Rapid Acceleration of Diagnostics (RADx)
Presentation to the ACD on June 10th

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Totally RADx @NIH

NIH Office of the Director

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

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

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

https://www.nih.gov/research-training/medical-research-initiatives/radx
RADx Tech Innovation Funnel

NATIONAL CALL FOR INNOVATIVE TECHNOLOGIES

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, 2020

Projects in each Phase

Small business
Academic
Start-up
Mid-size business
Large business
Other
Non-Profit Lab/CRO

Innovation, entrepreneur community

716
140
47
32

~$590M

Validation, Clinical Testing, Regulatory, Manufacturing, Distribution

NIH National Institute of Biomedical Imaging and Bioengineering
RADx Impact thru May 2021

Cumulative EUA Authorized Tests by Month

Major Milestones

- ~390 million capacity thru May 2021
- ~3 M tests and products/day May 2021
- 23 EUAs; 1st OTC EUA, 2 “at home”
- >100 companies supported

With FDA studies for:
- Sequential use screening guidance An tests
- Pooling use guidance for POC PCR
- Pediatric use guidance for self swabbing

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CDC – NIH COVID-19 At-Home Testing Initiative: Say Yes! COVID Test

Overall Goal

Implement and quickly measure the **effectiveness** of rapid, at-home testing 2-3 times a week in reducing community transmission of SARS-CoV-2 in two large communities over a 4-6 week period.

Public Health Intervention Component (lead, CDC)

- CDC, state, local public health departments in Hamilton County (TN) and Pitt County (NC)
- Public health campaign* to notify residents of the availability of free tests:
  - Online fulfilment in partnership with Amazon
  - Community center pick up, at local centers, churches, schools and other sites
  - Additional efforts to reach and engage with underserved communities

* In collaboration with UNC Chapel Hill, Duke University, DCRI and Community Campus Partnerships for Health
Research Evaluation Component (lead, NIH)

– NIH-funded team at UNC / Duke University to conduct ecological study, including matched controls

– Planned outcome measures, based on publicly available data:

  Positive tests for SARS CoV-2
  Measures of SARS-CoV-2, including variants, in wastewater
  Mobility outcomes
  Hospitalizations attributable to SARS-CoV-2
  SARS-CoV-2 ICU admissions

– Results expected Fall 2021

Optional research study will evaluate feasibility of frequent testing and its associations with socio-behavioral mechanisms of community transmission, including social interactions, health behaviors, healthcare utilization, knowledge, and disease burden.
Make free, rapid, at-home COVID-19 test kits available to households in selected communities to help reduce COVID-19 spread.
Three tests a week. One healthier community.

people per household
2
3
0
tests per week
until all tests are used
Status of the “Say Yes ! Covid Test” on June 2\textsuperscript{nd} 2021

- In Pitt County, North Carolina: 40,000 kits = 1 million tests
  - Public health intervention: April 4 – May 19
  - 52% community distribution
  - 14% online ordering direct from consumer
  - 34% kits remaining

- In Hamilton County, Tennessee: 40,000 kits = 1 million tests
  - Public health intervention: May 4 – June 4
  - 67% community distribution
  - 33% online ordering direct from consumer

- Ann Arbor/Ypsilanti, Michigan: 20,000 kits = 500,000 tests
  - Planning for third arm in this location to launch in June 2021

1 Kit = 25 tests
40K kits = 2 Million tests
Significance of the SYCT Initiative

- Real time collaboration between federal public health and research agencies to address an urgent public health issue and conduct a robust scientific evaluation of the intervention

- Immediate use, in a public health emergency, of a technology supported by NIBIB’s RADx program

- Close, real time, collaboration with other federal agencies, such as the Food and Drug Administration (FDA), to address regulatory and operational barriers to the implementation of an at-home testing program

- Advances in public health reporting of rapid antigen tests through collaboration with Office of the National Coordinator (ONC) and American Public Health Laboratories (APHL)

- Rapid learnings on optimal modes of test distribution, community engagement with underserved populations, public awareness, and the public’s use of at-home tests that will inform national testing strategy in a rapidly shifting COVID-19 environment.
Acknowledgements: Say Yes! Covid Test

- National Institutes of Health
  - Office of the Director
  - National Institute of Biomedical Imaging and Bioengineering (NIBIB)

- Centers for Disease Control

- State and local public health departments
  - North Carolina public health department
  - Pitt County public health department
  - Tennessee public health department
  - Hamilton county public health department

- Research and community engagement partners
  - University of North Carolina
  - Duke University
  - Duke Clinical Research Institute
  - Community-Campus Partnerships for Health
  - Local community leaders in Pitt County and Hamilton County

- Digital app and logistics:
  - CareEvolution
  - Amazon
  - Quidel

- Residents of Pitt County and Hamilton County!