AMA
AMERICAN MEDICAL ASSOCIATION

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April 27, 2020

The Honorable Admiral Brett P. Giroir, MD
Assistant Secretary for Health
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Admiral Giroir:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am writing to thank you for your tireless efforts to ensure laboratory testing services used to diagnose COVID-19 are available across the country. We appreciate your work and your collaboration during this unprecedented time. However, the AMA continues to have concerns about the current state of diagnostic testing for SARS-CoV-2 in certain settings, access to testing components in supply, and ensuring laboratories are adequately resourced including in preparation for any potential resurgence of COVID-19 this fall. We also have growing concern about the performance of many currently available serological tests, as well as their use by individual members of the general public to help inform personal physical distancing decisions.

In order to ensure access to diagnostic testing services is readily available to all who need it and to ensure laboratories are adequately resourced to handle the persistent and intense demands placed on them by the COVID-19 pandemic, the AMA has the following recommendations:

Pursue National Strategy for Testing During the COVID-19 Pandemic

While we appreciate your work and that of the taskforce to help procure testing components in short supply and ensure hard-hit areas are resourced in the best possible manner, the AMA recommends stronger federal leadership on this critical issue. Laboratories around the country, particularly those in hospital and academic settings, are still struggling to provide ready access to testing services for their patients, in large part due to inconsistent and constrained availability of critical testing components. While we understand the challenge in procuring these items due to the overwhelming global demand, more can be done on the federal level to provide clarity to non-commercial labs about the current status of the supply chain, transparency around federal actions to procure and distribute testing supplies, and information about where labs can reliably secure available supplies. Further, **the AMA believes there is additional opportunity to provide greater clarity and transparency around existing testing capacity and where that capacity is located to help states best manage local and regional resources, as well as provide strong federal guidance on how best to do so.**

As we anticipate that the threat of COVID-19 may persist into the fall, the coming months represent a critical time for federal leadership to help ensure states are adequately resourced and prepared with critical strategies to manage what may be increased demand for testing services. The current outbreak has taught us what can occur if adequate diagnostic testing is not available in the early stages of a rapidly

emerging and serious public health threat. We need continued focus on preparation to ensure widespread access to critical diagnostic testing services is available to meet both current needs and future needs for any potential surge in cases coinciding with the next influenza season. Federal guidance and leadership as we move through new phases of this global pandemic will be critical to the rapid identification and management of new cases as we work together to eliminate this global threat.

Receive Consultation from All Sectors of the Laboratory Community, Including Hospital, Academic, and Community Laboratories

Laboratories in all settings have played and will continue to play a vital role in the diagnosis and management of patients with COVID-19. Critically important to the fight against this insidious disease are laboratories in academic and other hospital settings. While patients with mild to moderate symptoms may be able to wait a few days for test results, rapid diagnosis of patients with COVID-19 in the hospital setting is essential to inform triage decisions and patient placement once admitted. However, these labs have informed the AMA of significant challenges in securing adequate testing supplies and have experienced requisition of ordered supplies by the federal government, with little explanation as to where or why those supplies are being diverted. In order to ensure our nation's hospitals have the tools they need to fight this pandemic, it is critical that the Administration understand the significant challenges they are facing and work closely with them to mitigate these challenges as best possible. **The AMA therefore strongly recommends the Administration receive regular input from members of the hospital and academic laboratory community, which the AMA would be pleased to help facilitate.**

Ensure Laboratories Are Adequately Resourced to Meet Ongoing Demand

While the AMA understands the significant and persistent testing component supply chain issues we are currently facing, we must do our best to ensure our laboratories are adequately resourced. Adequate resources include not only components of the test itself, but also adequate personal protective equipment (PPE) for laboratory workers and a robust laboratory workforce. For testing components, we support any action by the Administration to invoke the Defense Production Act to ensure consistent supplies of test kits, reagents, transport media, and swabs, where appropriate. **We strongly encourage the Administration to also consider what actions can be taken to bolster the supplies of PPE and ensure a strong laboratory workforce is in place to perform these critical services.**

Provide Additional Guidance and Education to Physicians and the Public Regarding Serological Testing

The AMA recommends that the Administration provide physicians and the general public additional guidance and educational materials around the use of serological testing to detect the presence of antibodies for SARS-CoV-2. The AMA has growing concern over the performance of many of these tests currently coming to market. Additionally, serological testing for SARS-CoV-2 antibodies currently has a number of limitations, including the possibility of false positive results due to cross-reactivity with other coronaviruses as well as potential errors in interpretation of a positive result in areas of low disease prevalence. We are growing increasingly concerned that, without proper guidance, physicians and members of the general public could consider results of these tests to be actionable on an individual level, potentially resulting in individuals making decisions to limit physical distancing on the basis of the results. While serological testing shows much promise in helping determine disease prevalence in a community, until more is known about the performance of these tests and there is evidence to suggest conveyance of immunity to COVID-19 with the presence of antibodies, **the AMA**

recommends that these tests be limited to use in epidemiological/population-level study or by physicians and laboratorians trained in interpretation of serological tests and with a strong understanding of the limitations of the results. At this time, the AMA does not recommend individuals pursue serology testing to make personal decisions on physical distancing or to attempt to determine immunity to COVID-19. **The AMA strongly recommends that the Administration issue further guidance to physicians and the public about the performance and limitations of these tests, including the risks for false positives.** The AMA would be happy to help amplify such guidance to labs, patients, and physicians.

We again thank you for your efforts to ensure access to SARS-CoV-2 diagnostic testing in the face of many persistent challenges. We look forward to continuing to work with you to implement our recommendations to ensure all sectors of the laboratory community are adequately resourced and prepared to meet the continued high demand for diagnostic testing services and to ensure tests offered to the public are accurate and used appropriately. For any questions or to discuss further, please contact Shannon Curtis, Assistant Director of Federal Affairs, at Shannon.Curtis@ama-assn.org

Sincerely,

James L. Madara, MD