Laboratory COVID-19 Response Call
Monday, August 9, 2021, at 3:00 PM EDT

• Welcome
  – Jasmine Chaitram, CDC Division of Laboratory Systems (DLS)

• Use of Cycle Threshold (Ct) Values
  – Brandi Limbago, CDC Laboratory and Testing Task Force for the COVID-19 Response

• SARS-CoV-2 Variants Update
  – Jessica Chen, CDC Laboratory and Testing Task Force for the COVID-19 Response

• RADx Update
  – Bruce Tromberg, National Institutes of Health (NIH) RADx

• Abbott BinaxNOW and Emerging Variants
  – Jennifer Frediani, Joshua Levy, Anuradha Rao, Leda Bassit, & Wilbur Lam, Emory University
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 of DLS**

1. **Quality Laboratory Science**
   - Improve the quality and value of laboratory medicine and biorepository science for better health outcomes and public health surveillance

2. **Highly Competent Laboratory Workforce**
   - Strengthen the laboratory workforce to support clinical and public health laboratory practice

3. **Safe and Prepared Laboratories**
   - Enhance the safety and response capabilities of clinical and public health laboratories

4. **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 the CDC Preparedness Portal.

The next call will be on **Monday, August 23** from **3:00 PM to 4:00 PM EDT**
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.
Use of Cycle Threshold (Ct) Values

Brandi Limbago
CDC Laboratory and Testing Task Force for the COVID-19 Response
CDC Update on National SARS-CoV-2 Surveillance

Jessica Chen, PhD
Strain Surveillance and Emerging Variants Team
Laboratory and Testing Task Force
CDC COVID-19 Emergency Response
National Nowcast Estimates of SARS-CoV-2 Lineages

- **Delta (including sublineages) increased**¹
  - From 82% to 93%
    - B.1.617.2 (83%)
    - AY.3 (9%)
    - AY.2 (0.8%)
    - AY.1 (0.1%)
- **Alpha (B.1.1.7) decreased**
  - From 9% to 3%
- **Gamma (P.1) decreased**
  - From 4% to 1%

¹Weighted estimates from period ending 07/17/2021 (as of 7/23/2021) used for comparison with Nowcast (as of 7/31/2021)

https://covid.cdc.gov/covid-data-tracker/#variant-proportions
Regional Nowcast Proportion of SARS-CoV-2 Lineages

- Delta (B.1.617.2) predominates in all HHS regions
  - AY.3 is highest in Region 7 (33%)
  - AY.2 is highest in Region 9 (2%)

- Alpha (B.1.1.7) decreasing in all regions
  - Less than 7% in each region

- Gamma (P.1)
  - Decreasing in all HHS Regions
  - 3% or less in each region

https://covid.cdc.gov/covid-data-tracker/#variant-proportions
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.
Rapid Acceleration of Diagnostics Technology (RADx Tech)

Bruce J. Tromberg, Ph.D.
Director, National Institute of Biomedical Imaging & Bioengineering (NIBIB)

NIBIB RADx Tech Leads: Jill Heemskerk, Tiffani Lash, Todd Merchak, Mike Wolfson, Doug Sheeley, David George, Gene Civillico, Bill Heetderks, Charles Anamelechi, Matt McMahon, Felicia Qashu, Tony Kirilusha, Mark Snyder, Andrew Weitz, Krishna Juluru, Ilana Goldberg, Taylor Gilliland, Kate Egan, Ray MacDougall, Patty Wiley, Jennifer Jackson
RADx: Unexpected Opportunity

April 24, 2020: $1.5B to NIH
$500 Million to NIBIB

1) Expand COVID-19 Testing Technologies:
Number, Type and Access

2) Optimize Performance: Technologic and Operational; Match Community Needs

NIH Office of the Director
Francis Collins  Rachael Fleurance  Larry Tabak  Tara Schwetz

RADx Tech – $500M
Highly competitive, rapid three-phase challenge to identify the best candidates for at-home or point-of-care tests for COVID-19

