



**RADx Tech: Delivering
COVID-19 Diagnostic
Technologies at
Unprecedented Speed
and Scale**

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Executive Summary

The Rapid Acceleration of Diagnostics (RADx ®) Tech program was launched in April 2020 as a collaboration between the Office of the Director (OD) and the National Institute of Biomedical Imaging and Bioengineering (NIBIB). As a part of the overall RADx initiative, RADx Tech's focus was to generate a robust pipeline of innovative diagnostic technologies to provide tests for COVID-19 to the nation. This effort enabled the validation, de-risking, manufacturing, scale-up, and deployment of novel at-home and point-of-care (POC) tests through an optimized pipeline in as little as six months. As a result, RADx Tech produced a U.S. capacity of over 7.8 billion tests and test products during the pandemic and shifted testing from labs to home and POC. RADx Tech continues to develop tests that target unmet needs, such as multiplex tests for respiratory illnesses and more accessible home tests that can be used independently by persons with disabilities.

Program Overview and Structure

NIBIB established the RADx Tech innovation funnel, a milestone-driven funding structure, to maximize the efficiency of developing and deploying COVID-19 testing technologies. It compressed the customary technology development process from years to months. The program leveraged the existing NIBIB Point-of-Care Technologies Research Network (POCTRN) infrastructure, including three core resource centers that support test validation, clinical studies, and test deployment.

The RADx Tech innovation funnel is structured to provide escalating support to awardees in a stage-gated manner. Technology proposals undergo a highly competitive, accelerated three-phase review and selection process to identify the best candidates for over the counter (OTC), POC tests, lab tests, and test products for COVID-19. Test developers are matched with technical, business, and manufacturing experts to guide the development process and increase the chance of success.

Over 900 collaborators from government, academia, and the private sector partnered to make the funnel mechanism a success. The program began with a national call for applications, seeking



innovative diagnostic technologies that could be readied for regulatory authorization within months. Subsequent solicitations to meet emerging needs has led to more than 1,000 submissions to date. Applications were evaluated by a diverse team of external consultants and experts from across the NIH.

Projects that were deemed promising by a panel based on proposed technical, clinical, regulatory, and commercial factors then underwent an intensive review process. The first step in this process was a two-week examination during which a team of RADx Tech experts worked closely with developers to understand all aspects of the technology and its promise for rapid deployment to the market. Technologies that were approved by the practitioners then moved into a de-risking phase, where detailed, milestone-driven workplans were developed and executed to mitigate technology risk. RADx Tech experts worked closely with companies during this phase and coordinated independent analytical and clinical validation through the RADx Tech resource cores. Successful projects moved into the final deployment phase, during which studies were conducted to support Food and Drug Administration (FDA) Emergency Use Authorization (EUA). During this phase, RADx worked with the companies to support and accelerate manufacturing and commercialization.

Since launching in 2020, there have been three separate solicitations from RADx Tech, each with a different focus to spur innovation and commercialization of testing technologies. The first instance of the RADx Tech innovation funnel urged all scientists and inventors with a rapid testing technology to compete in a national COVID-19 testing challenge for a share of up to \$500 million over all phases of development. The goal of this first call for applications was to make millions of accurate and easy-to-use tests per week available to all Americans by the end of summer 2020. The second RADx Tech solicitation sought proposals to further advance SARS-CoV-2 testing technologies in order to accelerate validation, manufacturing scale up, and commercialization of innovative COVID-19 testing capabilities including multiplex tests, tests with better performance such as a level of detection comparable to lab-based tests, and tests that could detect variants. This solicitation only considered proposals for technologies in an advanced stage of readiness that could reach the market in 2021. The most recent funnel, RADx Tech III,



had two distinct solicitations that applicants could apply to. The first solicitation was for accessible OTC tests that can be used by persons with disabilities, specifically blindness, low vision, fine motor skill difficulties, and aging-related disabilities. The second solicitation focused on improving performance of OTC and POC tests as well as integrating universal design features to ensure ease of use. Tests should aim to minimize or eliminate the need for serial testing and performance should be unaffected by variants. RADx Tech III has recently completed application review and has funded a total of 25 Work Package 1 projects (WP1s).

