April 29, 2020

American Clinical Laboratory Association

By Electronic Mail

Secretary Alex M. Azar II U.S. Department of Health & Human Services 200 Independence Avenue, S.W. Washington, D.C. 20201 Secretary@HHS.gov

Re: Allocate PHSSEF Funds to Support Laboratories and Help Americans Get Back to Work

Dear Secretary Azar:

Thank you for taking the time to speak with me earlier this week. Per your suggestion, I am following up with you to urge HHS to allocate the necessary resources for our nation's laboratories to increase COVID-19 testing capacity. The COVID-19 pandemic must be met with the full force of America's laboratory community, including public health labs, academic and hospital labs, regional and national commercial reference labs.

To date, ten ACLA member labs have answered the call to perform COVID-19 testing. As of this week, ACLA member labs, which have served as the backbone of America's testing response, have performed more than 3.3 million tests—a majority of the tests performed in the country—and they remain focused on continuing to increase COVID-19 testing capacity for both molecular and serologic tests. Further increases in testing capacity are needed at laboratories in order to meet the objectives described in the Administration's plan to reopen America.

As you know, Congress appropriated significant funds to support additional testing under the Paycheck Protection Program and Health Care Enhancement Act (PPPHCE Act), enacted just last week to support state efforts to contain the pandemic and reopen the economy. These funds were allocated to the Public Health and Social Services Emergency Fund (PHSSEF) that HHS administers and were intended to scale America's testing capacity to perform vital COVID-19 testing. It is essential that HHS allocate \$10 billion from the fund to support labs' further expansion of testing capacity to fulfill the testing needs of all of the states and to protect the lives and livelihood of all Americans.

ACLA commends HHS for its support of the \$25 billion allocated under the PPPHCE Act to enhance America's COVID-19 testing efforts. By investing \$10 billion of these funds in our country's laboratories, HHS can spur a rapid increase in the country's testing capacity and help get Americans back to work. In order to deliver accurate, reliable results for patients at a national scale, HHS must allocate funding to support the expanded efforts of our country's laboratories.

As you are well aware, public health officials are calling for a vast increase in the country's testing capacity in the coming months. Data from the *COVID Tracking Project* estimates the

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current U.S. testing capacity is approximately 1.5 million tests per week.¹ By some estimates, however, we will need to double the nation's weekly testing capacity, if not expand capacity even further.² ACLA member laboratories will lead the way in providing the necessary volume of accurate, widespread testing necessary to meet these goals.

Given the high cost of testing platforms, increasing supply costs, and the steep decreases in routine test volume in light of the COVID-19 pandemic, funds from the PHSSEF are essential for laboratories to scale capacity to meet these testing goals. By allocating \$10 billion in funds, HHS can support ACLA members and other laboratories in vastly increasing their testing capacity for both COVID-19 diagnostic and serologic tests, including the purchase and validation of additional platforms, training and hiring of additional workforce, supplies and components and PPE. Achieving this volume of testing will be crucial to ensuring widespread access to testing, protecting the public health, and jumpstarting the economy.

Further, HHS should note that investing in the nation's laboratories will not only enhance testing capacity in the short-term, but it also will allow the country to benefit from a robust testing infrastructure for the duration of the COVID-19 pandemic and beyond.

Congress and the Administration have brought considerable resources to bear to help slow the spread of COVID-19. Now, to ensure that the country can "reopen for business," the Administration must play the leading role in supporting increased capacity for testing. We would welcome the opportunity to work with you and your staff on identifying efficient funding mechanisms and facilitating this critical public health investment.

On behalf of ACLA, thank you for your ongoing efforts to ensure Americans can access the testing services they need to protect themselves and their families, and to get back to work. Please contact me at jkhani@acla.com with questions.

Sincerely,

Julie Khani President

¹ See "U.S. Historical Data", COVID Tracking Project, https://covidtracking.com/data/us-daily. (accessed Apr 29, 2020)

² See <u>Kates</u>, Jennifer; Michaud, Josh; Orgera, Kendal, Levitt, Larry, "What Testing Do We Need?", Kaiser Family Foundation, Apr 17, 2020. (summarizes multiple estimates, including an estimate by former FDA Commissioner, Scott Gottlieb, estimating a need of 3 million tests per week.)