Rapid Acceleration of Diagnostics Technology (RADx Tech)

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1) Expand COVID-19 Testing Technologies: Number, Type and Access
2) Optimize Performance: Technologic and Operational; Match Community Needs

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

>12 NIH Institutes, Centers, and Offices

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

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

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

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

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

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

Validation Core
- >70 projects complete,
- >3000 participants

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

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

Todd Merchak Tiffany Lash
RADx Tech Process: *Innovation Funnel*

**NATIONAL CALL FOR INNOVATIVE TECHNOLOGIES**

- Validation, Clinical Testing, Regulatory, Manufacturing, Distribution

**PHASE 0:** "Shark Tank" Like Rapid Selection Process

**PHASE 1:** Validation and Risk Review

**PHASE 2:** Clinical Tests, Regulatory Approval, and Scaling Up

**END OF SUMMER/FALL 2020**

~3000 Applications Started

Rolling submission open April 29

5-6 Months

Funnel 1 May 2020: 3.5 mos.  
Funnel 2 June 2021: 1 month

Innovation, entrepreneur community

- Small business: 405
- Academic: 157
- Start-up: 187
- Mid-size business: 72
- Large business: 52
- Other: 18
- Non-Profit Lab/CRO: 14

Projects in each Phase:

- PHASE 0: 824
- PHASE 1: 179
- PHASE 2: 47
- END OF SUMMER/FALL 2020: 44

~$660M
**Point of Care & Home**
- Visby
- Mesa
- MicroGem
- Talis
- Ubiquitome
- Meridian
- GenBody
- Quidel Sophia
- Quidel QuickVue
- Luminostics
- ANP
- Ellume
- Xtrava
- Qorvo
- Maxim
- Salignostics
- ANP
- BD Veritor
- Princeton Biomeditech
- Palogen
- Detect
- Lumira Dx
- Anavasi
- Uh-Oh Labs
- Broad Inst
- Illumina
- Helix
- Gingko
- Sonic Healthcare
- PathogenDx
- Lab Products
- Mammoth Biosci
- Ceres Nanosciences

**Laboratory**
- Flambeau (+Saliva Direct)
- MatMaCorp
- Fluidigm
- Quanterix
- Minute Molecular
- PathogenDx
- Broad Inst
- Illumina
- Helix
- Gingko
- Sonic Healthcare
- PathogenDx
- Octant/UCLA

**Tech**
- ANP
- Qorvo
- Mologic
- Maxim
- Salignostics
- BD Veritor
- Princeton Biomeditech
- Palogen
- Detect
- Lumira Dx
- Anavasi
- Uh-Oh Labs
- Broad Inst
- Illumina
- Helix
- Gingko
- Sonic Healthcare
- PathogenDx
- Octant/UCLA

**Labs**
- Lab Products
- Mammoth Biosci
- Ceres Nanosciences
- Oasis
- Yukon
- Anapathway

**NIH**
Cumulative EUA Authorized Tests by Month

- Laboratory
- Point of Care
- Home
- Test Products

Major Milestones

- 1.14 billion capacity thru October 2021
- ~5.1 M tests and products/day October 2021
- 35 EUAs; 1st OTC EUA, 4 “at home”

~$1.1 Billion: Special Congress Authorization
($600M in Phase 2)

~1.3 Billion: Private Capital Raised

Impact: National Policy

How at-home coronavirus testing is becoming part of Biden’s plan for managing the pandemic

- Work (OSHA): vaccine, weekly testing
- Entertainment: show negative test
- School: regular testing
- Procurement: $3B OTC/POC tests, DPA
- Retailers: sell OTC at cost, Medicaid reimbursement
- Community: distribute OTC to high SVI regions
- Pharmacy: Expand free POC access

September 9, 2021

https://sayyescovidtest.org
https://whentotest.org
RADx Impact: *whentotest.org*

**STOP THE SPREAD OF COVID-19**

**FOR INDIVIDUALS**
- START CALCULATOR

Don’t spread COVID-19 in your community! The When To Test Calculator for Individuals helps you decide whether you should consider getting tested.

**FOR ORGANIZATIONS**
- START CALCULATOR

CDC guidelines provide a COVID-19 testing approach that applies to the population nationwide. The When To Test Calculator is designed to offer a more granular testing strategy for individual organizations based on their unique mitigation strategies, level of compliance, and community prevalence.

- Vaccination rates
- R0 altered for Delta
- Pooling guidance
- K-12 playbook (CDC)
- Individual risk calculator
- Link purchase, guidance

>50,000 users

Since Launch (Dec 2020):
- 43,916 users
- 53,568 sessions
- 33,817 Calculator views
- 6,151 Calculator interactions
- 2,235 Calculator shares
This report reflects tests purchased directly by NIH to support specified projects. Tests purchased separately by awardees are not shown.

