

August 24, 2020

The Honorable Alex Azar
Secretary
Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Dear Secretary Azar:

In light of the department's recent announcement modifying the role of FDA oversight for SARS-CoV-2 laboratory-developed tests (LDTs), the American Society for Microbiology (ASM) respectfully requests that you take action to ensure continued reimbursement for such tests conducted by CLIA-certified laboratories. ASM is a global society dedicated to the advancement of the microbial sciences and composed of 30,000 scientists and health practitioners. Thousands of ASM's members are on the front lines of the fight against SARS-COV-2, many of them work in, and direct, clinical microbiology laboratories and hospital laboratories around the country.

CLIA-certified laboratories are a critical partner in the public health emergency. Testing in these settings is overseen by highly trained, board-certified, doctoral-level professionals who follow strict procedures for validating tests for accuracy and reliability before offering them to the public. It is imperative that there is no gap in coverage for these tests, as the negative effects could be twofold: (1) some patients will lose access to tests because those available will be unaffordable; and, (2) it will cause additional financial harm to microbiology laboratories that already have experienced financial, among other, challenges during this pandemic.

We believe the authority for such a clarification is granted in the Coronavirus Aid, Recovery, and Economic Security (CARES) Act in section 3201, which requires coverage for all tests, including those with an EUA, those awaiting FDA approval, and those that are overseen by their individual state. Section 3201 also provides for coverage of tests "that the Secretary determines appropriate in guidance." It is critical that both HHS and the Center for Medicare and Medicaid Services (CMS) use the authority granted in the CARES Act to not only ensure coverage of tests that fall under the revised HHS policy guidance, but also see that these tests are reimbursed at a fair and adequate amount.

We look forward to continuing to work with the Administration to improve access to safe, accurate, and reliable testing during the public health emergency. For questions, please contact Allen Segal, ASM Director of Policy and Advocacy, at asegal@asmusa.org or 202-942-9294.

Sincerely,



Stefano Bertuzzi, PhD
Chief Executive Officer

cc: Seema Verma, Administrator, Centers for Medicare and Medicaid Services