AMERICAN SOCIETY FOR MICROBIOLOGY

February 28, 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 (ASM), we are writing to express concerns about the effects that current regulations under the FDA Emergency Use Authorization (EUA) are having on the use of diagnostic tests by clinical laboratories. Specifically, under the current EUA in place as a result of the COVID-19 outbreak, laboratory developed tests (LDTs) created outside the CDC and public health labs may not be performed in clinical settings.

We respectfully ask that you consider adjustments to the regulations to allow clinical laboratories to have access to the test assay from CDC **in addition to** the public health laboratories. Clinical laboratories follow a rigorous process for validation and implementation of laboratory-developed tests. If this pathway was considered during an outbreak, it would allow for a more rapid response to implementation of diagnostic testing. Many clinical laboratories have already validated high-complexity LDTs for SARS-CoV-2 and could begin testing tomorrow, but cannot do so due to the FDA EUA process. Testing is overseen by board-certified doctoral-level directors of clinical laboratories that are routinely inspected and certified to perform CLIA high-complexity testing. While we appreciate that the intent of the EUA is to safeguard the public and ensure tests are safe and effective early in outbreaks, the EUA process is proving a hindrance to rapid identification of potential COVID-19 infections. If we have tests that are safe and effective that cannot be used, this can put people at risk.

The regulatory process under the EUA is significantly more stringent than that required for other viral tests in CLIA-certified clinical laboratories. The current CDC test for COVID-19 remains the only test available with EUA status, and it has not been made available to hospital laboratories. This creates undue pressure on both the CDC and state public health labs to rapidly scale manufacturing and clinical testing. As a result, turnaround time may slow, which will present significant challenges should the number of infected individuals, or suspected infections, dramatically increase here in the United States.

Because COVID19 poses a major threat to the public health of the United States, diagnostic testing for the virus causing COVID19 (SARS-CoV-2) is an essential component of our nation's response to the current outbreak. In this situation, rapid identification of cases is critical. This is due to several factors, including the need to make appropriate patient management decisions and the need to curb further spread of the disease. The widespread availability of diagnostic testing enables rapid identification of infected individuals so they can be quickly isolated to prevent onward transmission of the virus and protect healthcare personnel. Furthermore, when patient is considered a "suspect" COVID-19 case, the healthcare providers and laboratories often manage the case differently than they normally would. This could include deferring or not performing certain procedures, which would have normally been done to diagnose, treat, or stabilize a patient. This alteration of the normal protocol is done to keep healthcare

and laboratory staff safe, and to help prevent the spread of disease. However, it can have a negative impact on the patient's outcome.

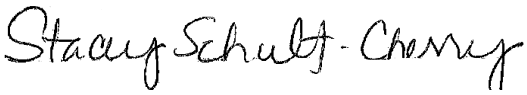
ASM's membership includes clinical microbiologists working in all laboratory settings, from community hospitals, to academic medical centers, to public health labs, all of whom are on the front lines in addressing COVID-19 and other infectious diseases at the point of care. We recognize that this is a complex, rapidly evolving situation. While we believe the policies are well-intentioned, the regulations are creating significant barriers to patient care at this time.

We appreciate your consideration of our concerns, and we look forward to working with you to address these challenges with an eye toward the long-term, including considering what legislative changes may be necessary to improve our response to a future outbreak. 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,

Robin Patel, MD
President

Stefano Bertuzzi, PhD
Chief Executive Officer



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