<table>
<thead>
<tr>
<th>Tests Purchased</th>
<th>Qty</th>
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<tbody>
<tr>
<td>Ordered</td>
<td>2.7M</td>
</tr>
<tr>
<td>Remaining</td>
<td>4.2M</td>
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Tests Ordered by NIH Program and Test Type

<table>
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<tr>
<th>Test Type</th>
<th>QuickVue</th>
<th>Sofia</th>
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<tr>
<td>SYCT</td>
<td>955,560</td>
<td>156,495</td>
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<tr>
<td>RADx UP Return to School</td>
<td>259,675</td>
<td></td>
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<tr>
<td>ACTIVaB</td>
<td>9,167</td>
<td></td>
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<tr>
<td>RADx Tech</td>
<td>42,945</td>
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<tr>
<td>RADx</td>
<td>24,887</td>
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<tr>
<td>RADx UP</td>
<td>12,921</td>
<td></td>
</tr>
<tr>
<td>RADx Digital Health</td>
<td>1,666</td>
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</tbody>
</table>

Program locations

Remaining = Purchased - Ordered

Orders 2.75M (40%)  
Remaining 4.15M (60%)
RADx Tech Impact: Digital Health

RADx POC Test

How to Use

Symptom Surveys

EHR & Claims

State and Federal

Contact Tracing

Health status

e.g. VCI

Need Standards

NIH National Institute of Biomedical Imaging and Bioengineering
RADx Team
Richard Creager
Eric Lai
John Blackwood
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Dale Gort
Emily Kennedy
D’lynne Plummer
Thomas Pribyl
Adam Samuta
Megan Shaw
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Eric Ortlund
Anuradha Rao
Raymond Schinazi
Allie Suessmith
Julie Sullivan
Thomas Vanderford

Univ of WA
Alex Grenninger

RADx Variant Task Force (est Jan 2021)

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

>75,000 samples
Jan 2021-present
RADx Variant Surveillance: “SNP Chip”

“Project Rosa”

Helix, Thermo-Fisher, CDC

16 Markers:
1) Positivity of sample
2) Lineage (>95% sens and spec all WHO variants + Omicron)
3) Mutations of biological interest

Genotyping Validation (TaqMan, TF), 10k sample study, 4 weeks

“SNP Chip” Advantages

Speed: no reflex, “real time” 1000s/day vs NGS ~4 weeks
Cost: CapX and price/test << NGS
Access: Adaptable to most labs: >50% vs 5% current NGS
Modify: New variant integration ~4-6 weeks

Submit FDA EUA w/partner

1) Impact of Variants on Test Performance (NAT, An)
2) Design tests for variant surveillance (e.g. “SNP chips”)
# 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>
</tr>
</thead>
<tbody>
<tr>
<td>ABL 7500</td>
<td>Mesa BioTech</td>
<td>Quidel Sophia</td>
<td>Ellume Dipstick LFA</td>
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### Tech to Bridge the Gap?

<table>
<thead>
<tr>
<th>Cost</th>
<th>Speed</th>
<th>Sens/Spec</th>
<th>LOD</th>
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</thead>
<tbody>
<tr>
<td>$$$$$</td>
<td>~30 min</td>
<td>&gt;90/95</td>
<td>&lt;10³ Cp/mL</td>
</tr>
<tr>
<td>$$$</td>
<td>&lt;15 min</td>
<td>&gt;90/95</td>
<td>&lt;10³ Cp/mL</td>
</tr>
<tr>
<td>$</td>
<td></td>
<td>&gt;90/95</td>
<td>&gt;10⁶ Cp/mL</td>
</tr>
</tbody>
</table>


New Tech: Nano in RADx

Images from Chudasama et al., Chemical Science 2016, Lim et al., Nanoscale 2015, Wikipedia

RADx-Tech Applications and Funded Proposals

112 Total Nano: ~16% of total
26 Funded Nano: ~18% of phase 2
>100 M tests/products produced w/nano

WP2 = ★
Quantum Dots on the shelves at CVS!
1) Reporting infrastructure

Crashing computers, 3-week delays tracking infections, lab results delivered by snail mail: State officials detail a vast failure to identify hotspots quickly enough to prevent outbreaks.

2) Insufficient screening, surveillance

Nearly 5 out of 6 coronavirus cases were undetected in pandemic’s early months.

Months into the pandemic, the U.S. had six times as many cases as reported, an N.I.H. study finds.

Nearly 17M Americans May Have Went Undiagnosed With COVID Last Year: Why These Cases Matter
Ongoing Challenges

3) Paradigm Shift

April 2020 ~5M tests

Lab >> POC

October 2021 ~240M tests

POC, OTC >> Lab

December 2021 >400M tests

Minimal POC/OTC reporting
4X increase OTC tests Sept - Dec

Impact: Guidance and policy decisions made based on lagging and incomplete test data
3) Cost of Rapid OTC Tests: demand >> supply

Independent Test Assessment Program (ITAP)

NIH-FDA: Accelerating OTC Authorizations

- Eligible companies invited to participate (Ex US and US); high volume potential
- Initial deep dive leads to detailed assessment and custom work plan
- Rapid decision to approve/reject; fund next level ITAP studies, review
- ITAP data + other info analyzed in “real time” with feedback as needed
- Completed work plan serves as EUA application for FDA review
- 10 tests in ITAP program, >250M tests/month potential

Goal

Add ~100M OTC tests/month to US in ~3 months

Concurrent

Phase 1
Selection of potential tests based on Product Documentation Review

Phase 2
Independent Test Performance Assessment

Phase 3
Formal EUA Analytics and Infrastructure Assessment

Phase 4
EUA Clinical Trials
Ongoing Challenges

Call to action...
RADx investment: *accelerated decades of in vitro diagnostic tech for COVID*

- **Better, accessible fast tests:** Inexpensive OTC/POC; some w/ laboratory test performance
- **Multiplex tests:** COVID, flu A/B, RSV, etc. for differential Dx *(POC, lab)*
- **Fast, accurate, cost-effective surveillance:** Genotyping w/Informatics, *(lab, POC)*
- **Real Time Reporting:** Modernize, expand digital health networks and communication/reporting
- **Low Cost OTC:** Increase supply, automation, distribution channels

**Future:** Leverage RADx process, tech, and networks for other pathogens, preparedness, precision medicine