U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30329-4027

July 29, 2020

Mark S. Birenbaum, Ph.D.
National Independent Laboratory Association
906 Olive Street, Suite 1200
St. Louis, Missouri 63101

Dear Dr. Birenbaum:

Thank you for your July 9, 2020, letter to the Secretary of Health and Human Services. I am responding on behalf of the Secretary. America's clinical laboratories have played an outsized role in America's response to the Coronavirus Disease 2019 (COVID-19) pandemic, scaling up laboratory testing in an unprecedented way and providing critical diagnostic and serologic testing capacity when the nation needed it most. These laboratories and their staff have been instrumental to the national response to this crisis, and we are grateful for their work and commitment.

Assuring a rapid and thorough public health response to the COVID-19 pandemic necessitates complete and comprehensive laboratory testing data, including standardized test results, relevant demographic details, and additional information that can improve both the public health response to SARS-CoV-2 and COVID-19. The June 4 HHS guidance, *COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act Section 18115* (www.hhs.gov/sites/default/files/covid-19-laboratory-data-reporting-guidance.pdf), seeks to standardize reporting to help ensure that public health officials have access to comprehensive and nearly real-time data to inform decision-making in their response to COVID-19. As the country begins to reopen, access to clear and accurate data is essential to communities for making decisions critical to a phased reopening.

I recognize that this is a challenging time for clinical laboratories. In addition to the massive increase in diagnostic testing for a novel pathogen, these laboratories have been asked to report detailed test result data to state and local health departments to comply with new federal requirements. These requirements, implemented as part of the *Coronavirus Aid, Relief, and Economic Security (CARES) Act* (www.congress.gov/bill/116th-congress/senate-bill/3548/text), are critical to inform the federal and state efforts to control and contain the virus. But I also recognize these requirements can be burdensome and present challenges for laboratories to implement.

Your letter outlined some of these challenges, and I want to assure you that you have a partner in the Centers for Disease Control and Prevention (CDC) to help work through the issues you identified. This includes improving our communication with health care providers about the information they should include when ordering a COVID-19 test. Since receipt of your letter, leaders from CDC's Division of Laboratory Systems and CDC's COVID-19 emergency response have reached out to you and your colleagues to begin working collaboratively toward solutions to the issues you identified. CDC is committed to an effective, trust-based working relationship with the National Independent Laboratory Association.

Thank you again for your partnership with CDC and work on this generation-defining public health crisis. Open communication and engagement between the public and private sectors are critical to an effective response, and I appreciate your outreach. Please follow up with Dr. Ren Salerno, PhD, Director, Division of Laboratory Systems, Center for Surveillance, Epidemiology, and Laboratory Services, at (404) 498-6516 or RSalerno@cdc.gov, Director, Division of Laboratory Systems, if you have any additional questions.

Sincerely,

Robert R. Redfield MD

Robert R. Redfield, MD
Director, CDC