RADx Tech adopted elements of the Innovation Funnel in 2021 to greatly expand the U.S. test market by accelerating FDA authorization of tests that were already being produced and sold in other countries. In close collaboration with the FDA, RADx Tech launched the Independent Test Acceleration Program (ITAP) to rapidly validate the performance of non-U.S. tests and shave weeks to months off the regulatory authorization timeline. ITAP independently conducted analytical and clinical analysis of tests according to protocols agreed upon by the FDA, allowing the FDA to authorize new tests in a matter of days after submission of the RADx data.

Program Accomplishments

Since launching in 2020, the RADx Tech program has yielded 55 FDA EUA tests and, as of April 2023, has produced a U.S. capacity of more than 7.8 billion tests and test products. By producing an abundance of OTC tests, RADx Tech enabled the shift of testing away from central labs and into peoples' homes. Other notable achievements include:

- Evaluation of 1,042 proposals, submitted from 47 different states/territories and 23 countries
- Over 250 organizations were funded to develop diagnostic technologies
- 242 applications (15-20% of total applications) were reviewed in depth by RADx expert teams
- 68 projects received funding for de-risking and validation
- 50 projects received funding for authorization and deployment
- A POC test received an EUA within 10 weeks of the program launch



- The first ever EUA for a COVID-19 OTC diagnostic-test in December 2020
- 18 FDA-authorized OTC COVID-19 tests
- Best practice guidelines published on June 20, 2023, for accessible test designs that can be used independently by people with disabilities
- The first EUA granted for a test that aligns with accessibility design principles
- 125 publications by RADx Tech members and collaborators

Coordination with other federal agencies has been key to the success of this program. The ITAP partnership between the NIH and the FDA is an extension of RADx Tech and streamlines regulatory authorization of mature technologies. To date, 12 OTC COVID-19 diagnostic devices have received authorization with support from ITAP. ITAP accounts for approximately half of the increased testing capacity in the U.S.

Close coordination with Administration for Strategic Preparedness and Response (ASPR) and Biomedical Advanced Research and Development Authority (BARDA) resulted in securing supplies and other material resources for RADx-supported projects, while collaboration with the Department of Defense (DoD) early in the pandemic helped overcome supply chain bottlenecks.

Community Engagement

In April 2022, in response to public demand, NIBIB partnered with Health & Human Services (HHS) agencies and other organizations to address the need for COVID-19 home tests that could be used independently by people with disabilities. Working closely with disability advocates and design experts, the RADx COVID-19 Test Accessibility program published a best-practices document (hosted on the [U.S. Access Board website](#)) with universal design recommendations for test developers. Additionally, RADx Tech launched its third innovation funnel to support the development of accessible and high-performance tests. To date, RADx Tech has funded five projects that aim to improve accessibility for test users and recently supported an EUA for the first at-home COVID-19 test to conform to accessible design principles. Efforts are ongoing to bring more widely accessible tests to the market.



In addition to working closely with other federal agencies and advocacy groups, the RADx Tech program established multiple programs to aid in COVID-19 test distribution and case tracking throughout the U.S.. The RADx Mobile At-Home Reporting through Standards (MARS) program promotes an approach built on IT communication standards to report COVID-19 self-test results and establishes best practices for future reporting of remote diagnostics. By standardizing how self-reported test results are collected, RADx MARS can transmit the data to state, federal, and local health systems. The Make My Test Count website for self-reporting results of home tests launched in November 2022 and effectively replaced manufacturer apps to provide a single reporting pathway for home test results to state and federal databases. The site currently supports reporting for all FDA-authorized/cleared OTC tests for COVID-19 and COVID-19/Flu multiplex tests, with over 152,000 test results self-reported to date.

