



ASSOCIATION FOR MOLECULAR PATHOLOGY

Education. Innovation & Improved Patient Care. Advocacy.

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Suzet McKinney, DrPH

Co-Chair, Forum on Medical and Public Health Preparedness for Disasters and Emergencies

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Washington, D.C., 20001

Richard Serino

Co-Chair, Forum on Medical and Public Health Preparedness for Disasters and Emergencies

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Delivered electronically to swollek@nas.edu

Dear Dr. McKinney and Mr. Serino,

On behalf of the Association for Molecular Pathology (AMP), thank you for coordinating and convening the workshop “Lessons from COVID-19 for the Public Health Emergency Enterprise: What Happened to the Plans”. AMP is an international medical and professional association representing approximately 2,600 physicians, doctoral scientists, and medical laboratory scientists (technologists) who perform or are involved with laboratory testing based on knowledge derived from molecular biology, genetics, and genomics. Membership includes professionals from the government, academic medicine, private and hospital-based clinical laboratories, and the in vitro diagnostics industry. Many of our members are molecular laboratory professionals who have been on the frontlines of responding to the COVID-19 pandemic by developing and providing molecular-based diagnostics for patients across the United States and are now gearing up to respond to the current monkeypox virus outbreak. Based on our members’ experiences over the last month, AMP is concerned that the limitations placed on usage of the authorized Orthopox test kit and the very narrow testing criteria are already resulting in undetected spread in our communities. It is critical it is that the same policy failures that were experienced during the COVID-19 pandemic are not repeated in this current monkeypox or any future infectious disease outbreak. We greatly appreciate your efforts to explore both the successes and failures throughout the COVID-19 public health emergency (PHE) to plan and respond to future catastrophic disasters and infectious disease outbreaks more effectively.

AMP is pleased that the forum addressed several important topics such as PHE preparedness capabilities, medical supply chain considerations, and public engagement. However, we would like to take this opportunity to emphasize that laboratory tests and the professionals who perform them are critically important for the PHE response efforts, and as you continue your study of this topic, we urge you to make testing, for both infectious disease surveillance and to diagnose disease, a central focus of future workshops. Academic and community molecular diagnostic laboratories, as well as public health and reference laboratories, have had and continue to have a valuable role in addressing infectious disease outbreaks. As such, in part to better inform policymaking efforts, we [surveyed our membership](#) multiple times over the course of 2020 and collected hundreds of

responses from molecular laboratory professionals to understand the successes and hurdles they experienced when providing the crucial and timely diagnostic services that patients needed during the COVID-19 pandemic¹.

One tremendous challenge at the beginning of the COVID-19 pandemic was a result of FDA's policy requiring emergency use authorization (EUA) for laboratory-developed testing procedures prior to using them clinically, which negatively affected the ability of clinical laboratories and developers to offer high quality SARS-CoV-2 molecular diagnostic tests and for the country to have enough capacity in diagnostics to adequately respond. As a result, the United States was without testing during the first few months of the PHE and in numerous instances, this country was unable to meet the surging clinical need for patient testing, especially as supply chain challenges began. Once the FDA provided more flexibility in its guidance, laboratories were able to quickly offer validated tests for clinical use and provide innovative solutions to respond to the disrupted supply chain (such as developing methods that allowed patients to collect their own specimens to circumvent the need for scarce PPE and validating the use of alternative testing components, materials, and specimens to address supply shortages). Additionally, clinical laboratories rapidly developed tests to ensure that the needs of their patients were met, such as tests with the ability to identify different variant strains and ensuring that testing in a geographic area was sensitive and specific for that particular region.

Our survey also identified that each sector of the laboratory testing system may not have been fully utilized to its best ability. We find that the diversity of laboratories in the United States is an enormous strength. Certified public health laboratories are essential to begin testing during an outbreak and conduct surveillance in non-emergent times. However, their limited testing capacity and lack of integration with the medical system make it difficult for those laboratories to have a significant clinical diagnostic role. Due to their direct physical proximity to patients, hospital laboratories and other local community clinical testing laboratories are optimally positioned on the frontlines during pandemics to meet testing capacity needs, and to provide appropriate turnaround times necessary to manage patients that need immediate care. Unfortunately, our 2020 surveys found that academic medical centers and community health laboratories were underutilized and deprioritized throughout the pandemic with regards to accessing limited testing supplies. This is not to discredit the advantages provided by commercial reference laboratories, which often are able to perform a great number of tests. All sectors of the clinical testing landscape need to be supported to ensure a complete laboratory response effort during a pandemic.

Overall, our findings highlight molecular based diagnostics as a critical tool in a PHE response. However, as these two examples highlight, there are areas that should be focused on to improve our capabilities. AMP humbly requests that laboratory testing be included in future conversations regarding pandemic preparedness. As a culmination of efforts to survey molecular professionals, we formulated numerous recommendations for improving response efforts.¹ We would be happy to further discuss these recommendations with the Forum on Medical and Public Health Preparedness for Disasters and Emergencies.

Thank you for your continued leadership and efforts to improve our nation's preparedness for, response to, and recovery from public health emergencies and disasters. Should you have any questions or wish to discuss these issues further, please don't hesitate to contact Sarah Thibault-Sennett at SThibaultSennett@amp.org.

Sincerely,

Daniel E. Sabath, MD PhD
President, Association for Molecular Pathology

¹ <https://www.amp.org/advocacy/sars-cov-2-survey/>