



February 22, 2021

The Honorable Jeffrey Zients  
COVID-19 Response Coordinator  
The White House  
1600 Pennsylvania Ave, NW  
Washington, DC 20500

Dear Mr. Zients,

Thank you for your recent efforts to support COVID-19 testing and critical laboratory infrastructure through the National Strategy for the COVID-19 Response and Pandemic Preparedness. As the nation's leading laboratories performing PCR and other tests for COVID-19, we are working around the clock to support the Biden Administration as it continues to confront the greatest public health threat in a century. Today, I am writing to seek your support to ensure the implementation of the January 21, 2021 executive order, "Establishing the COVID-19 Pandemic Testing Board and Ensuring a Sustainable Public Health Workforce for COVID-19 and Other Biological Threats", which recognizes the critical need to clarify coverage requirements for testing and replenish the fund that covers the cost of COVID testing for uninsured Americans.

The American Clinical Laboratory Association (ACLA) is the national trade association representing laboratories that deliver essential diagnostic health information to patients and providers. In March 2020, ACLA member laboratories were among the first to validate and scale novel tests for the SARS-CoV-2 virus. Since then, ACLA members have performed more than 100 million PCR tests for COVID-19, while adapting platforms and workflows, navigating supply constraints and working creatively and collaboratively with federal, state and local governments to meet patients' evolving health needs.

Despite our collective progress, uncertainty about coverage and costs has created unnecessary barriers for many patients to access COVID-19 testing. Over the course of this public health crisis, the protections Congress promised to patients have significantly eroded, exacerbated by the tri-agency guidance issued on June 23, 2020<sup>1</sup>. As such, we were pleased to see the Biden Administration's national testing strategy and executive orders recognize the need to clarify health insurers' responsibilities to cover and pay for COVID-19 testing. We write to support President Biden's directive to federal agencies to clarify insurers' obligation to cover COVID-19 testing to detect the virus that causes SARS-CoV-2 or diagnose the disease, and to stress the urgency given that our laboratory members continue to see health plans deny claims for COVID-19 testing. 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.

This ongoing uncertainty in testing coverage undermines our collective efforts to get Americans back to work and school. Ensuring that testing is available to all Americans is a critical part of the overall public health response, and for groups like teachers, students, employees of nursing homes and restaurants, and others, testing will help reopen our nation. These groups need certainty that their tests will be covered. We recognize the

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<sup>1</sup> *FAQs About Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation, Part 43*, June 23, 2020, <https://www.cms.gov/files/document/FFCRA-Part-43-FAQs.pdf>.

number of issues on the new Administration's agenda, and we urge early action on closing testing coverage loopholes so that all Americans can access the COVID-19 testing they need without hesitation and worry.

For the many uninsured Americans, we also support adequate funding of the uninsured test fund, originally established by the *Families First Act*. The fund, administered by the Health Resources & Services Administration (HRSA), has successfully reimbursed for the cost of COVID testing for uninsured Americans since the fund's inception. The success was a critical step in helping to address health disparities in the COVID-19 response and supporting access to testing for all individuals, regardless of insurance status. As of February 17, 2021, the HHS COVID-19 Funding webpage reports that \$1.8 billion out of the total \$2 billion fund have been paid out to cover testing for uninsured individuals.<sup>2</sup>

With emerging SARS-CoV-2 variants continuing to spread across the country, we anticipate continued critical need for these funds. The exhaustion of the uninsured test fund will threaten access to testing for the most vulnerable at a critical time in our nation's COVID-19 response effort. We urge the Administration to use the Provider Relief Fund or transfer such appropriations to the Uninsured Test Fund, as needed, and as authorized through the administrative discretion granted by Congress. Paired with strengthening insurance coverage requirements for testing, robust replenishment of the uninsured test fund will fortify the pandemic response and protect the health of all Americans, regardless of insurance status.

Thank you for your leadership and commitment to addressing these unprecedented challenges. ACLA looks forward to partnering with the Biden Administration as we continue to expand access to accurate and reliable testing for the patients who are counting on us. We stand ready to serve as a resource to your team and welcome the opportunity to discuss these critical issues in further detail.

Sincerely,

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

Julie Khani, President  
American Clinical Laboratory Association

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<sup>2</sup> <https://taggs.hhs.gov/Coronavirus/Uninsured>