NIH leadership details unprecedented initiative to ramp up testing technologies for COVID-19

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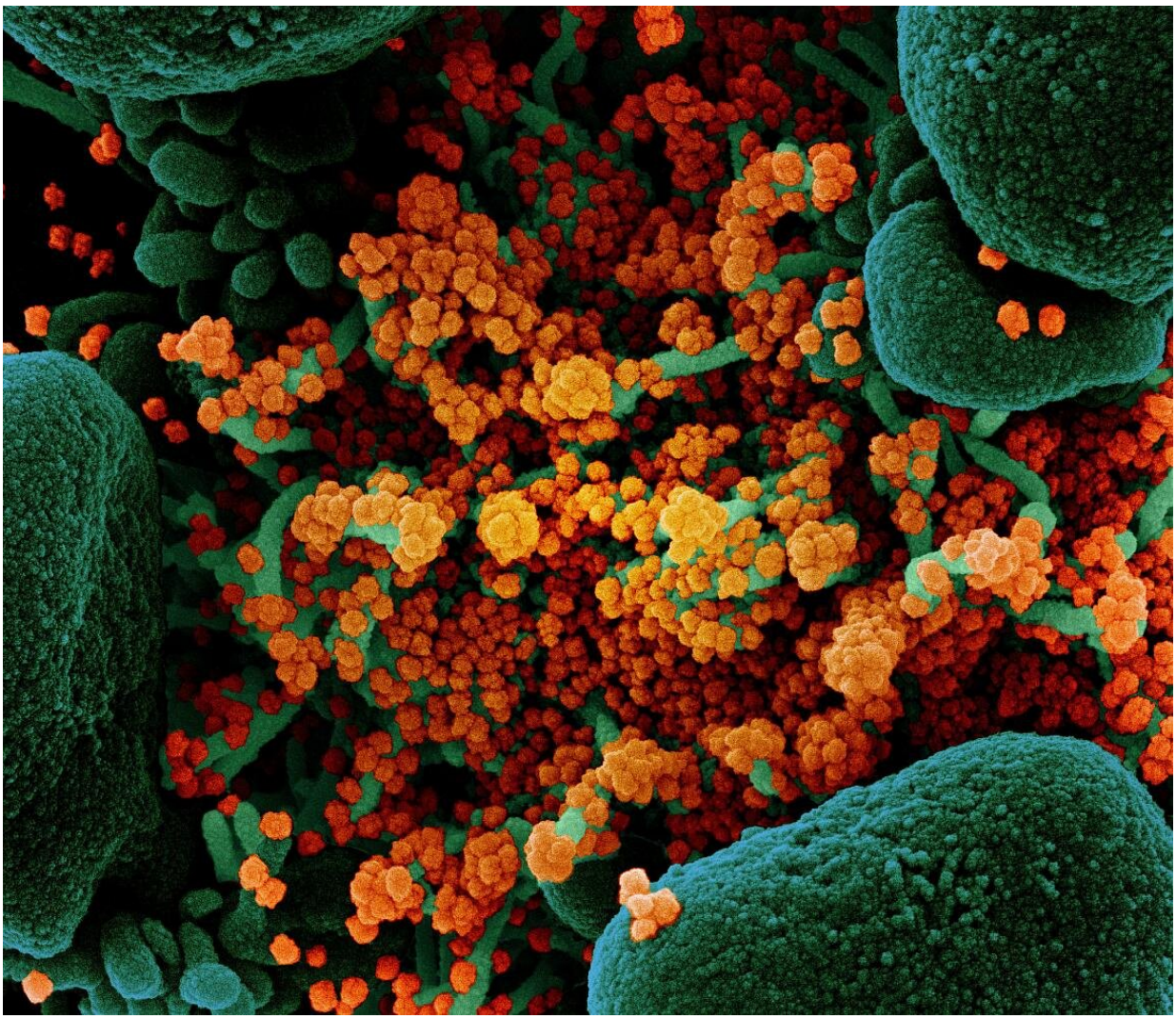

Colorized scanning electron micrograph of an apoptotic cell (green) heavily

infected with SARS-CoV-2 virus particles (orange), isolated from a patient sample. Image at the NIAID Integrated Research Facility (IRF) in Fort Detrick, Maryland. Credit: NIAID

In a paper in the *New England Journal of Medicine*, scientific leaders from the National Institutes of Health set forth a framework to increase significantly the number, quality and type of daily tests for detecting SARS-CoV-2, the virus that causes COVID-19, and help reduce inequities for underserved populations that have been disproportionally affected by the disease. The authors describe the current testing landscape and explain the urgent need for nationwide deployment of low-complexity, point-of-care molecular diagnostics with rapid results.

