Congress of the United States House of Representatives

Washington, DC 20515

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To Mr. Rusckowski, Mr. Schechter, and Dr. Cohen:

We applaud your continued efforts to ramp up SARS-CoV-2 testing during these unprecedented times. As you are well aware, with the surge in COVID-19 cases around the country, the turnaround time for testing results at private-sector clinical laboratories often exceeds 10 days. To further address these delays, we write to encourage the use of pooled testing, where possible, as part of your larger strategy to increase output and preserve valuable testing supplies.

The U.S. Centers for Disease Control and Prevention (CDC) describes "pooled testing" as a technique in which respiratory samples from several people are combined so that only one test is used on a combined pool of samples (as opposed to one test per sample). If a pooled test result is negative, then all the samples can be presumed negative with the single test. If the pooled test result is positive, each of the samples in the pool will need to be tested individually to determine which samples are positive.¹

The nation's top infectious disease experts have voiced their support for pooled testing. During a keynote at last month's virtual conference for the American Society for Microbiology, Dr. Deborah Birx urged laboratories to expand the use of pooled testing.² "Pooling would give us the capacity to go from a half a million tests a day to potentially 5 million individuals tested per day," she remarked.³ Dr. Anthony Fauci described at a Senate hearing, "It can be used in any of a number of circumstances, at a community level or even in schools if you wanted to do that." The CDC suggests that pooled testing could be useful in scenarios like returning groups of workers to a workplace. We recognize that pooled testing is most effective at increasing efficiency and output in areas of the country where the positivity rate is low. According to The Johns Hopkins University and The COVID Tracking Project, the Tri-State area has a positivity rate below 2% (seven-day moving average) as of August 31, with New Jersey at 1.1%, New

¹ https://www.cdc.gov/coronavirus/2019-ncov/lab/pooling-procedures.html

² https://asm.org/Articles/2020/July/COVID-19-Pool-Testing-Is-It-Time-to-Jump-In

https://www.statnews.com/2020/06/26/pool-testing-covid-19/

⁴ https://www.npr.org/sections/health-shots/2020/07/06/886886255/pooling-coronavirus-tests-can-spare-scarce-supplies-but-theres-a-catch

⁵ https://www.cdc.gov/coronavirus/2019-ncov/lab/pooling-procedures.html

⁶ https://www.nytimes.com/interactive/2020/07/27/upshot/coronavirus-pooled-testing.html

York at 0.8%, and Connecticut at 0.9%.⁷ Therefore, laboratories that service the Tri-State area would benefit greatly through the use of pooled testing.

Laboratories will need to seek an Emergency Use Authorization (EUA) for pooled testing. We were very encouraged to see that on July 18, the U.S. Food and Drug Administration (FDA) issued an EUA for Quest Diagnostics to begin pooled testing, allowing up to four samples to be tested at once.⁸ We were also encouraged to see an EUA issued on July 24 for LabCorp to begin pooled testing, allowing up to five samples to be tested at once.⁹ If a laboratory has not already submitted an EUA application for pooled testing, the FDA created a template to make this process easier.¹⁰

We encourage you to implement pooled testing where possible, especially at laboratories that service the Tri-State area (New Jersey, New York, and Connecticut) where the positivity rate remains low. We look forward to continuing to work together to increase testing capacity across the nation.

Sincerely,

Mikie Sherrill Member of Congress Max Rose Member of Congress Seth Moulton Member of Congress

⁷ https://coronavirus.jhu.edu/testing/tracker/overview/northeast-pr-and-usvi

⁸ https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-first-emergency-authorization-sample-pooling-diagnostic

⁹ https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-first-diagnostic-test-screening-people-without-known-or

¹⁰ https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-facilitating-diagnostic-test-availability-asymptomatic-testing-and