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April 13, 2020

The Honorable Deborah Birx, M.D.
Coronavirus Task Force Coordinator
The White House
1600 Pennsylvania Avenue, NW
Washington, DC 20500

Dear Ambassador Birx:

On behalf of the Association of American Medical Colleges (AAMC), I write to thank you for engaging the academic medicine community in discussions related to the capacity for testing for the SARS-CoV-2 virus, the cause of Coronavirus Disease 2019 (COVID-19) and to request the federal government's assistance in helping labs across the country reach our mutual goal of maximizing diagnostic testing. As you and the other members of the White House Coronavirus Task Force are aware, our member medical schools and teaching hospitals remain at the front lines of this crisis, employing health care providers across the nation, developing and deploying SARS-CoV-2 tests, providing cutting edge care to the sickest COVID-19 patients, continuing research to understand the biology of the virus and the spread of the disease, and working to develop new treatments and vaccine candidates.

The AAMC is a not-for-profit association dedicated to transforming health care through innovative medical education, cutting-edge patient care, and groundbreaking medical research. Its members are all 155 accredited U.S. medical schools; nearly 400 major teaching hospitals and health systems, including 51 Department of Veterans Affairs medical centers; and more than 80 academic societies. Through these institutions and organizations, the AAMC serves the leaders of America's medical schools and teaching hospitals and their more than 173,000 full-time faculty members, 89,000 medical students, 129,000 resident physicians, and more than 60,000 graduate students and postdoctoral researchers in the biomedical sciences.

AAMC member institutions have extensive experience in developing and performing diagnostic tests and have been at the forefront of creating and validating new SARS-CoV-2 tests. We recognize, as you do, the need to substantially increase testing of both symptomatic and asymptomatic individuals. They have expended considerable resources of their own in order to enhance their testing capacity. Once the peak hospitalizations begin to abate as the result of strict mitigation efforts in regions of the country, the need for efficient and effective testing procedures will only increase. Without sufficient testing capacity, we cannot know which patients and communities are most at risk, where the virus is spreading, which first responders and health care providers have become infected, and when it is advisable to begin to adjust restrictions on movement and physical proximity. Our members are particularly sensitive to this need given their disproportionate role in diagnosing and treating potential and confirmed COVID-19 patients.

We appreciate the actions the FDA has taken in the last month to reduce regulatory barriers to developing, validating, and deploying SARS-CoV-2 tests. We have also been pleased to see the continued issuance of Emergency Use Authorizations (EUAs) for tests developed by commercial labs that are designed to run on existing machines. The promise of these tests is that labs that already own the relevant machines can start running the tests quickly, *provided that* the machines are in working order and that the labs have the proper reagents, transport media, and specialized equipment for the specific test; adequate training of technicians to run the complex test; and sufficient swabs and personal protective equipment (PPE) for collecting the specimens without endangering the health of the health care provider. As we have come to learn over the past several weeks, despite the best efforts of all parties, **not one of these components is readily available in sufficient quantities to each and every lab that needs them.** Widespread but uneven shortages in one or more of the essential components for testing have resulted in a situation where few labs are able to maximize the testing capacity of any one machine, platform, or test.

We appreciate your outreach to the directors of laboratories and hospital CEOs at institutions that own the Abbott m2000 platform to ascertain why there were fewer tests being conducted than the number of existing m2000 machines and distributed reagent cartridges would have predicted, as you noted in the White House briefing on April 8th.

As the lab directors and CEOs described in these two calls, laboratories across the country are working day and night to expand testing capacity but are severely hampered by shortages of needed reagents, swabs for testing, PPE, and specialized equipment designed by companies to be used with their own machines. The inability to secure adequate quantities of any of these components will result in lower testing capacity. The absence of certain components could result in testing machines sitting unused. Notably, the nature of the challenges faced by any one lab may differ from issues slowing testing at a different lab, and may be affected by geographic location, prior relationships with commercial vendors, type or setting of the lab (whether independent, state-run, or academic). In some cases, we have heard that labs trying to purchase parts, reagents, or test cartridges for use with their existing machines have been told that either the federal government or other laboratories have been given higher priority and that no such purchases can be made.

While the calls which you convened on April 8 and 9 were focused on the testing capacity specifically of the SARS-CoV-2 tests run on the Abbott m2000 system, we wish to bring to your attention that the same challenges are present for any single test granted an EUA, whether from a commercial vendor or developed and validated within an independent or academic laboratory. While collection swabs can be used across tests, because each test requires its own specific reagents, many labs have worked to diversify the platforms they are running so that a shortage in one set of reagents will not halt testing entirely.

What we have heard from institutions across the country is that all labs are working to maximize their ability to increase SARS-Cov-2 testing. Rather than allowing machines to sit idle while more

testing is required, we hear a constant cry to remedy the various shortages that leave individuals untested and our member institutions at a loss to improve the situation on a lab-by-lab basis.

The federal government can help remedy these challenges by taking a more definitive role in understanding and managing the SARS-CoV-2 testing environment so that we can best understand and respond to this crippling pandemic. The AAMC recommends that the Coronavirus Taskforce, working with the Department of Health and Human Services (HHS), Federal Emergency Management Agency (FEMA), and the state public health departments, take the following actions:

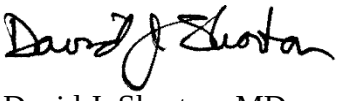
- **Move quickly to deploy a web portal that would allow all laboratories to easily report reagent or other supply shortages that are slowing or preventing testing from occurring.** Lab directors have indicated that there is no central system where the shortages faced by one lab can be assessed, leaving labs to fend for themselves, trying to leverage existing vendor, state government, or federal relationships. This portal should be an optional reporting and search tool that would both collect and demonstrate areas of need for specific supplies. Labs and vendors should be encouraged to enter and update shortages that could be addressed through directed supply chain management.

- **Take a clearer role in the assessment and management of the supply chain for key testing reagents and supplies.** To maximize testing capacity, working machines must be aligned with test reagents, supplies, and need, based on the best scientific and medical evidence of hotspots or other areas that have insufficient testing.

- **Implement a transparent communication system to inform vendors and labs about the priorities, directions, and specific needs of the community.** To the extent that commercial vendors are being directed or permitted to provide reagents, testing machines, or testing supplies to some labs preferentially over others, this information should be readily available to both commercial partners and all labs. This will allow lab directors and other institutional representatives to focus their time and resources on obtaining the platforms and supplies that are most readily available to them.

Again, the AAMC appreciates the magnitude of the problem that the Coronavirus Taskforce is facing against COVID-19 and is committed to continuing to partner with you in this response. Should you have any additional questions, please do not hesitate to contact me directly or AAMC Chief Scientific Officer Ross McKinney, MD (rmckinney@aamc.org).

Sincerely,



David J. Skorton, MD
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