March 3, 2020

Alex M. Azar II, MD
Secretary
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: *Policy for Diagnostics Testing in Laboratories Certified to Perform High Complexity Testing under CLIA prior to Emergency Use Authorization for Coronavirus Disease-2019 during the Public Health Emergency (FDA-2020-D-0987)*

Dear Secretary Azar:

On behalf of the American Society for Clinical Pathology (ASCP), I am writing to provide our strong support and appreciation for your leadership in response to the Coronavirus Disease-2019 (COVID-19) outbreak. Declaring a public health emergency and helping to expand the capacity of our nation's clinical laboratories to test for and diagnose patients suspected of having the SARS-CoV-2 virus is key to dealing with this public health challenge.

ASCP greatly appreciates the efforts of the U.S. Department of Health and Human Services (HHS), the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) and their staff to combat the spread of this coronavirus. While the United States is fortunate to have an outstanding network of public health laboratories, the SARS-CoV-2 virus has the potential to overwhelm the capabilities of this diagnostic network to test patient samples in a timely fashion. To effectively respond to COVID-19, rapid detection of cases and contacts as well as appropriate clinical management and infection control and implementation of community mitigation efforts are critical.

ASCP strongly supports the recently announced emergency use authorization (EUA) as well as FDA's recent policy guidance to accelerate the ability of clinical laboratories that are authorized to perform high complexity testing to develop and use their own molecular diagnostics. The FDA's recent policy will allow laboratories authorized to perform high-complexity testing under CLIA to develop and use their own validated molecular diagnostics pursuant to the recent EUA. Once a test has been successfully validated, the developing laboratory will have 15 days to submit a EUA submission to FDA. This will greatly expand the capacity of our nation's clinical laboratories to provide diagnostic testing for the SARS-CoV-2 virus, which we believe will help expedite the detection of this virus and its containment.

In addition, ASCP wants you to know that we strongly support the recent appointment of Ambassador Deborah Birx, MD, by Vice President Michael Pence, as the White House Coronavirus Response Coordinator and as a member of the White House Coronavirus Task Force. Ambassador Birx is a world-renowned medical expert and leader in the field of HIV/AIDS. Her three-decade-long career has focused on HIV/AIDS immunology, vaccine research, and global health. As the U.S. Global AIDS Coordinator,

Ambassador Birx has overseen the implementation of the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), the largest commitment by any nation to combat a single disease in history, as well as all U.S. Government engagement with the Global Fund to Fight AIDS, Tuberculosis and Malaria. Having worked with Dr. Birx on PEPFAR projects for several years, we are confident that she will be an outstanding White House Coronavirus Coordinator.

The ASCP is a 501(c)(3) nonprofit medical specialty society representing over 100,000 members. Our members are board certified pathologists (including medical examiners), other physicians, clinical scientists (PhDs), certified medical laboratory scientists/technologists and technicians, and educators. ASCP is one of the nation's largest medical specialty societies and is the world's largest organization representing the field of laboratory medicine and pathology. As the leading provider of continuing education for pathologists and medical laboratory personnel, ASCP enhances the quality of the profession through comprehensive educational programs, publications, and self-assessment materials.

On behalf of our members, many of whom provide diagnostic testing services in these clinical laboratories, we thank you for your leadership. Moreover, as a FDA-vetted member of the Agency's Network of Experts, we re-affirm our commitment to work with the Department, its individual agencies, and the White House in any manner on which we can assist.

Sincerely,

Gene Siegal, MD, PhD, FASCP
President, ASCP

cc: Stephen Hahn, MD, Commissioner, FDA
Robert R. Redfield, MD, Director, CDC
Jeff Shuren, MD, JD, Director, Center for Devices and Radiological Health, FDA
Robert Kadlec, MD, Assistant Secretary for Preparedness and Response, HHS