



Better health through
laboratory medicine.

February 2, 2021

The Honorable Charles Schumer
Majority Leader
U.S. Senate
Washington, D.C. 20510

The Honorable Mitch McConnell
Minority Leader
U.S. Senate
Washington, D.C. 20510

The Honorable Nancy Pelosi
Speaker of House
U.S. House of Representatives
Washington, DC 20515

The Honorable Kevin McCarthy
Minority Leader
U.S. House of Representatives
Washington, DC 20515

Dear Majority Leader Schumer, Speaker Pelosi, and Minority Leaders McConnell and McCarthy:

The American Association for Clinical Chemistry (AACC) has been conducting a recurring survey since May 2020 to assess the testing capabilities of clinical laboratories performing COVID-19 testing. We are concerned that many of the supply shortage problems identified in the spring remain to this day. AACC urges Congress to work with the new administration and increase the production and distribution of testing supplies.

From December 2020 to January 2021, AACC received survey responses from 41 commercial, hospital, and public health laboratories. Nearly 60% of the responding laboratories continue to encounter problems obtaining the supplies they need to perform COVID-19 diagnostic testing. Their primary obstacle remains an inability to procure test kits and reagents.

- The percentage of laboratories able to procure a sufficient test kits to meet demand has worsened over the past few months. In May 2020, 48% of responding laboratories stated they were unable to obtain test kits. This figure currently stands at 58%.
- Similarly, testing facilities continue to have trouble getting the reagents they need to perform testing. In May, 54% of laboratories reported this as a significant problem. This figure remains uncharacteristically high at 50%.

Two areas where there has been significant improvement are obtaining swabs (a reduction from 62% to 13%) and personal protective equipment (PPE) (a reduction from 32% to 13%).

AACC is alarmed, however, by the number of laboratories that cannot perform all their non-COVID-19 tests due to a shortage of supplies. This problem has worsened, increasing from 53% to 58% since September. We are concerned that unless more supplies are procured and appropriately allocated our nation will continue to have difficulty addressing typical, ongoing health needs while working to gain control of this crisis.

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AACC asserts that the federal government must assume a larger role in coordinating supply chain management activities to facilitate the production and distribution of these much-needed supplies. While we agree that state and local officials must continue to play a central role in this process, there are some things that only the federal government can accomplish.

AACC recommends that Congress work with the federal agencies, healthcare community, and public health officials to develop a clear, transparent plan for ensuring that officials at the national level are aware of essential medical supply needs of the laboratory community and a distribution process is put in place to ensure supplies are more efficiently produced and allocated to facilities in need.

We also urge legislative action to reverse a recent policy decision by the previous administration that reduces Medicare payments for molecular pathology high throughput COVID-19 diagnostic tests that are not completed within two days of the specimen being collected. As of January 1, 2021, laboratories that do not meet this criterion are reimbursed \$75 per test rather than the previous fee of \$100.

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, including the supply chain issues addressed previously in this letter. Cutting payments to laboratories, which are already incurring significant costs to perform these tests, is unlikely to improve the testing situation. 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.

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 important issues. If you have any questions, please email Vince Stine, PhD, AACC's Senior Director of Government and Global Affairs, at vstine@aacc.org.

Sincerely,



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