AMERICAN SOCIETY FOR MICROBIOLOGY

April 21, 2020

The Honorable Stephen M. Hahn, MD
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Dear Commissioner Hahn:

On behalf of the American Society for Microbiology, which includes thousands of public health and clinical laboratory microbiologists, we appreciate the FDA's willingness to maintain an open dialogue with our leadership and members as the COVID-19 pandemic continues. As we look to the next phase of addressing the impact of the virus, ASM recognizes the need for widespread adoption of serology, or antibody testing to put our nation back on a path of public and economic health. In order to do that, antibody tests need to be accurate, reliable, and provide meaningful information.

With major health and economic policy decisions hanging in the balance as the U.S. seeks to get a handle on the effects of the COVID-19 pandemic, it is imperative that these tests are effective and conducted in a way that ensures both reliability and accuracy.

We urge FDA to clarify its current guidance that serology tests that have not received Emergency Use Authorization (EUA) must be conducted in CLIA or CAP-certified high complexity labs. This policy ensures that appropriate validation has been done before testing begins.

We are concerned that uncertainty around the current guidance may result in non-EUA tests being performed outside these tightly controlled environments. FDA must use its oversight authority to prevent unauthorized testing from taking place.

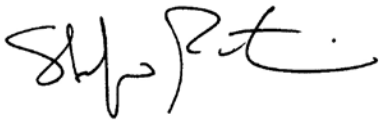
In March, we acknowledged the steps you took to streamline the regulatory process to enable the pursuit of antibody tests given they can inform doctors and public health officials about a person's exposure to and potential immunity to the virus. We support the FDA's current position that the only tests allowed to *voluntarily* submit to the EUA process are those that are to be conducted in CLIA-certified or CAP-certified high complexity laboratories. We appreciate FDA's recognition that testing in these settings is overseen by highly trained, board-certified doctoral-level directors of clinical laboratories that follow strict procedures for validating tests for accuracy and reliability before offering them to patients and/or the public.

We also appreciate the invitation for our members to share validation information with the FDA as they bring these tests online in their labs, and we encourage FDA to provide validation information conducted in federal agency-led post-market reviews back to the

clinical microbiologists. Having a two-way communication channel will allow a more rapid exchange of valuable information and allow all parties to work more efficiently and effectively. Any system devised by the FDA for collecting this data from our members should allow for confidentiality and if possible, anonymity.

We recognize that this continues to be a complex and evolving situation. ASM looks forward to working with you to ensure millions of Americans will have greater access to antibody tests at this critical juncture in the pandemic, and that these tests are accurate and reliable. We appreciate your consideration of our concerns, and if we can be of further assistance, please contact Allen Segal, ASM Director of Public Policy and Advocacy, at asegal@asmusa.org or 202-942-9294.

Sincerely,



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