

United States Senate

WASHINGTON, DC 20510

August 26, 2020

John R. Cohen, M.D.
Executive Chairman
BioReference
481 Edward H. Ross Drive
Elmwood Park, New Jersey 07407

Dear Dr. Cohen:

We write seeking information regarding your company's capacity to process coronavirus disease 2019 (COVID-19) diagnostic tests and communicate results in a timely fashion. Testing allows for the timely detection of COVID-19 cases, which is crucial to combatting the spread of the virus and a key part of ending the ongoing pandemic. But reports indicate that the sharp rise in COVID-19 cases in July 2020 strained lab capacity, causing "some testing sites [to] struggle[e] to provide results in five to seven days," with "others ... taking even longer."¹ In recent weeks, the number of cases has declined from its peak – but there has been a troubling decline in the number of daily tests, a "major obstacle in America's effort to stop the coronavirus."² Policymakers and the public need to better understand the reasons for delayed testing results and declining test numbers, and the resources needed to guarantee the timely delivery of results so the nation can continue its work to combat the pandemic and, where the virus is well-controlled, safely reopen.

The Trump Administration's failure to plan and provide for adequate COVID-19 testing early in the pandemic resulted in significant testing delays, though the U.S. ramped up its testing capacity significantly by June.³ However in June and July 2020, the United States saw a significant increase in COVID-19 cases as states across the country began relaxing their stay-at-home orders and reopening parts of their economies.⁴ States such as Florida, Texas, Arizona, and California saw significant increases in COVID-19 cases and hospitalizations, followed by a sharp increase

¹ Washington Post, "Long delays in getting test results hobble coronavirus response," Rachel Winer, William Wan and Abigail Hauslohner, July 12, 2020, https://www.washingtonpost.com/health/long-delays-in-getting-test-results-hobble-coronavirus-response/2020/07/12/d32f7fa8-c1fe-11ea-b4f6-cb39cd8940fb_story.html.

² New York Times, "'We're Clearly Not Doing Enough': Drop in Testing Hampers Coronavirus Response," Sarah Mervosh, Nicholas Bogel-Burroughs, and Sheryl Gay Stolberg, August 15, 2020, <https://www.nytimes.com/2020/08/15/us/coronavirus-testing-decrease.html>.

³ New York Times, "Months Into Virus Crisis, U.S. Cities Still Lack Testing Capacity," Sarah Mervosh and Manny Fernandez, July 15, 2020, <https://www.nytimes.com/2020/07/06/us/coronavirus-test-shortage.html>.

⁴ Associated Press, "Confirmed coronavirus cases are rising in 40 of 50 states," Jake Coyle and Terry Spencer, July 2, 2020, <https://apnews.com/0468a60b64947879926d2a16e45c00ee>.

in fatalities.⁵ Florida alone recorded more than 75,000 cases in just one week in July.⁶ Tens of thousands flocked to testing sites in these states and across the country, and labs and local officials struggled to keep pace. Public health officials have even been forced to turn away patients from testing sites and re-impose testing restrictions.⁷

It is imperative that tests are not only readily available to anyone who suspects they may have been exposed to the virus, but also that individuals receiving tests are informed of the result quickly. This timely delivery allows individuals who test positive to self-isolate and avoid spreading the disease any further. However, reports during the COVID-19 peak this summer indicated that the demand for test results had exceeded the capacity to process them and that labs were struggling to procure critical testing supplies such as “reagents, swabs, [and] plastics,”⁸—resulting in backlogs that forced some Americans to wait up to two weeks for results, rendering the test effectively useless as an active diagnostic tool.⁹ This is particularly troubling given that “a delay of even two to four days could be disastrous in terms of mitigation efforts.”¹⁰

But as COVID-19 case levels declined in August, new reports revealed that “U.S. testing for the coronavirus is dropping even as infections remain high and the death toll rises by more than 1,000 a day, a worrisome trend that officials attribute largely to Americans getting discouraged over having to wait hours to get a test and days or weeks to learn the results.”¹¹ And even if the backlog has largely been cleared, the confluence of COVID-19 circulation and the annual influenza season may again strain labs’ ability to perform and deliver test results in a timely manner.¹² Meanwhile, the U.S. Food and Drug Administration recently issued a list of medical devices in shortage during the COVID-19 pandemic that included eight devices labeled as

⁵ NBC News, “Florida, Texas, and California account for about one-fifth of the world’s new coronavirus cases,” Nigel Chiwaya and Corky Siemaszko, July 14, 2020, <https://www.nbcnews.com/news/us-news/florida-texas-california-account-about-one-fifth-world-s-new-n1233793>.

⁶ New York Times, “Florida Coronavirus Map and Case Count,” <https://www.nytimes.com/interactive/2020/us/florida-coronavirus-cases.html>.

