

October 6, 2020

The Honorable Mike Pence
Vice President of the United States
The White House
Office of the Vice President
1600 Pennsylvania Avenue NW
Washington, DC 20500

Dear Vice President Pence:

The undersigned organizations, representing laboratory professionals from regional, community, academic, hospital, and public health laboratories, thank you for your efforts to address the COVID-19 pandemic that continues to threaten the United States. We write to ask the White House Coronavirus Task Force (Task Force) to provide transparency into the allocation and availability of laboratory supplies needed to respond to the COVID-19 public health emergency. Our organizations stand ready and willing to partner on any efforts to facilitate the release and dissemination of this information.

Our members provide SARS-CoV-2 RT-PCR, antibody, and antigen testing using a variety of platforms. These tests require supplies that are currently in severe shortage, including pipette tips, reagents, and test kits. Because of these shortages, our members are operating below their potential capacity and below the capacity that their communities demand. For example, one regional laboratory reports an allocation from a manufacturer of enough reagent to process 500 tests per day, yet their laboratory's capacity is at least 3,000 tests per days. As a result, COVID-19 test volume and turnaround time are lower and longer than they should be. Compounding this problem is a lack of transparency into the federal government's acquisition and distribution of testing supplies to states and private laboratories.

Efforts to date to share information on supply availability, such as the FDA's Medical Device Shortage listing, lack the specificity necessary to allow laboratories to understand what supplies are in production, where the supplies can be procured, and when the supplies will be available. Further, while we appreciate the recent request for information published in the Federal Register on September 10, we are concerned that it only addresses supplies for one specific test and manufacturer and there has otherwise been little progress on increasing transparency around the collection and dissemination of information on the availability of testing supplies.

Instead, our organizations urge the White House Coronavirus Task Force to lead a coordinated federal effort to transparently communicate information on the availability of COVID-19 testing supplies and to do everything possible to encourage the production of sufficient testing supplies to meet the needs of every state across the nation. Again, our organizations would like to offer our partnership in that pursuit, but believe your leadership is greatly needed. We cannot rely on one test platform or two or three large manufacturers to increase our testing capacity to the level our country demands. We must make use of our entire laboratory capacity and ensure that labs all over the country in every setting have access to the testing supplies they need immediately. Such a response would enhance our nation's response to the pandemic, reduce wait time for COVID-19 test results, and permit our members to operate closer to the needed testing capacity. Nearly eight months into the COVID-19 public health emergency, the medical supply chain remains weak and laboratories still do not have the supplies needed to meet the testing needs of their communities. We urge the Task Force to take bold action to encourage the manufacturing of COVID-19 test supplies and to transparently share information on the

availability of supplies among the entire laboratory community. Until the federal government takes action, these shortages will persist, future surges in the pandemic will occur, and patients will continue to suffer.

Thank you for your attention to this important matter. We would greatly appreciate a meeting with the Task Force and its staff to discuss this issue in greater detail. Meghan Riley at mriley@dc-crd.com is available to coordinate schedules for a meeting. We look forward to working with you to address these testing barriers.

Sincerely,

American Association of Bioanalysts
American Association for Clinical Chemistry
American Medical Technologists
American Society for Microbiology
Association for Molecular Pathology
National Independent Laboratory Association

cc: The Honorable Alex Azar
Secretary of Health and Human Services

The Honorable Deborah Birx, MD
Response Coordinator, White House Coronavirus Task Force

ADM Brett Giroir, MD
Assistant Secretary for Health
Testing Coordinator, White House Coronavirus Task Force