RADx Advanced Technology Platforms (RADx-ATP) – $230M
Rapid scale-up of advanced technologies to increase rapidity and enhance and validate throughput – create ultra-high throughput machines and facilities

RADx Radical (RADx-Rad) – $200M
Develop and advance novel, non-traditional approaches or new applications of existing approaches for testing

RADx Underserved Populations (RADx-UP) – $500M
Interlinked community-based demonstration projects focused on implementation strategies to enable and enhance testing of COVID-19 in vulnerable populations

National Institute of Biomedical Imaging and Bioengineering (NIBIB)
Jill Heemskerk  Bruce Tromberg

$307 M Partnership

https://www.nih.gov/research-training/medical-research-initiatives/radx
RADx: Leverage Existing Network (POCTRN)

NIBIB Point of Care Tech Network: NHLBI, NIAID, NCCIH, FIC, OBSSR, OAR, ODP

Established 2007, Expanded 2020: >900 RADx experts & contributors
(USG, Academia, Industry, NFP)

https://www.poctrn.org

Operations:
• Review & Fund
• Test & Validate
• Expert Guidance

GaTech/Emory
✓ Engineering
✓ Design/Prototype
✓ Clinical Validation
✓ Biobank samples
✓ In-Home Validation

Northwestern
✓ HIV/AIDS
✓ Engineering
✓ Global Health
✓ Clinical Validation
✓ Validation in LMICs

CIMIT/MGH
✓ Coordinating Center
✓ Collaboration/Management Platform
✓ Business/Commercialization

Johns Hopkins
✓ Public Health/STD
✓ Global Health
✓ Clinical Validation
✓ Biobank samples
✓ Validation in LMICs

UMass
✓ Heart, lung, blood
✓ Engineering
✓ Clinical Validation
✓ Biobank samples
✓ Clinical Trials
✓ Business/Commercialization

Validation Core
>60 projects complete,
>2500 participants

Clinical Studies Core
Standard Trial Design, Digital Health Platform,
Single IRB, Center Network

Deployment Core
Supply chain, Manufacturing,
User Community, whenotest.org
ASU testing common
Project N95

Todd Merchak
Tiffany Lash
RADx: Tech Innovation Funnel Process

~3000 Applications Started

Rolling submission open April 29

Projects in each Phase
- 716
- 140
- 47
- 33

Nhale.com~

Validation, Clinical Testing, Regulatory, Manufacturing, Distribution

~$600M
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<tr>
<td>Home Rx &amp; OTC</td>
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<tr>
<td>Home OTC</td>
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</table>

- **Mesa BioTech**
- **Quanterix Simoa**
- **Quidel Sophia**
- **Ellume**
- **Genbody**
- **ANP**
- **Luminostics**
- **Visby Medical**
- **Flambeau**
- **Fluidigm**
- **Luminostics**

*Images and logos are used to represent the companies and technologies mentioned.*

RADx Impact thru June 2021

Cumulative EUA Authorized Tests by Month

- Laboratory
- Point of Care
- Home

Major Milestones

- 514 million capacity thru June 2021
- ~4 M tests and products/day June 2021
- 27 EUAs; 1st OTC EUA, 2 “at home”
- >100 companies supported

~$1.1 Billion: Special Congress Authorization
~1.3 Billion: Private Capital Raised

Assess **efficacy** and **effectiveness** of at-home testing 2-3 X/week

Outcome measures:
- SARS-CoV-2 prevalence and incidence
- % test positivity, volume
- Cell phone mobility
- Wastewater surveillance

Optional app used for:
- Ordering tests (partnership with Amazon)
- Reminders and instructions
- Interpretation & guidance when positive
- Reporting results to the state (MI, TN)

