

April 14, 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), one of the largest life science societies whose membership includes thousands of public health and clinical laboratory microbiologists, we thank you and your staff for the ongoing willingness to engage with our leadership and members in an open dialogue about challenges associated with diagnostic testing for COVID-19. As this pandemic has unfolded, FDA has implemented unprecedented policy changes in an effort to boost laboratory testing capacity and availability of SARS-COV-2 tests diagnostic tests. We also appreciate that you continue to consider regulatory actions to further assist clinical microbiologists and clinical labs around the country that are essential to the response to COVID-19.

As we move into the next phase of the pandemic, we urge stronger oversight and evaluation of the serology tests coming to market. This starts with the need to ensure the accuracy of the tests themselves. But it also includes efforts to ensure the availability of test kits and test supplies as well as their delivery in a timely manner. Absent such assurances, we risk a repeat of the same challenges with diagnostic viral tests we have experienced to this point.

The need for antibody tests to be accurate and reliable, and to provide meaningful information, cannot be overstated. Specifically, we urge FDA to do the following:

- Revise current policy to increase oversight of these tests to ensure they provide consistent and accurate results.
- Require companies marketing the tests to make validation data available to clinical laboratories.
- Provide more detailed and definitive guidance for when serologic testing *is* and *is not* useful.
- Provide appropriate serologic test utilization strategies to public health and clinical entities to ensure sufficient supplies are produced and distributed.

Antibody tests are fundamentally different from viral RNA testing. Whereas ASM advocated for greater regulatory flexibility for lab developed viral RNA testing, that request came in the context of tests being conducted in high complexity CLIA labs. Such an environment provides a level of reliability that may not be available for an antibody test being conducted outside such a regulated environment.

We appreciate the FDA's efforts in March 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 immunity to the virus. Now that antibody tests are becoming more readily available and without an EUA from the agency, it is imperative that the FDA re-evaluate its oversight of these tests. This includes particular attention to direct-to-consumer test kits that have the potential to mislead the public and provide a false sense of security.

It also is critical that companies make the test validation data available to clinical laboratories so as myriad options become available from multiple vendors, our members in these labs can make informed decisions about which tests to perform. With more than 70 companies notifying FDA of their intent to market antibody tests that are largely unregulated, there is the potential for confusion that will ultimately slow the path to recovery.

Real-time, evidence-based guidance on what these tests can and cannot tell us is needed to ensure that we appropriately use them to identify those who have been exposed to the virus, and discern who may have sufficient immunity to return to work and avoid reinfection. These steps are paramount to getting a handle on the potential trajectory of COVID-19 and restarting the U.S. economy.

We recognize that this continues to be a complex and evolving situation. While we believe the policies are well-intentioned, the guidance in place currently for antibody tests is insufficient to ensure that the tests on the market are accurate and reliable. For our members in labs that are near the point of patient care, this creates significant confusion over which product to use. Our members also continue to have serious concerns about the ability of commercial manufacturers to maintain the necessary supply of antibody test kits that will be needed, given the significant challenges they have faced with supplies for RNA diagnostic tests.

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,

A handwritten signature in black ink, appearing to read 'Stefano Bertuzzi'.

Stefano Bertuzzi, PhD
Chief Executive Officer, ASM

Cc: Dr. Jeff Shuren
Dr. Tim Stenzel