

September 1, 2021

Carole Johnson
COVID Response Team Testing Coordinator
The White House
1600 Pennsylvania Avenue, NW
Washington, DC 20500

Dear Ms. Johnson,

On behalf of leading diagnostics manufacturers and clinical laboratories, and the millions of patients we serve, thank you for your continued leadership during the COVID-19 pandemic. We write to express our ongoing and deep commitment to fully supporting our nation's COVID-19 response, and, as we face another critical juncture in the pandemic, urge increased attention to strong collaboration between the public and private sectors to meet our nation's testing needs.

AdvaMedDx, a Division of the Advanced Medical Technology Association (AdvaMed), represents over 75 companies that manufacture laboratory and point-of-care diagnostic tests and laboratory instrumentation used to run tests for the commercial market in the U.S. and abroad. The American Clinical Laboratory Association (ACLA) is the national trade association whose member laboratories perform clinical diagnostic tests to diagnose, screen and monitor a full range of medical conditions.

At every stage of the pandemic, testing has been critical, and the historic private sector response, in collaboration with the federal government, has driven innovation and expanded access to quality testing to screen and diagnose patients, direct care, guide the development of vaccines, improve our collective understanding of immunity, and track the genetic sequence of the virus as it changes.

In the earliest stages, lab-based molecular testing provided essential surge capacity for Centers for Disease Control and Prevention (CDC) and state and local public health labs, dramatically expanding our nation's testing capacity. ACLA members were among the first laboratories to validate and scale novel COVID-19 tests. Commercial manufacturers further fueled the unprecedented increase in laboratory testing, swiftly manufacturing tests at scale. Broad access to serology/antibody testing, followed by antigen tests then became available and innovations in highly flexible and rapid point-of-care testing, at-home specimen collection, and over-the-counter tests further increased access to testing.

Together the mobilization of ACLA and AdvaMedDx members has resulted in unprecedented increases in clinical testing. For example, ACLA members performed over 125 million tests through May of this year and continue to work around the clock to meet our nation's testing needs. AdvaMedDx members have driven the growth of molecular testing by 179% since the year prior to the pandemic, while facilitating the augmentation of automated, molecular laboratory instrumentation used to run tests by 82% since early 2020. Together our members have also delivered millions of serology/antibody, antigen, and T-cell tests throughout the country. Yet, more must be done.

Presently, the nation faces its most significant increase in new cases since the days prior to the broad availability of vaccines and testing remains an essential tool of our response. Driven by the Delta variant, the virus is surging among unvaccinated populations, and breakthrough infections are also occurring. As children return to their third school year impacted by COVID, businesses and workers

navigate workplace arrangements, and those in our most vulnerable communities continue to face a disproportionate impact from the virus, robust and meaningful planning and collaboration with the private sector, and clear and consistent communication to the public on the range of testing options is vital.

From the beginning of your Administration's Transition, each of our organizations has had the opportunity to individually and together meet with officials to offer recommendations for what is needed to enhance public-private collaboration, maintain, and enhance access to testing. We reiterate the following recommendations for what is needed today:

- Robust expansion of specimen collection/testing sites. The shift of testing sites to mass vaccination centers drove access to critically needed vaccinations. However, reopening sample collection/testing sites is necessary to leverage the laboratory capacity available to increase testing, particularly in the two dozen states with over ten percent positivity during this surge.
- Formalized and permanent forum for frequent, real time and meaningful communication and collaboration between the Administration and the diagnostics manufacturers and laboratories driving access to testing.
- Development and communication of forward looking policy and insurance of testing availability for whatever may come, based on pandemic modeling, to strategize how commercial labs and manufacturers can best support the nation's testing needs.
- Maintain and bolster testing capacity by fully leveraging mechanisms such as the Strategic National Stockpile and agreements with diagnostics manufacturers like vendor managed inventory and warm-base contracting. Ensure CDC directly contracts with high complexity laboratories to retain and reserve personnel, equipment, test supplies and facilities necessary to quickly bring new tests and substantial capacity online when called upon to respond to an emerging pathogen threat. Strengthening public-private preparedness collaboration with the CDC and private sector laboratories and diagnostics manufacturers is critical to ensure up to date diagnostics are available and rapidly deployed, and laboratory capacity is maintained.
- Comprehensive, consistent information to states about testing, emphasizing fully leveraging all high-quality molecular, antigen, serology, and T-cell tests across laboratory, point-of-care and over-the-counter modalities is necessary to extend the reach of testing. Strategies such as pooling should be utilized, as appropriate, and tools such as wastewater surveillance testing should be employed.
- Significantly augment and make public CDC's epidemiological studies using serology/antibody testing to understand the pervasiveness of the impact of COVID for all communities, while improving our collective understanding of correlative immunity as we prepare for broader administration of vaccine boosters.
- Allow states flexibility to modify testing plans, fully supported by American Rescue Plan funding as the need arises.
- Continued extension of public health emergency (PHE), allowing maintenance of reimbursement levels that have allowed labs to procure instrumentation and supplies, and maintain capacity.

AdvaMedDx and ACLA members remain fully committed to supporting our nation's response efforts. A strong public-private partnership in support of clear recognition of the critical role that testing has and will continue to have in the months ahead is essential to the most robust response.

Respectfully,



Susan Van Meter
Executive Director
AdvaMedDx



Julie Khani
President
ACLA

Cc: The Honorable Patty Murray
The Honorable Richard Burr
The Honorable Frank Pallone, Jr.
The Honorable Cathy McMorris Rodgers