2 million free home tests
*Pitt Co, NC; Hamilton Co, TN; Washtenaw Co, MI*


RADx UP
Digital Health Infrastructure

RADx POC Test

LFA

How to Use

Symptom Surveys

Cell Phone Reader

EHR & Claims

State and Federal

Need Standards

Contact Tracing

Data Hubs e.g. APHL

Health status

e.g. VCI

Need Standards

https://vaccinationcredential.org
RADx Variant Task Force

RADx Team
Richard Creager
Eric Lai
John Blackwood
Mia Cirrincione
Dale Gort
Emily Kennedy
D'lyrne Plummer
Thomas Pribyl
Adam Samuta
Megan Shaw
Brian Walsh

Emory
Leda Bassit
Filipp Frank
Morgan Greanleaf
Wilbur Lam
Cangyuan Li
Eric Ortlund
Anuradha Rao
Raymond Schinazi
Allie Suessmith
Julie Sullivan
Thomas Vanderford

Univ of WA
Alex Greninger

1) Impact of Variants on Test Performance (NAT, An)
2) Design tests for variant surveillance (e.g. “SNP chips”)

Diagnostics Devices
Manufacturer defines or uploads test parameters

Wet Lab testing
- At Emory
- At manufacturers
- At third party sites

RADx VTF and FDA Reporting

Sequence Databases
U.S. & Global
- Other Sequence Providers
- GenBank
- GISAID

FASTA Import

Identify VOC

Federal Agency Collaboration
FDA risk assessment; results format; CDC; VOC/I; NCBI: database software tools

Variants BioBank
- Sample selection
- Biobank collection
- Testing sample pools

ROSALIND Database
## RADx Tech Future Directions

<table>
<thead>
<tr>
<th>Lab RTPCR</th>
<th>POC RTPCR</th>
<th>POC An (LFA/reader)</th>
<th>POC An (LFA/visual)</th>
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<tbody>
<tr>
<td>ABL 7500</td>
<td>Mesa BioTech</td>
<td>Quidel Sophia</td>
<td>Ellume</td>
</tr>
</tbody>
</table>

### Cost
- Lab RTPCR: $$$$$
- POC RTPCR: $$$
- POC An (LFA/reader): $$
- POC An (LFA/visual): $

### Speed
- Lab RTPCR: hours
- POC RTPCR: ~30 min
- POC An (LFA/reader): <15 min

### Sens/Spec
- Lab RTPCR: >90/95
- POC RTPCR: >90/95
- POC An (LFA/reader): >90/95

### LOD
- Lab RTPCR: <10³ Cp/mL
- POC RTPCR: <10³ Cp/mL
- POC An (LFA/reader): >10⁶ Cp/mL
- POC An (LFA/visual):  

### Tech to Bridge the Gap?

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National Institute of Biomedical Imaging and Bioengineering
RADx Tech Future Directions

1) New Technology
- Microfluidics
- Nanomaterials
- Single Molecule
- ASICs
- Waveguides
- Photonics

2) New Guidance, FDA Authorizations
- **Screening**: Multiple LFA, e.g. every 2-3 days >95% sensitivity (same as RTPCR)
- **Pool POC RTPCR**: “social pod”, e.g. up to 10 in classroom, home, etc.
- **Pediatric self-swabbing**: optimize work flow, e.g. home, schools

POC RTPCR
- Visby Medical
- Mesa BioTech

POC An (LFA/reader)
- Quidel Sophia
- Ellume

POC An (LFA/visual)
- Dipstick LFA

<table>
<thead>
<tr>
<th>Cost</th>
<th>Speed</th>
<th>Sens/Spec (EUA)</th>
<th>LOD</th>
</tr>
</thead>
<tbody>
<tr>
<td>$$$</td>
<td>~30 min</td>
<td>&gt;90/95</td>
<td>&lt;10^3 Cp/mL</td>
</tr>
<tr>
<td>$$</td>
<td>&lt;15 min</td>
<td>&gt;90/95</td>
<td>&gt;10^6 Cp/mL</td>
</tr>
</tbody>
</table>

RL Smith et al, JID, June 2021. DOI:10.1093/jid/jiab337
E. Burke, medrxiv.org/cgi/content/short/2021.03.24.21254230v1
Summary

