



March 12, 2020

The Honorable Michael Pence
Vice President of the United States
The White House
1600 Pennsylvania Avenue, NW
Washington, DC 20500

Dear Vice President Pence:

We are the National Independent Laboratory Association (NILA) and the American Association of Bioanalysts (AAB).

Our members work in regional and community independent clinical laboratories across the United States performing clinical laboratory testing for physicians, hospitals, skilled nursing facilities (SNFs), and other health care professionals. A number of our member clinical laboratories who are providing, or are trying to provide, testing for COVID-19 are experiencing challenges in getting their laboratories set up to test for the new coronavirus.

We understand that you and your team are taking laboratory testing seriously as part of the response to COVID and understand you have already met with a subset of the laboratory industry. However, as the regional and community laboratories on the ground in many of the states that are hardest hit by this outbreak we would like the opportunity to offer additional suggestions for your consideration:

1. NILA and AAB laboratories operate in specific geographic regions. Our laboratories often run tests in the same state or region where specimens are collected. This on-the-ground infrastructure allows us to reduce turnaround times for test results. For example, one of our laboratories, a major laboratory in the northwest, is offering to courier specimens, free of charge, to state public health laboratories that are already approved and equipped to perform testing for COVID-19.
2. Many AAB and NILA member labs are in the process of setting up testing for COVID-19. However, CDC's EUA-approved testing kits for COVID-19 are only approved (and in some cases only work) on testing equipment from just two manufacturers (Applied BioSystems and Qiagen). If a lab does not have this specific equipment, it is costly to obtain and takes time for delivery, set-up, and calibration. We are requesting your help in speeding up this process and making it easier for small businesses to make this up-front investment.

3. CMS issued two billing codes for the COVID-19 tests, but did not specify the payment amount, leaving that decision to Medicare Administrative Contractors (MACs). If you are committed to ensuring patients have access to these tests, the Administration must issue a universal payment amount for all MACs—a payment amount sufficient to cover the costs for providing the COVID-19 tests.

Going forward, we urge you to include regional and community laboratories in your emergency planning. LabCorp and Quest are big laboratories, but they cannot adequately cover laboratory testing in all areas of the United States. Further, many of their specimens are transported by air to core testing facilities. This model has certain weaknesses—such as an airport or air travel shut-down as happened during 9/11. Most of our laboratories do not ship specimens by air and can provide supplemental and alternative testing capacity in states and regions that need them most. The Administration can help increase the nation's COVID-19 testing capacity by providing emergency funding and resources to ensure that our laboratories have the capacity needed, and are prepared, to offer the tests.

Sincerely yours,



Mark S. Birenbaum, Ph.D.
Executive Director

National Independent Laboratory Association (NILA)
American Association of Bioanalysts (AAB)