



April 27, 2021

President Joseph R. Biden
The White House
1600 Pennsylvania Avenue

Dear Mr. President:

On behalf of the nation's leading clinical laboratories and the millions of patients we serve, thank you for your continued leadership during this devastating public health crisis. In addition to the accelerated rollout of critical vaccines, your administration has taken several important and meaningful actions in your first 100 days on coronavirus testing and sequencing, including closing insurance coverage gaps that contributed to many individuals foregoing COVID-19 testing altogether, and most recently, investing in a \$1.7 billion national network to identify and track worrisome coronavirus mutations.

The American Clinical Laboratory Association (ACLA) is the national trade association representing leading laboratories that deliver essential diagnostic health information to patients and providers. ACLA member laboratories were among the first to validate and scale novel tests for the SARS-CoV-2 virus. Since then, our members have worked around the clock to perform more than 120 million PCR tests for COVID-19 while adapting platforms and workflows, navigating supply constraints and working creatively and collaboratively to meet patients' evolving health needs. ACLA member laboratories have also worked closely with the Centers for Disease Control and Prevention (CDC) and state and local public health labs to support sequencing efforts in response to emerging SARS-CoV-2 variants. Our nation's capacity for sequencing has dramatically expanded as a result of the efforts of ACLA members and other private sector laboratories, and we stand ready to support more sequencing and testing.

As your administration reflects on the first 100 days and the important work that remains, we appreciate the opportunity to share with you several core issues critical to address in the next 100 days:

- **Strengthen Public-Private Partnerships To Prepare for Future Public Health Threats**
Private sector labs are uniquely situated to support public health partners during an outbreak, and yet the current public health framework does not adequately recognize or leverage the power of the private laboratory community to respond to a pandemic, particularly in the earliest phases. This must change moving forward. The federal government must build on existing efforts, such as the memorandum of understanding between ACLA, CDC, the Association of Public Health Laboratories and the Council of State and Territorial Epidemiologists, to strengthen coordination between private industry and public health agencies. As part of this coordination, the federal government must also make resources available to support execution of these critical public-private efforts.

- **Support Return to Care**

One of the most lasting and damaging impacts of the pandemic may be the rise of undiagnosed or unmanaged diseases. Physicians have recently raised the alarm regarding a [troubling new trend](#) in advanced cancers, citing a dramatic drop in screenings. We urge the Administration to educate Americans and the medical community about the importance of routine lab testing as well as advanced diagnostics as critical tools in health care diagnosis, treatment and prevention efforts.

- **Address Persistent Health Disparities**

ACLA members are also concerned about the significant and enduring consequences of the pandemic on communities of color and stand ready to support the Administration's actions to address persistent inequities in our health system. The pandemic exposed long established disparities in access and coverage. The laboratory community has long recognized that chronic diseases, such as heart disease, cancer and diabetes all disproportionately impact communities of color. Lab testing gives patients tools to better manage their illness and provides the information they need to connect patients with personalized treatment. ACLA is eager to work with the Administration to ensure equal access to laboratory testing for better management of chronic diseases in communities of color.

Protect Seniors' Access to Testing

- Access to testing is particularly important for seniors, 85 percent of whom have at least one chronic health condition, [according to the CDC](#). Despite pre-pandemic evidence illustrating how cost-effective and critical lab services are to diagnosing and managing disease, lab services are facing another round of Medicare payment cuts in 2022. It's critical that Congress halt these cuts and amend the Protecting Access to Medicare Act of 2014 (PAMA) by establishing a clinical laboratory fee schedule that supports continued innovation and access. Now more than ever, we must eliminate year-over-year payment cuts and support continued access to the high-quality lab services that the nation depends on.
- **Establish Appropriate and Clear Pathways for Test Development and Regulation**

The value of Laboratory Developed Tests (LDTs) is well-documented. These tests are often developed in response to an unmet need and have long played a critical role in care for patients facing a range of complex health conditions, from cancer to rare disease. With respect to the pandemic, the first COVID-19 tests available in the United States, beyond the CDC's kits, were highly-accurate and reliable LDTs, and ACLA members were among the first to bring these tests to market. That's why we remain focused on working with leaders in Congress to advance a modernized regulatory framework to protect access to innovative tests. Laboratories need clarity and certainty about how these critical services are regulated, and the time is now to advance meaningful comprehensive diagnostic reform legislation – a priority ACLA and other stakeholders have been advocating for over the past three administrations.

Meeting the needs of the future requires clinical laboratories to make sustained investment in high precision instruments, adequate testing supplies, a highly trained workforce, modernized reporting systems, cutting edge research and specialized logistics. We look forward to continuing our shared work together to

ensure laboratories can make these necessary investments to support the ongoing COVID-19 response, develop the next generation of innovative diagnostics, and continue to improve the care available to all Americans.

Sincerely,

A handwritten signature in black ink, appearing to read 'Julie Khani', written over a light gray rectangular background.

Julie Khani, President
American Clinical Laboratory Association