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ONE HUNDRED SIXTEENTH CONGRESS

# Congress of the United States

## House of Representatives

### COMMITTEE ON ENERGY AND COMMERCE

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WASHINGTON, DC 20515-6115

Majority (202) 225-2927

Minority (202) 225-3641

October 29, 2020

The Honorable Francis Collins  
Director  
National Institutes of Health  
9000 Rockville Pike  
Bethesda, MD 20892

Dear Dr. Collins:

We write to request that the National Institutes of Health (NIH) provide information in the form of a briefing and a written response on how data from studies on COVID-19 testing could be used to help the U.S. utilize COVID-19 testing capacity more effectively to contain outbreaks and reopen the economy.

The NIH Rapid Acceleration of Diagnostics (RADx) initiative supports studies to generate data and insights that could help inform how to best use COVID-19 diagnostic and surveillance testing for people who are pre-symptomatic, symptomatic, and asymptomatic. As efforts are being made to manage the pandemic response with the re-opening of schools, houses of worship, and workplaces, the U.S. needs to leverage every test and every modality. Earlier this month, the Department of Health and Human Services (HHS) and the Rockefeller Foundation recently reached an agreement on such a study.<sup>1</sup> Under this agreement, effective approaches will be identified and shared for using rapid point-of-care (POC) antigen tests to screen for COVID-19 in communities, with a focus on safely reopening K-12 schools. We are interested in learning about similar studies supported by the RADx initiative.

The U.S. has amassed a significant amount of testing capacity.<sup>2</sup> Containing the virus and reopening the economy depend on how we effectively use our testing capacity. According to

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<sup>1</sup> HHS Press Release, HHS Teams Up With the Rockefeller Foundation To Share Best Practices for Increased COVID-19 Testing (October 1, 2020), available at <https://www.hhs.gov/about/news/2020/10/01/hhs-teams-up-with-the-rockefeller-foundation-to-share-best-practices-for-increased-covid-19-testing.html>

<sup>2</sup> Neel V. Patel, The US now has more covid-19 tests than it knows what to do with, Technology Review (June 27, 2020), available at <https://www.technologyreview.com/2020/06/27/1004545/us-covid-19-coronavirus-test-capacity-unused-available-reopening/>

recent, publicly released data from AdvaMed,<sup>3</sup> the following indicates that there is increased capacity for COVID-19 testing in the U.S.:

- Across leading COVID-19 diagnostic manufacturers, about 200 million molecular COVID-19 tests have been shipped since March, including about 145 million commercial tests and about 55 million extraction reagents.
- Manufacturers have increased molecular test shipments from about 600,000 per day at the start of May to about 1.4 million shipments per day by October 10, 2020.
- Per public sources, daily molecular tests run increased by about 5 percent compared to the previous week, up to an average of about 1.1 million per day in early October.
- High-quality serology testing, authorized by the U.S. Food and Drug Administration (FDA), remains available at scale with industry capacity to manufacture 100 million tests per month.
- Registry participants are bringing antigen testing to the market with significant manufacturing capacity.

In addition, HHS has purchased 150 million antigen tests from Abbott to provide to states,<sup>4</sup> as well as antigen tests from Becton, Dickinson and Company (BD), and Quidel to provide testing in 15,000 skilled nursing facilities in the U.S.<sup>5</sup>

We understand RADx is supporting ongoing efforts that would be helpful in determining the utility of certain kinds of testing. The RADx Underserved Populations (RADx-UP) program has supported research intended to better understand COVID-19 testing patterns among underserved and vulnerable populations disproportionately affected by the pandemic and develop strategies to reduce the disparities in COVID-19 testing, rates of infection, and outcomes.<sup>6</sup> In addition, a team at Children's Healthcare of Atlanta, the Emory University School of Medicine, and the Georgia Institute of Technology (Georgia Tech) has received an additional \$18.2 million from RADx to continue their verification of COVID-19 diagnostic tests.<sup>7</sup> Among the projects supported by the \$18.2 million award, the team will assist in testing adolescent and adult populations at Emory and Georgia Tech to build the infrastructure for testing asymptomatic positive cases.<sup>8</sup> Finally, Fluidigm Corporation received a \$34 million contract under RADx to