RADx: New process for acceleration and impact
• Leverage existing NIBIB network w/added capabilities for evaluation, validation, funding
• Connect with USG partners to guide regulatory, policy, supply, markets, manufacturing

Technology Needs Change with ↑Vaccination and ↑Variants
• More sensitive, accessible OTC/POC tests; Multiplex w/other pathogens, expand digital health/reporting
• Rapid variant assessment, layered surveillance: bioinformatics, NGS, SNP chips, POC

Future: Leverage RADx process and tech for other pathogens, preparedness

Funnel Reopened
104 applications
34 “Shark Tank”
3 weeks, June 2021
Multidisciplinary assessment of the Abbott BinaxNOW SARS-CoV-2 point-of-care antigen test in the context of emerging viral variants and self-administration

THE NIBIB’S POINT-OF-CARE TECHNOLOGIES RESEARCH NETWORK (POCTRN)

NIH U54-funded Centers that foster the development, clinical assessment, and commercialization of point-of-care (POC) diagnostics across the US

- The Center for Advancing Point of Care in Heart, Lung, Blood and Sleep Diseases (CAPCAT) at U Mass
- Consortia for Improving Medicine with Innovation & Technology (CIMIT) at Harvard
- The Center for Innovation in Point of Care Technologies for HIV/AIDS at Northwestern
- Atlanta Center for Microsystems Engineered Point-of-Care Technologies (ACME POCT) at Emory/Georgia Tech/Children’s
- Center for Point-of-Care Technologies Research for Sexually Transmitted Diseases at Johns Hopkins
How Do We “Test The Tests?”

Our Emory and Children’s Healthcare of Atlanta pathologists and their clinical laboratories, and their biorepositories

Our Emory Biosafety Level-3 (BSL-3) laboratories and virologists

Our prospective pediatric and adult specimen collection at drive thru, community, healthcare worker, and student/faculty sites and hospital inpatient wards and emergency rooms

Our engineers and staff at Georgia Tech’s Institute for Electronics and Nanotechnology and HomeLab
Abbott BinaxNOW COVID-19 Antigen test

- Rapidly diagnosing highly transmittable variants of concern (VOC) of SARS CoV-2 using accurate tests can prevent spread of VOC
- BinaxNOW is a qualitative, SARS-CoV-2 diagnostic assay that detects the viral nucleocapsid (N) protein from anterior nasal swabs
- BinaxNOW, was the first LFA to receive a FDA Emergency Use Authorization (EUA) for the home setting
- Here, we summarize an assessment of the BinaxNOW test in the context of its ability to detect VOC, and in self administration of tests

In vitro testing

VOC Testing

Clinical Evaluation

LOD: serial dilutions of live SARS-CoV-2 and testing in Emory BSL3 lab
The LoD of BinaxNOW varied from 750 to 94 TCID50/swab, depending on the isolate (TCID$_{50}$: 50% tissue culture infectivity dose)
## CDC-Estimated Proportions of SARS-CoV-2 Lineages

