AMERICAN SOCIETY FOR MICROBIOLOGY

May 4, 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 thank the FDA for clarifying its current online guidance that serology tests for SARS-CoV-2 that have not received Emergency Use Authorization (EUA) must be conducted in CLIA or CAP-certified high complexity labs. This policy helps ensure quality testing of serologic testing for SARS-CoV-2 in the United States.

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- 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.

Our leadership appreciates the ongoing, open dialogue you and your staff have had with us since the pandemic began. As we look to the next phase of addressing the impact of the virus, which includes widespread adoption of antibody testing, ASM urges you to do everything you can to ensure that these tests are accurate, reliable, and provide meaningful information; and prevent unauthorized testing.

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.

Sincerely,

Robin Patel, MD
President

Stefano Bertuzzi, PhD
Chief Executive Officer

Melissa Miller, PhD
Chair, ASM Clinical and Public Health Microbiology Committee

Cc: Dr. Jeff Shuren
Dr. Tim Stenzel