



December 8, 2020

President-Elect Joseph R. Biden  
Coronavirus Advisory Board  
c/o Biden-Harris Transition Team  
1401 Constitution Ave NW Washington, DC 20230

Attention: David Kessler, MD, Co-Chair; Vivek Hallagere Murthy, MD, MBA, Co-Chair; and  
Marcella Nunez-Smith, MD, Co-Chair

Dear Drs. Kessler, Murthy, and Nunez-Smith,

The American Association for Clinical Chemistry (AACCC) congratulates President-elect Joseph Biden on his electoral victory and welcomes the opportunity to work with him and his advisors in addressing the coronavirus pandemic that is affecting our nation and the global community. By working together, we can address the current problems that are hindering our efforts to identify and treat those individuals infected with the virus, while taking necessary measures to prevent its spread.

AACCC is a global scientific and medical professional organization dedicated to clinical laboratory science and its application to healthcare. AACCC brings together more than 50,000 clinical laboratory professionals, physicians, research scientists, and business leaders from around the world focused on clinical chemistry, molecular diagnostics, mass spectrometry, translational medicine, lab management, and other areas of laboratory science to advance healthcare collaboration, knowledge, expertise, and innovation.

AACCC has called on public officials to take steps to improve our ability to respond to the need and demand for COVID-19 testing. Early in the nation's response, the laboratory medicine community marshalled all its resources to quickly develop and deploy tests and to increase testing capacity. Despite this success, challenges remain. Foremost, the shortage of laboratory supplies needed to perform COVID-19 testing is a serious and ongoing problem that requires immediate attention and a recent decision to cut lab reimbursement for certain COVID-19 tests must be reversed. Moving forward, we must also rebuild our public health infrastructure, which has been underfunded in recent years.

#### **Improve Access to Laboratory Supplies**

AACCC believes the federal government needs to play a larger role in the manufacture and distribution of laboratory supplies to ensure laboratories have access to them when needed. During the current pandemic, laboratories have had to compete with one another, and with state testing facilities, to obtain supplies to test and care for their patients. Laboratories have also encountered problems getting supplies from state public health coordinators and finding out what supplies are available.

Data from our ongoing surveys of laboratories conducting COVID-19 testing illustrates this problem. In our most recent September survey, 57% of respondents reported that they continue to have problems obtaining supplies needed to perform coronavirus diagnostic testing. Nearly 70% of the laboratories state they cannot obtain needed test kits and reagents and 36% cannot get the swabs needed to collect specimens. These findings are consistent with our previous surveys.

A new area of concern, however, is access to personal protective equipment (PPE). In our August survey only 11% percent of the respondents identified obtaining PPE as an issue. In the most recent canvass, this number has increased to 27%. AACC urges the new Administration to make addressing this shortage a high priority. AACC will deploy its survey again this month and will report those finding to the taskforce when the data are available.

While we agree that state and local officials must continue to play a central role in coordinating efforts, there are some things that only the federal government can accomplish. We recommend that the new Administration work with the healthcare community to develop a plan for ensuring that supplies are more efficiently produced and allocated to facilities in need.

#### **Repeal CMS Decision to Tie Lab Payments to Turnaround Time**

AACC urges you to repeal a recent action by the Centers for Medicare and Medicaid Services (CMS) to reduce Medicare payments for molecular pathology high throughput COVID-19 diagnostic tests that are not completed within two days of the specimen being collected. Starting January 1, 2021, laboratories that do not meet this criterion will be paid at 75% of the current payment level.

AACC agrees that timely testing is vital to diagnosing, isolating, and treating patients with the coronavirus and performing much needed contact tracing. Clinical laboratories are committed to providing high quality, timely, accurate tests. Many laboratories are completing their testing within the timeframe specified by CMS. For those laboratories not meeting this timeframe, it is often for reasons outside of their control.

As mentioned previously, many testing facilities cannot obtain the supplies, particularly the test kits and reagents, needed to rapidly perform the high volume of COVID-19 tests they continue to receive. It is this lack of supplies that hinders labs' ability to complete test results quickly. Cutting payments to laboratories, which are already incurring significant costs to perform these tests, will not improve the testing situation. In fact, it likely will have the opposite effect, causing cash-strapped laboratories even further difficulty in obtaining the supplies they need. We are concerned that reducing payments may force some laboratories to outsource COVID-19 tests, which would further delay the reporting of timely, actionable results.

#### **Strengthen Our Nation's Public Health Infrastructure**

AACC recommends that the new Administration and Congress work together to improve public health infrastructure. Federal expenditures for the Centers for Disease Control and Prevention (CDC), when adjusted for inflation, remain at fiscal year 2008 levels. This flat funding has resulted in the elimination

of more than 50,000 local public health services jobs over the past decade. As a result, the CDC does not have the infrastructure or resources it needs to carry out its assigned responsibilities, particularly during a pandemic.

AACC is pleased that the coronavirus relief bills passed by Congress have provided additional interim funding to help CDC to carry out its activities. More information is needed on how this money is being spent and whether it is sufficient for the agency to accomplish its tasks. We believe CDC, working closely with state and local health departments, should oversee pandemic surveillance activities, such as testing capacity and related supply chain issues, the rate of disease transmission across the nation, and the recognition and reporting about where the virus is spiking or falling, as well as contact tracing data.

Moving forward, given the likelihood that COVID-19 will be a health issue for the foreseeable future, additional funding should be provided to CDC to rebuild the public health infrastructure, not only to address the current situation, but also to prepare for future health crises. It takes significant time to identify and acquire necessary technology, to hire and train personnel, to develop and implement response strategies, and to identify and adopt useful reporting measures. Providing CDC with additional funding to carry out these important duties should be central to any pandemic strategy.

#### **COVID-19 Transition Coronavirus Advisory Board**

AACC would like to reiterate its past support for adding a laboratory professional to the COVID-19 Transition Coronavirus Advisory Board. A laboratory expert on the Board can suggest strategies for expanding access to testing in the face of surging coronavirus cases. Having dealt with the shortage of supplies, they can recommend approaches that take into consideration real-world constraints, such as the testing capacity of instruments and the availability of supplies and personnel needed to perform the tests. This intimate knowledge makes them well positioned to help develop solutions to overcome these limitations. AACC is willing to assist you in identifying qualified individuals that could serve in this capacity.

We look forward to working with you on this important issue. If you have any questions, please email Vince Stine, PhD, AACC's Senior Director of Government and Global Affairs, at [vstine@aacc.org](mailto:vstine@aacc.org).

Sincerely,



David G. Grenache, PhD, D(ABCC)  
President, AACC