### United States: 4/25/2021 – 7/31/2021

<table>
<thead>
<tr>
<th>Lineage #</th>
<th>Type</th>
<th>%Total</th>
<th>95%PI</th>
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</thead>
<tbody>
<tr>
<td>Alpha</td>
<td>B.1.1.7</td>
<td>VOC</td>
<td>2.9%</td>
</tr>
<tr>
<td>Beta</td>
<td>B.1.351</td>
<td>VOC</td>
<td>0.0%</td>
</tr>
<tr>
<td>Gamma</td>
<td>P.1</td>
<td>VOC</td>
<td>1.3%</td>
</tr>
<tr>
<td>Delta</td>
<td>B.1.617.2</td>
<td>VOC</td>
<td>83.4%</td>
</tr>
<tr>
<td></td>
<td>AY.3</td>
<td>VOC</td>
<td>9.1%</td>
</tr>
<tr>
<td></td>
<td>AY.2</td>
<td>VOC</td>
<td>0.8%</td>
</tr>
<tr>
<td></td>
<td>AY.1</td>
<td>VOC</td>
<td>0.1%</td>
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<tr>
<td>Epsilon</td>
<td>B.1.427</td>
<td>VOI</td>
<td>0.0%</td>
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<tr>
<td></td>
<td>B.1.429</td>
<td>VOI</td>
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<tr>
<td>Eta</td>
<td>B.1.526</td>
<td>VOI</td>
<td>0.0%</td>
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<td>Iota</td>
<td>B.1.526</td>
<td>VOI</td>
<td>0.2%</td>
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<tr>
<td></td>
<td>B.1.621</td>
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<tr>
<td></td>
<td>B.1.621.1</td>
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<tr>
<td></td>
<td>B.1.628</td>
<td>VOI</td>
<td>0.3%</td>
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<tr>
<td></td>
<td>B.1</td>
<td>VOI</td>
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<tr>
<td></td>
<td>A.2.5</td>
<td>VOI</td>
<td>0.0%</td>
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<tr>
<td>Other*</td>
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<td>VOI</td>
<td>0.0%</td>
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<tr>
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<td>B.1.617.3</td>
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<tr>
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<td>VOI</td>
<td>0.0%</td>
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</tbody>
</table>

* Enumerated lineages are VOI/VOC or are circulating >1% in at least one HHS region during at least one two week period; remaining lineages are aggregated as “Other”.

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

# Sublineages of P.1 and B.1.351 (P.1.1, P.1.2, B.1.351.2, B.1.351.3) are aggregated with the parent lineage and included in parent lineage’s proportion. AY.1, AY.2, and AY.3 are no longer aggregated with B.1.617.2.

### USA

<table>
<thead>
<tr>
<th>WHO label</th>
<th>Lineage #</th>
<th>Type</th>
<th>%Total</th>
<th>95%PI</th>
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<tbody>
<tr>
<td>Alpha</td>
<td>B.1.1.7</td>
<td>VOC</td>
<td>2.9%</td>
<td>1.2-4.7%</td>
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<tr>
<td>Beta</td>
<td>B.1.351</td>
<td>VOC</td>
<td>0.0%</td>
<td>0.0-0.2%</td>
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<tr>
<td>Gamma</td>
<td>P.1</td>
<td>VOC</td>
<td>1.3%</td>
<td>0.2-2.5%</td>
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<tr>
<td>Delta</td>
<td>B.1.617.2</td>
<td>VOC</td>
<td>83.4%</td>
<td>79.6-87.0%</td>
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<tr>
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<td>VOC</td>
<td>9.1%</td>
<td>6.2-12.0%</td>
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<td>AY.2</td>
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<td>0.1%</td>
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<td>Epsilon</td>
<td>B.1.427</td>
<td>VOI</td>
<td>0.0%</td>
<td>0.0-0.2%</td>
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<td>VOI</td>
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* Enumerated lineages are VOI/VOC or are circulating >1% in at least one HHS region during at least one two week period; remaining lineages are aggregated as “Other”.

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

# Sublineages of P.1 and B.1.351 (P.1.1, P.1.2, B.1.351.2, B.1.351.3) are aggregated with the parent lineage and included in parent lineage’s proportion. AY.1, AY.2, and AY.3 are no longer aggregated with B.1.617.2.
Emory is part of the NIH-RADx-VTF program
  - Large biobank of remnant SARS-CoV-2 clinical samples (RCS)
  - >5,000 VOC/I

Create panels with RCS to test the ability of diagnostic tests to accurately detect the VOC/I

Evaluate sensitivity of BinaxNOW to detect Delta (B.1.617.2), Lambda (C37), and other VOC
Sample Pooling, Panel Creation and Testing of VOC/I using RCS