Say Yes! COVID Test (SYCT) was a cooperative effort with state and local health departments, NIH, and Centers for Disease Control and Prevention (CDC). The program offered access to free, rapid, at-home COVID-19 testing in select communities throughout the U.S. The goal was to pilot test distribution mechanisms and understand if access to frequent, at-home testing for COVID-19 impacts community spread of the virus. Through SYCT, more than 2 million COVID-19 home tests have been distributed and results demonstrated that home testing can impact behavior and reduce transmission in a community. Lessons learned from this effort, along with increased test availability through ITAP, enabled the USG [covidtest.gov](https://www.covidtest.gov) distribution of free tests nationwide. More recently, the RADx Tech program launched the Home Test-to-Treat program: an entirely virtual community health intervention that provides free COVID-19 tests, telehealth consultations, and treatments to eligible individuals in their own homes. The program initially launched in three geographically targeted areas and has since expanded to eligible participants nationwide and added influenza testing and treatment in addition to COVID-19. Home Test to Treat is a collaboration between NIBIB, ASPR, and CDC. The goal of this program is to better understand how technologies such as at-home tests and telemedicine can improve healthcare access for individuals across the country.



Impact and the Path Moving Forward

The success of RADx Tech can be attributed in part to three key factors. First, providing an interdisciplinary consulting team to each test developer allowed projects to quickly accelerate past development hurdles and gave each team rapid access to in-kind program resources, such as analytical and clinical testing, as the needs arose. Second, the availability of flexible, rapid, and responsive funding mechanisms allowed stage-gated funding that focused increasing resources on the most successful projects. Third, close partnerships with HHS and other federal agencies created synergies that accelerated the entire development and deployment timeline across the domains of individual agencies. The ITAP collaboration with the FDA and the supply chain partnership with the DoD are notable examples of the power of government partnership to speed the path of new technologies to the public. While these relationships initially took time, they helped rapidly accelerate progress once established. Keeping a “warm base” of engagement in non-emergency times could help accelerate future efforts and avoid starting from square one.

Another important lesson learned in RADx Tech is the importance of universal design principles in developing technologies for home use. Many of the RADx Best Practices for Accessible Design can be applied to any technology marketed to the public and serve as a unique resource to the entire home medical device industry. Consideration of these principles benefits everyone through greater simplicity and usability and ensures that everyone can use home medical devices independently.

The RADx Tech Innovation Funnel and ITAP approaches can be effectively applied beyond COVID-19 to address a range of unmet health needs. RADx has expanded to develop multiplex home and POC diagnostic products for COVID-19, Flu, and RSV. ITAP has enabled two EUAs for multiplex COVID/flu tests to date. ITAP has also enabled the first EUA for a POC Mpox (formally known as monkeypox) diagnostic and has submitted an EUA package for an Mpox home self-swabbing kit. By maintaining the RADx infrastructure, NIBIB is leveraging funding from government and non-government organizations to solve other pressing health needs, including:



- POC multiplex tests for the detection of lesion-presenting diseases including Mpox, HSV1/2, VZV, and Syphilis
- A POC test for Hepatitis C to support a program to eliminate the disease in the U.S.
- A Fetal Monitoring Challenge to accelerate development of technologies to reduce fetal mortality
- Blueprint MedTech, a program to develop groundbreaking medical devices for pain and diseases of the nervous system
- A Maternal Health Challenge to develop devices to reduce maternal mortality in underserved settings
- Advanced Platforms for HIV Viral Load Testing at the POC to reduce HIV transmission

Conclusion

The RADx Tech program has been extremely successful in accelerating the development and availability of COVID-19 diagnostics. The RADx Tech infrastructure has been adapted to develop and translate technologies to address a range of other public health concerns, such as fetal and maternal health, nervous system disorders, Mpox, Hepatitis-C, and HIV. RADx Tech will continue to support meaningful projects, such as the Home Test-to-Treat and Test Accessibility programs, to help address community health inequity issues within our nation. RADx Tech is well-positioned to adapt to future needs within the COVID-19 landscape, and, through funding partnerships, to respond to other emerging pathogens and health emergencies beyond COVID-19.