To fill this urgent need, the Rapid Acceleration of Diagnostics (RADx) program was established in just five days following the announcement of $1.5 billion in federal stimulus funding in April 2020. RADx covers the entire life cycle of the target testing technologies, is tightly focused on timelines and outcomes, receives applications from small and large companies and is expressly focused on health disparities. While based at NIH, RADx is closely coordinating with the Office of the Assistant Secretary for Health, the Biomedical Advanced Research and Development Authority, and the Department of Defense.

Current testing methods to diagnose COVID-19 detect either viral RNA or viral antigens. These tests are highly sensitive and specific when conducted in centralized laboratories with standardized protocols, but require a large amount of lab space, complex equipment, regulatory approvals for the laboratory operations and skilled technicians. Results may take hours to days, and samples often need transport to a central laboratory, furthering delays. During that time someone who is unknowingly carrying the virus may go on to infect others, instead of

being quickly isolated. These issues highlight the need for reliable, rapid, point-of-care testing diagnostics.

RADx includes four major components to enable approximately 6 million daily tests in the United States by December 2020, many times the current daily testing rate. In the near term, RADx confronts the pandemic by expanding testing capacity by fall 2020 as the nation faces the beginning of seasonal flu. In the slightly longer-term RADx aims to produce additional innovative diagnostic technologies and strategies for making testing available to diverse, vulnerable and underserved populations.

- RADx Tech aims to identify, accelerate development, scale up and deploy innovative point-of-care technologies throughout the fall of 2020. The program uses an "innovation funnel" design where applications quickly move through multiple stages of review with increasing scrutiny. This has been compared to a "shark tank" model. About 15-20% of RADx Tech applications will qualify for additional consideration and review. Of those applications, less than one-third will move to rigorous Phase 1 testing and validation through NIH's Point-of-care Technology Research Network (POCTRN). If a project is judged successful at that point, rapid scale up and clinical testing gets underway, with substantial financial assistance provided. As of July 13, over 600 applications had been submitted, with 27 projects advancing to Phase 1 and one project advancing to Phase 2.
- RADx Advanced Technology Platforms (RADx-ATP), will support the scale-up of more advanced technologies that can achieve immediate, substantial increases in capacity. The program uses a rapid-response application process for companies with existing point-of-care technologies authorized by the U.S. Food and Drug Administration for detecting SARS-CoV-2 that can scale production to between 20,000 and 100,000 tests per

day by the fall. Additionally, RADx-ATP will seek to expand "mega-labs" across the country that can increase testing capacity to 100,000 to 250,000 tests per day.

- RADx Radical (RADx-rad) will focus on truly non-traditional approaches for testing that have a slightly longer horizon. This program will evaluate a wide range of technologies, such as home-based testing and repurposing of existing technologies for detecting SARS-CoV-2. Moreover, RADx-rad will support projects that use of biological or physiological biomarkers to detect an infection or predict the severity of disease, including the likelihood of developing multisystem inflammatory syndrome in children (MIS-C), or using chemosensory changes as an early indicator of viral positivity. Other examples include the use of biosensors to detect the presence of the virus in the breath, or the analysis of wastewater to conduct community-based surveillance.
- RADx Underserved Populations (RADx-UP) will establish community-engaged implementation projects to improve access to testing in underserved and vulnerable populations. Racial and ethnic minorities bear a higher burden of disease and mortality from COVID-19. Blacks, Latinos and American Indians/Alaska Natives are hospitalized and die at disproportionately higher rates compared to other groups. The goal of RADx-UP is to understand factors that have led to the disproportionate burden of the pandemic on underserved populations, and to support optimal access and uptake of SARS-CoV-2 testing. The program aims to examine infection patterns and efforts to increase access to and effectiveness of testing methods by building an infrastructure that can be leveraged for the ongoing COVID-19 public health efforts.

More information: Bruce J. Tromberg et al. Rapid Scaling Up of Covid-19 Diagnostic Testing in the United States—The NIH RADx Initiative, *New England Journal of Medicine* (2020). DOI:

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