

December 2, 2020

Dear President-Elect Biden:

On behalf of the undersigned organizations representing laboratory professionals from regional, community, academic, hospital, and public health laboratories around the country, congratulations on your recent election to President of the United States. Our members have been working tirelessly on the front lines of the response to the pandemic to increase essential testing for COVID-19. As the U.S. is currently experiencing record-high daily infection rates, we need a strong and effective national testing strategy that guarantees access to the essential laboratory supplies critical to increasing and maintaining testing capacity throughout the country.

We are encouraged to see that the Biden-Harris transition plan lists responding to COVID-19 as a top priority and also recognizes the importance of ensuring access to timely testing for all who need it. To meet this unprecedented demand for testing, our members have been successfully navigating unanticipated supply chain shortages. To truly ensure all Americans have access to regular, reliable, and free testing as you propose, we must alleviate supply shortages that threaten testing capacity at many laboratories. You have promised to use the full power of the federal government to rebuild domestic manufacturing capacity of our supply chains for critical products. As you begin this effort in your first days in office, we implore you to also include COVID-19 testing supplies as part of this effort. Compounding the problems our member laboratories faced this past year has been a lack of transparency into the federal government's acquisition and distribution of testing supplies to states and private laboratories. As you take office, we ask that you lead a coordinated federal effort to increase transparency and communicate information on the availability of COVID-19 testing supplies and do everything possible to encourage the production of sufficient testing supplies to meet the needs of every laboratory across the nation.

Our members provide SARS-CoV-2 RT-PCR, antibody, and antigen testing using a variety of testing platforms. These tests require numerous 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 need as testing demand continues to increase. Testing requires the simultaneous use of several equally critical components. While some supplies may be available, if even one component is unavailable (i.e., plastic pipette tips), tests cannot be performed and results are delayed. It is a constant challenge to procure all the necessary supplies to meet potential testing capacity and laboratories have validated numerous methodologies to build redundancy in anticipation of these challenges. As a result, COVID-19 test volume is lower and turnaround times are longer than they should be. The longer individuals wait for test results, the greater the risk COVID-19 poses to their families and communities.

As our members work to respond to the COVID-19 crisis, our organizations have been gathering information and communicating their needs to the federal government. Several organizations have compiled helpful resources that may aid the transition team in better understanding the supply chain challenges laboratories have faced during the pandemic:

- The Association for Molecular Pathology recently conducted a [survey](#) that overwhelmingly showed that supply shortages continue to impact testing capacity. 72 percent of respondents reported that supply chain issues have caused delays or interruptions in testing.
- The American Society for Microbiology has created the [Clinical Microbiology Supply Shortage Collection Tool](#) to identify patterns and trends in the supply chain in real time. This effort has demonstrated that three in four laboratories do not have enough COVID-19 test kits to meet demand. Further, the strain placed on the supply chain by COVID-19 has impacted supplies for routine tests, leaving some laboratories without the means to test for common illnesses.
- Since April, the American Association for Clinical Chemistry has been [surveying](#) clinical laboratories performing COVID-19 testing to learn what problems they are encountering. Unfortunately, the results indicate an ongoing shortage of critical laboratory supplies, such as test kits, reagents, and swabs. AACC

has shared this data with policymakers both within the administration and on Capitol Hill to help them shape policy moving forward.

- Beginning April 13, 2020, the Association of Public Health Laboratories has conducted a weekly survey of 99 state, local and territorial public health laboratories (PHLs) to collect the status of current and projected capability and capacity of laboratories to test for COVID-19. Data from this [survey](#) is used to inform HHS, FEMA, CDC and other federal partners to support public health laboratory supply and reagent needs.
- The National Independent Laboratory Association surveyed its members who [reported](#) that regional and community laboratories are also facing supply shortages, but have capacity to perform many more COVID-19 tests if supplies are made available.

Thank you for your consideration of this important issue. Our organizations stand ready to partner with your Administration, to offer our expertise, and to share our real-time assessment of the laboratory response to COVID-19. We are hopeful that together with a coordinated effort we will succeed at easing testing supply shortages and guarantee that Americans can both access needed COVID-19 testing and receive their results quickly. We appreciate your consideration of our request and we hope to have the opportunity to meet with you and/or your COVID-19 Advisory Group and members of the transition team focused on this important public health crisis. For assistance, please contact Meghan Riley at mriley@dc-crd.com.

Sincerely yours,

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

cc: David A. Kessler, MD
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