⁷ New York Times, “Months Into Virus Crisis, U.S. Cities Still Lack Testing Capacity,” Sarah Mervosh and Manny Fernandez, July 15, 2020, <https://www.nytimes.com/2020/07/06/us/coronavirus-test-shortage.html>.

⁸ Healthcare Finance News, “AMA and others struggling to perform testing urge HHS to reprioritize COVID-19 guidelines,” Mallory Hackett, August 11, 2020, <https://www.healthcarefinancenews.com/news/ama-and-others-struggling-perform-testing-urge-hhs-reprioritize-covid-19-guidelines>; Associated Press, “US labs buckle amid testing surge; world virus cases top 15M,” Matthew Perrone, Tammy Webber, and Matt Sedensky, July 22, 2020, <https://apnews.com/969fbbf44dd2ba1acea130f95b21ef62>; New York Times, “Spike in U.S. Cases Far Outpaces Testing Expansion,” <https://www.nytimes.com/2020/07/22/world/coronavirus-covid-19.html>.

⁹ Kaiser Health News, “As COVID Testing Soars, Wait Times For Results Jump To A Week – Or More,” Phil Galewitz, July 9, 2020, <https://khn.org/news/as-covid-testing-soars-wait-times-for-results-jump-to-a-week-or-more/>; The Wall Street Journal, “Growing Wait Times for COVID-19 Test Results Hinder Virus Response,” Brianna Abbott and Sarah Krouse, July 16, 2020, <https://www.wsj.com/articles/growing-wait-times-for-covid-19-test-results-hinder-virus-response-11594891800>.

¹⁰ The Wall Street Journal, “Growing Wait Times for COVID-19 Test Results Hinder Virus Response,” Brianna Abbott and Sarah Krouse, July 16, 2020, <https://www.wsj.com/articles/growing-wait-times-for-covid-19-test-results-hinder-virus-response-11594891800>.

¹¹ Associated Press, “Virus testing in the US is dropping, even as deaths mount,” Matthew Perrone, Nicky Foster, Michelle Liu, August 5, 2020, <https://apnews.com/aebdc0978de958f20ab3f398cdf6f769>.

¹² Axios, “Quest warns flu season will further hurt coronavirus testing,” Marisa Fernandez, July 22, 2020, <https://www.axios.com/quest-diagnostics-coronavirus-testing-crunch-flu-season-6f445d96-69c6-4bff-bf77-380e41424b9b.html>.

“testing supplies and equipment.”¹³ These device shortages could further limit the country’s testing capacity as the virus continues to spread in the Fall.

Delayed test results and the inability to conduct enough tests seriously weakens the country’s efforts to combat the pandemic. Delays in results can obfuscate public health officials’ view of the virus and how it is spreading, hindering their ability to respond effectively and, in turn, prolonging the pandemic.¹⁴ While testing numbers and turnaround times have improved in recent weeks, it is imperative we take steps now to prevent future delays and backlogs. To help us understand the current capacity of your labs, the demand you are receiving, and the resources needed to deliver test results as rapidly as possible and avoid backlogs, we request answers to the following questions no later than September 9, 2020:

1. What is the current turnaround time, as of August 26, 2020, for a COVID-19 diagnostic test sample submitted to your lab?
 - a. Are these results delayed beyond the average turnaround times, and if so, what are the reasons for these delays?
 - b. Please provide a breakdown of the above information by each test your labs perform.
 - c. What is the average amount of time between a lab receiving a test result and communicating the result to state and local health officials, medical providers, or individuals that requested the result?
2. On average for each full week in the month of July and August 2020, how many tests did your company process per day?
 - a. What was the average turnaround time for these tests?
 - b. Please provide a breakdown of the above information by state.
 - c. To the extent you observed a decline in the number of tests in August 2020, what accounts for this decline?
3. As of August 26, 2020, what is the maximum daily capacity of your labs to process COVID-19 diagnostic tests? What is the limiting factor on this capacity?
 - a. Please provide a breakdown of the above information nationally and by state.
4. Please provide a list of all supplies that you have experienced shortages of which has negatively impacted your ability to perform COVID-19 diagnostic tests.
5. To the extent there are capacity limits or delays in obtaining and delivering test results, what can Congress and the Administration do to alleviate these capacity limits and delays?

We thank you for your attention to this important issue.

¹³ U.S. Food and Drug Administration, “Medical Device Shortages During the COVID-19 Public Health Emergency,” August 20, 2020, <https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/medical-device-shortages-during-covid-19-public-health-emergency#shortage>.

¹⁴ Boston Globe, “Testing delays are hurting the effort to contain COVID-19,” Kay Lazar and Dasia Moore, July 21, 2020, <https://www.bostonglobe.com/2020/07/20/nation/backlog-covid-19-tests-imperils-push-contain-infections/>.

Sincerely,

/s/ Elizabeth Warren
Elizabeth Warren
United States Senator

/s/ Tina Smith
Tina Smith
United States Senator