

**Statement from the American Society for Microbiology
in response to the
Senate Health, Education, Labor and Pensions Committee Hearing:
“COVID-19: Safely Getting Back to Work and Back to School”
May 12, 2020**

On behalf of our 30,000 members in the United States and around the world, the American Society for Microbiology (ASM) thanks Chairman Lamar Alexander, Ranking Member Patty Murray, and members of the Senate Health, Education, Labor and Pensions (HELP) Committee for holding this hearing with federal health agency leaders to provide an update on the response to and efforts toward recovery from the COVID-19 pandemic. We appreciate steps taken by Congress in recent weeks to provide emergency funding for public health agencies, to supplement funding for research and development towards better diagnostics for SARS-CoV-2 and novel vaccines and treatments, and to enact provisions to address the needs faced by clinical laboratories, whether in public health departments or in hospitals and academic medical centers.

At this time, we offer the following specific points to the Committee:

- **It is essential that federal government officials consistently communicate science-based, accurate information in full and in a timely manner to continue to protect the public while coordinating an effective response and recovery.**
- **Persistent testing material shortages in clinical microbiology laboratories around the country must be addressed in a coordinated way and in a manner that allows labs to plan accordingly.** The federal government has an important role to play in addressing these challenges.
- **FDA must provide appropriate oversight and enforcement of diagnostic and antibody tests that come to market.** We thank FDA leadership for maintaining an open dialogue with ASM leadership and adapting its diagnostic and antibody testing policies and guidance as the pandemic has evolved. However, this situation brought to light current shortcomings of the EUA process and had the unintended consequence of erecting barriers to timely and accurate testing at the point of patient care. At the same time, the current crisis has highlighted challenges of balancing the need to foster innovation while ensuring oversight of newly developed serology tests.
- **A national COVID-19 vaccination plan must be developed to ensure that once an effective vaccine has been developed, we can rapidly scale up manufacturing and distribution of the vaccine.** We also know that it will do no good to have a vaccine if the public is unable or unwilling to be vaccinated. The need to educate and raise awareness with the public, as well as reduce barriers to vaccination, must be considered in advance and strategies and policies deployed at the right time.

ASM believes the following key principles are essential to a continued response to, and eventual recovery from, the COVID-19 pandemic.

- We need a national testing strategy and a national plan to study COVID-19 interfaces, its spread, and levels of exposure in communities to mitigate the current pandemic and better prepare our country for the next one. State and local plans are important components, but leadership and coordination needs to occur at the federal level.

- The federal government must continue to assist states and stakeholders to track, communicate, and help resolve laboratory testing supply issues. ASM and its members have been advising the White House Coronavirus Task Force on the needs of public health and clinical microbiology laboratories and around the country. These efforts point to the need for a large scale and coordinated system to connect the public, clinical, commercial, and industry sectors to ensure sufficiently robust supply lines, transparency about when and where shortages exist and for what materials, and cross-sector communication about supply levels, so that we can leverage the power of testing to reopen our economy. In order to carry out this important mission, clinical labs should have the supplies (e.g. reagents, swabs, buffers) and testing kits they need to meet the demands in their area. Laboratory clinicians should have access to personal protective equipment (PPE) due to the risk of exposure to infectious material.
- Broad access to accurate and reliable diagnostics and reporting of test results is fundamental to addressing the pandemic. Diagnostic testing is currently our strongest weapon in identifying the needs of patients and saving lives by limiting spread of the virus.¹ Testing and tracking of the virus are essential elements for fully reopening the U.S. economy. We cannot afford the human and economic cost of rationing diagnostics because of limited capacity.
- Antibody tests used to assess exposure to the virus and potential immunity must be accurate and reliable. ASM has called on FDA to provide strong oversight and enforcement of tests that do not meet this standard. Effective antibody testing is key to facilitating contact tracing, conducting surveillance at the local, regional and state levels, and identifying those who may be immune and thus be allowed to return to work or school.
- Clinical research to determine the utility of antibody tests must continue, as we do not know for certain whether individuals infected with SARS-CoV-2 who subsequently recover will be protected, either fully or partially, from future infection with SARS-CoV-2 or how long protective immunity may last. We also must take the current limitations into account when applying antibody test results in population-based, policy decision-making regarding reopening the economy.
- Robust funding for multiple public health agencies such as CDC, NIH, BARDA and FDA, and including funding for preparedness, response, laboratory capacity, surveillance and infrastructure, is required to meet the ongoing demands placed on the system by the pandemic.

ASM reiterates our commitment to assisting the Committee, its members, the Congress, the White House Coronavirus Task Force and the agencies as the U.S. continues to respond to the COVID-19 pandemic. More information from ASM on nCov2019: <https://asm.org/Press-Releases/2020/COVID-19-Resources>

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The American Society for Microbiology is one of the largest professional societies dedicated to the life sciences and is composed of 30,000 scientists and health practitioners. ASM's mission is to promote and advance the microbial sciences.

ASM advances the microbial sciences through conferences, publications, certifications and educational opportunities. It enhances laboratory capacity around the globe through training and resources. It provides a network for scientists in academia, industry and clinical settings. Additionally, ASM promotes a deeper understanding of the microbial sciences to diverse audiences.

¹ Patel, R et al. Report from the American Society for Microbiology COVID-19 International Summit, 23 March 2020: Value of Diagnostic Testing for SARS-CoV-2/COVID-19. *mBIO* 11: e00722-20