AMERICAN CLINICAL LABORATORY ASSOCIATION

February 23, 2021

The Honorable Ron Wyden
Chairman
U.S. Senate Committee on Finance
219 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Mike Crapo
Ranking Member
U.S. Senate Committee on Finance
219 Dirksen Senate Office Building
Washington, DC 20510

Dear Chairman Wyden and Ranking Member Crapo,

On behalf of the nation's leading clinical laboratories and the millions of patients we serve, I am writing to express our views ahead of the hearings to consider the presidential nomination of Xavier Becerra to serve as Secretary of the U.S. Department of Health and Human Services (HHS).

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 100 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. In recent weeks, 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.

The purpose of this letter is not to weigh in on the individual merits of this nominee, but rather to ensure that the committees of jurisdiction are aware of the unique challenges facing the next HHS Secretary. Below are the core issues we feel are important for the committee to be aware of as it proceeds with the hearings:

- **Role of testing in on-going COVID-19 response:** Innovation by the diagnostics community has brought forth a range of testing options for COVID-19 – lab-based, point of care and recently at-home testing. Clinical laboratories have introduced a range of new tests and techniques to meet widespread patient need, including the development of the at-home specimen collection kits, the expanded use of specimen pooling and multiplex testing and the launch of novel RNA extraction methods. All accurate and reliable tests have a role in getting us through this pandemic and utilizing the full range of testing options should be top of mind

as policymakers weigh new strategies to increase testing for travelers, students, teachers and other essential workers. We also recognize that testing alone is not going to stop spread of the virus. Testing is one facet of a public health strategy, but we have to take the actions necessary to contain the virus in communities.

- **On-going COVID-19 testing access and coverage challenges:** Over the course of this public health crisis, the federal protections Congress promised to patients have significantly eroded. Moreover, one month after President Biden directed federal agencies to clarify insurers' obligation to cover COVID-19 testing, health plans continue to deny claims for COVID-19 testing. This uncertainty undermines our collective efforts to get Americans back to work and school. According to a recent survey of a subset of ACLA members, health plans have denied at least one million claims for COVID-19 PCR tests since June 2020. Unfortunately, this snapshot represents just the tip of the iceberg. Providers, including laboratories, are routinely absorbing the costs of performing testing and the congressionally established uninsured fund designed to expand access to COVID-19 testing is now running low. We strongly urge the Administration to take immediate action to address these coverage loopholes and take steps to ensure Americans can access the COVID-19 testing they need without hesitation.

- **Diagnostic reform:** Over the past several years, ACLA has actively worked with stakeholders to advance meaningful comprehensive diagnostic reform that can encourage innovation and support continued access to accurate and reliable laboratory developed tests (LDTs) necessary for the diagnosis, monitoring and treatment of disease. Lessons from the pandemic have continued to highlight this need. The first COVID-19 tests available in the United States, beyond the CDC 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, including those required during a future public health emergency, and to support the next generation of diagnostic breakthroughs for patients. ACLA believes that reform must ultimately create a modernized, risk-based model for federal review that accounts for the full range of tests and diagnostics coming to market. Reform should also establish clear, objective standards and grandfathering provisions to guarantee patients can continue to access the life-saving tests they need during transitions to a new regulatory framework. These key provisions will help ensure both continued innovation and robust patient access to high-quality, accurate and reliable clinical laboratory diagnostics.

- **Public-Private Partnerships**: Private-sector clinical laboratories – particularly CLIA-certified, high-complexity laboratories with the technical expertise and infrastructure to rapidly expand capacity at a national scale – are uniquely qualified to support public health laboratories and develop, validate and perform high-quality diagnostic tests that are necessary for managing a pandemic response. 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, and this must change moving forward. Specifically, 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 a part of this coordination, the federal government must make resources available to support execution of these critical public-private efforts.

- **PAMA Reform:** Despite the 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 delay 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. At a time when we've strengthened and expanded our vital laboratory infrastructure, eliminating year-over-year payment cuts and supporting continued access to the high-quality lab services that the nation depends on is mission critical.

Meeting the evolving needs of patients nationwide requires significant investment in high precision instruments, adequate testing supplies, a highly trained workforce, modernized reporting systems, cutting edge research and specialized transportation logistics. ACLA and our members look forward to working with the Biden Administration and the new Congress to ensure laboratories can make the necessary investments and increase capacity for both COVID-19 testing and the next generation of innovative diagnostics.

On behalf of ACLA, our member laboratories and the millions of patients we serve, thank you for holding this important hearing. We look forward to working with you and your colleagues to ensure labs can help meet this challenging moment and deliver the testing our country needs, now and in the future.

Sincerely,

Julie Khani, President
American Clinical Laboratory Association