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<sup>3</sup> AdvaMed COVID-19 Diagnostic Supply Registry, (Key data-driven Summary of the U.S. COVID testing supply from leading test manufacturers representing 90-95 percent of the commercial market) (last updated October 16, 2020), available at <https://www.advamed.org/sites/default/files/resource/advamed-covid-testing-supply-registry-weekly-report-101620.pdf>

<sup>4</sup> HHS Press Release, Trump Administration Deploys Abbott BinaxNOW Tests to States (September 28, 2020), available at <https://www.hhs.gov/about/news/2020/09/28/trump-administration-deploys-abbott-binaxnow-tests-to-states.html>

<sup>5</sup> Maggie Flynn, Federal Government Will Send Point-Of-Care Testing Units, Kits to All Nursing Homes in U.S., Skilled Nursing News (July 14, 2020), available at <https://skillednursingnews.com/2020/07/federal-government-will-send-point-of-care-covid-19-testing-units-kits-to-all-nursing-homes-in-u-s/>

<sup>6</sup> Yale School of Medicine, NIH Supports Two Yale-based Projects to Address COVID-19 Population Disparities (October 1, 2020), available at <https://medicine.yale.edu/news-article/27706/>

<sup>7</sup> Emory News Center, Emory shares in \$18.2 million NIH award to continue work on COVID-19 tests (October 5, 2020) available at [https://news.emory.edu/stories/2020/10/coronavirus\\_choa\\_emory\\_gatech\\_diagnostic\\_tests/index.html](https://news.emory.edu/stories/2020/10/coronavirus_choa_emory_gatech_diagnostic_tests/index.html)

<sup>8</sup> *Id.*

develop, commercialize, and implement its Advanta Dx SARS-CoV-2 RT-PCR Assay.<sup>9</sup> The Fluidigm COVID-19 Campus Safeguard Program will provide millions of noninvasive, saliva-based tests for the SARS-CoV-2 virus to qualifying institutions at a cost as low as \$5 per test.<sup>10</sup>

Given the strong public interest in effectively leveraging testing technologies in response to the COVID-19 pandemic, and in furtherance of our request, please arrange for a briefing with Minority Committee staff by November 12, 2020 to discuss the following:

1. Are any of the RADx-supported studies identifying and sharing effective approaches for using rapid POC antigen testing, or saliva-based testing such as the Fluidigm program, to screen for COVID-19 in communities, especially to detect asymptomatic cases of COVID-19? If so, how will these studies be used to inform COVID-19 screening policies?
2. What ongoing RADx-supported studies on college campuses are being conducted that would be useful in determining the utility of certain kinds of testing?
3. What RADx-supported studies are being conducted on the different kinds of testing technologies?
4. Could any of data from these RADx-supported studies be used to modify FDA emergency use authorizations for COVID-19 tests?

We would also request a written response following the briefing. Your assistance is greatly appreciated. Should you have any questions, and to schedule the requested briefing, please contact Alan Slobodin of the Minority Committee Staff at (202) 225-3641.

Sincerely,



Greg Walden  
Republican Leader  
Committee on Energy and Commerce



Michael C. Burgess, M.D.  
Republican Leader  
Subcommittee on Health



Brett Guthrie  
Republican Leader  
Subcommittee on Oversight and Investigations

<sup>9</sup> Fluidigm News Details, Fluidigm to Offer Millions of Advanta COVID-19 Tests at Low Cost to U.S. Colleges and Universities (October 8, 2020), available at <https://investors.fluidigm.com/news-releases/news-release-details/fluidigm-offer-millions-advanta-covid-19-tests-low-cost-us>

<sup>10</sup> *Id.*