

August 11, 2020

The Honorable Alex Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, District of Columbia 20201

Dear Secretary Azar:

The undersigned organizations write to you regarding a matter of critical importance as we work to contain the widespread transmission of COVID-19 in the United States. We are increasingly concerned about the serious strains being placed on testing services for COVID-19, the impact those strains have on our ability to provide timely medical care to our patients, and ultimately on our ability to contain the spread of this dangerous virus. As the country continues to struggle to provide laboratories with a consistent supply of reagents, viral transport media, plastics (such as a pipette tips), and other items essential to providing both COVID-19 and non-COVID-19 testing, **we recommend that the Administration consider updating testing prioritization guidelines to ensure that the limited testing resources available are directed at those with a medically-indicated need for tests and those identified by well-defined public health surveillance efforts.** Updated guidelines are critical to manage the ever-increasing demand for COVID-19 testing, as it has been made clear that, despite the best efforts of many, no additional manufacturing capacity for many testing supplies is likely to be available through the remainder of this year. Updated guidelines will also allow physicians and laboratories to better manage the surging demand for non-medically indicated tests, as the current capacity will not be able to meet all demands.

As you know, the supply chain for testing supplies has been under tremendous strain from overwhelming global demand. Laboratories in hospitals and academic centers have been particularly hard hit by strains on the supply chain and have been unable to obtain a consistent supply of reagents, swabs, plastics, viral transport media, and other items that they require. The shortages have been particularly burdensome for laboratories in these settings as they are on the front lines of treating COVID-19 patients and must be able to appropriately triage incoming patients so as to best control the infection within those facilities. In addition to serious supply chain shortages, laboratories continue to struggle with access to personal protective equipment (PPE) and are in many places dealing with staffing issues that present additional challenges.

Constraints on available testing supplies, PPE, and staffing issues impacts not only COVID-19-related care in hospitals and academic centers but are also beginning to detrimentally impact non-COVID-19 care as well. As the healthcare system begins to perform procedures that have been delayed due to COVID-19, these laboratories are struggling to accommodate demand for pre-procedure COVID-19 testing, which further jeopardizes clinical care for millions of Americans. Supply chain issues are also impacting testing for other conditions that rely on the same supplies. Testing for other infectious diseases are at risk, and our colleagues report that many molecular tests are being delayed as they simply cannot all be offered while attempting to meet the demands for COVID-19 testing.

As significant surges in new COVID-19 cases create significant demand for new tests, we are also seeing an increase in demand for testing of asymptomatic individuals with no medically indicated need for

testing services. These include tests for employees going back to work, students returning to colleges and universities, and individuals wishing to engage in non-essential travel. Given that laboratories already face significant issues in providing access to medically indicated tests and timely return of results, we urge the Administration to consider the utility of new testing prioritization guidelines. Without improvement in available supplies, we simply do not have the resources to meet the huge demand for testing by asymptomatic individuals without exposure to COVID-19. **Therefore, we recommend that the Administration consider updating its testing prioritization guidelines to ensure that those with a medically-indicated need for COVID-19 diagnostic testing, such as those with COVID-19 symptoms, those with known exposures to COVID-19, and those in need of pre-procedure testing can have ready access to testing services and timely return of test results.** We also recognize the importance of testing as part of a public health surveillance and recommend that updated testing guidelines include a well-designed surveillance strategy that achieves public health goals while appropriately managing testing resources. Further, rapid screening tests, designed to be administered at home or at the point of care, could play a significant role in asymptomatic screening and surveillance efforts, as well as re-opening efforts, without placing additional strain on the polymerase chain reaction (PCR) diagnostic test market indicated for those with a medical need for a PCR test. We strongly recommend the Administration prioritize support for development of these tools.

During critical public health emergencies, where a rapidly spreading novel pathogen presents a significant risk to the health and wellbeing of those infected, limited testing resources must first be directed towards those who need them most—those at immediate risk of infection and serious illness. Outside of necessary public health surveillance strategies, limited resources should not be utilized by those with no symptoms or known exposure and whose needs could be equally served by following quarantine measures. Without adequate testing capacity to rapidly serve those with a medically indicated need for testing, we risk continued widespread transmission of this disease. We also threaten the ability of healthcare facilities to continue to offer critical medical services to those in need of care.

We remain hopeful that the United States will soon be able to bolster manufacturing to meet the needs of everyone desiring a COVID-19 test. However, until manufacturing can meet our unprecedented demand for testing services, it is critical that we prioritize our testing resources where they are needed most. We look forward to continuing to work with you on this critical issue and to help ensure access to essential testing services. Please do not hesitate to contact Shannon Curtis, American Medical Association Assistant Director of Federal Affairs (Shannon.Curtis@ama-assn.org) with any questions or to further discuss appropriate testing guidelines.

Sincerely,

American Medical Association
American College of Medical Genetics and Genomics
American Society for Clinical Pathology
Association for Molecular Pathology
Association of Pathology Chairs
College of American Pathologists
Infectious Diseases Society of America