8-10 remnant human samples (+ for SARS-CoV-2 & Sequenced) Categorized as VOC/VOI

Pool

100μl aliquots

Store at -80°C

Thaw and serially dilute in PBS, UTI, VTM or other preferred matrix

Prepare a blinded panel

Use for Benchtop Testing

Test with BinaxNow

Unblind after testing is complete

Data interpretation

Thaw tubes

Quality control of pools and dilutions
*Extract RNA, then perform RT-qPCR for N2 Gene (CDC primers) and endogenous control

Ct between 22/23 to 36
Ability of Abbott BinaxNOW COVID-19 Ag card to detect VOC using pools of remnant clinical samples

<table>
<thead>
<tr>
<th>Lineage</th>
<th>Highest Detected Pool N2 Ct</th>
<th>BinaxNOW Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>B.1.2</td>
<td>26.79</td>
<td>Positive</td>
</tr>
<tr>
<td>B.1.1.7</td>
<td>28.90</td>
<td>Positive</td>
</tr>
<tr>
<td>B.1.351</td>
<td>25.92</td>
<td>Positive</td>
</tr>
<tr>
<td>P.1</td>
<td>26.14</td>
<td>Positive</td>
</tr>
<tr>
<td>P.2</td>
<td>28.89</td>
<td>Positive</td>
</tr>
<tr>
<td>B.1.525</td>
<td>26.28</td>
<td>Positive</td>
</tr>
<tr>
<td>B.1.617.2 (Pool A)</td>
<td>25.52</td>
<td>Positive</td>
</tr>
<tr>
<td>B.1.617.2 (Pool B)</td>
<td>25.87</td>
<td>Positive</td>
</tr>
<tr>
<td>C37</td>
<td>23.81</td>
<td>Positive</td>
</tr>
</tbody>
</table>

N Protein Mutations

| Delta (Pool a) | D63G | R203M | -   | D377Y |
| Delta (Pool b) | D63G | R203M | G215C | D377Y |

All VOC pools are detected with equivalent sensitivity to non-VOC B.1.2

*Unpublished data
In vitro testing

309 participants recruited from RADx testing centers (Nov 2020 – Jan 2021)

Age ≥7 years with symptoms < 7 days

SOC NP RT-PCR within 24 hours
• Cobas 6800
• Abbott Alinity
• Panther Fusion

Structured usability assessment
Concordance of Antigen Assays vs. RT-PCR

**BinaxNOW**
- Sensitivity: 74% (95% CI 64-82)
- Specificity: 99% (95% CI 97-100)
BinaxNOW % Agreement with PCR by Ct Value
Staff vs Self-Collection

% Agreement with PCR

N PCR Positives

Ct Value

- Adult-Staff Result
- Adult-Self Result

Binax-CoV2 Positive

 Binax-CoV2 Negative

ACME POCT
Evaluation for the independent use of BinaxNOW

Caregiver: n = 17
Adolescent: n = 3
Adult: n = 42

Sensitivity: 57%  
(95% CI 37-76)
Specificity: 100%  
(95% CI 79-100)
# Usability Rating for BinaxNOW

<table>
<thead>
<tr>
<th>Error Rating</th>
<th>1</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>2</td>
<td>4</td>
<td>5</td>
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</tr>
<tr>
<td>3</td>
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</tbody>
</table>
Conclusions

• Antigen tests have lower sensitivities compared to RT-PCR, especially with increasing Ct values

• Sensitivity may decrease even more due to user error once moved to home tests

• BinaxNOW accurately detects new viral variants
Acknowledgements

Abbott BinaxNOW™ COVID-19 Ag Cards were graciously provided by Brett P. Giroir of the U.S. Department of Health and Human Services and Bruce J. Tromberg of the National Institute of Biomedical Imaging and Bioengineering of the NIH.

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The following reagent was deposited by Dr. Maria R. Capobianchi for distribution through BEI Resources, NIAID, NIH: SARS-Related Coronavirus 2, Isolate Italy-INMI1, NR-52284.

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Thank You For Your Time!

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

This box being opened by an American Hero

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