

May 26, 2020

The Honorable Mitch McConnell Majority Leader U.S. Senate Washington, D.C. 20510 The Honorable Charles Schumer Minority Leader U.S. Senate Washington, DC 20510

Dear Majority Leader McConnell and Minority Leader Schumer,

The American Association for Clinical Chemistry (AACC) appreciates Congress' rapid and comprehensive approach to dealing with the current COVID-19 pandemic. Over the past few months, the healthcare sector has made significant advances in expanding testing capacity, reducing the time to obtain results, and improving the accuracy of the tests. These advances make it possible to better diagnose and triage patients and provide appropriate care. While there has been significant progress in combating this virus, there is still much to do.

### **Integrated Testing Strategy**

Efficient and effective COVID-19 testing across a large area requires improved coordination among all levels of government. Federal, state, and local agencies must employ shared terminology, and have similar understandings of the problems that need to be addressed, specific goals for combating them, and the resources needed to succeed. For example, a May 21st article reported that at least 4 states are counting COVID-19 molecular tests and antibody tests together, but these two approaches give different information. Such mistaken understanding may produce incorrect future decisions, such as when schools may reopen.

Government stakeholders, working together, should develop a strategy that:

- Establishes a common terminology;
- Identifies current challenges;
- Specifies necessary resources;
- Sets forth a plan for acquiring and distributing the materials; and
- Creates benchmarks and timelines for measuring progress.

We recommend that the Department of Health and Human Services take the lead in organizing this effort.

## **Better Coordination of Supply Chain**

Many laboratories continue to encounter supply chain issues. Our members report continuing delays in obtaining needed medical devices, reagents, swabs, specimen transport media and personal protective equipment. Unfortunately, laboratories and states compete with one another to obtain the supplies

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they need to test and care for their patients. AACC believes that greater federal involvement is necessary to help ensure the manufacture and distribution of these supplies to laboratories on a timely basis.

Further, we support the creation of a mechanism that would permit healthcare facilities to regularly report their level of inventories, which could be used by the government to identify need and more equitably allocate resources to facilities.

## **Strengthen 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. Therefore, the CDC does not have the infrastructure or resources it needs to carry out the responsibilities assigned to it, particularly during a pandemic like this one.

AACC is pleased that previous COVID-19 packages have provided additional interim funding to help the 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 carry out its tasks. We believe the CDC, working closely with state and local health departments, should oversee the COVID-19 surveillance activities, such as testing capacity, the rate of transmission, where the virus is spiking and falling, and contact tracing, among other data gathering measures.

Given the likelihood that COVID-19 will be a health issue for the foreseeable future, Congress should also provide the necessary funds so that the CDC can rebuild the public health infrastructure that will be needed to address this, and potentially other, health crises moving forward. It takes time to hire and train personnel, develop and implement response strategies, and identify and adopt useful reporting measures. AACC urges additional funding be provided to the CDC to carry out its duties.

### **Expansion of COVID-19 Serological Testing**

Increasingly, the healthcare community is recommending that serological or antibody testing be expanded to identify those individuals who may have already contracted and recovered from the virus. The use of serology testing can provide the healthcare community with insight into the prevalence of the SARS-CoV-2 virus as well as a more accurate assessment of its mortality rate.

Serology testing can also help policymakers and public health officials develop strategies to constrain the pandemic. Blood from recovered patients may help researchers determine whether individuals have developed an immunity to the virus, as well as assist in the development of vaccines vital to preventing the spread of the infection.

While this type of testing is becoming increasingly available, not all serology tests are of the same quality. The federal government should use its oversight authority to certify the quality of these tests and ensure that accurate serology tests are sufficiently reimbursed to facilitate widespread patient access to the testing.

# **Safeguard Financial Solvency of Healthcare Providers**

Healthcare providers, such as hospitals and commercial laboratories, are suffering significant losses of revenue due to the COVID-19 pandemic. The Coronavirus Aid, Relief, and Economic Security (CARES) Act provided \$100 billion in assistance to relieve the financial burdens of hospitals and other healthcare providers. While helpful, both sectors continue to endure huge financial losses due to lower demand for services. As a result, many hospitals have reduced the hours or furloughed technologists that normally perform laboratory testing, including for COVID-19. Continued financial aid is needed to ensure these frontline healthcare facilities remain financially solvent during this crisis and beyond.

AACC is a global scientific and medical professional organization dedicated to clinical laboratory science and its application to healthcare. AACC 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.

We look forward to working with you on these most important issues. To facilitate these interactions, or if you have any questions, please email Vince Stine, PhD, AACC's Senior Director of Government and Global Affairs, at vstine@aacc.org.

Sincerely,

Carmen L. Wiley, PhD, DABCC, FAACC

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President, AACC