



ASSOCIATION FOR MOLECULAR PATHOLOGY
Providing global expertise in molecular testing that drives patient care
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March 27, 2023

The Honorable Bernard Sanders
Chair, Senate Committee on Health,
Education, Labor, and Pensions
332 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Bill Cassidy
Ranking Member, Senate Committee on
Health, Education, Labor, and Pensions
455 Dirksen Senate Office Building
Washington, DC 20510

Re: request for information on the Pandemic and All-Hazards Preparedness Act

Comments submitted electronically at PAHPA2023Comments@help.senate.gov

Dear Chairman Sanders and Ranking Member Cassidy,

On behalf of the Association for Molecular Pathology (AMP), thank you for the opportunity to provide these comments as you begin considering the reauthorization of the Pandemic and All-Hazards Preparedness Act (PAHPA). AMP is an international medical and professional association representing approximately 2,900 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.

Codify the Laboratory Response Network into Law and Include Clinical Laboratories

Throughout 2020, AMP [surveyed](#) our members to understand in real time their experience with responding to the COVID-19 pandemic, including how they built testing redundancy within their laboratories to not only address supply chain challenges, but to help meet the testing capacity needs of their local communities.¹ We found that the diversity of laboratories in the United States is an enormous strength. Of concern, our survey identified that each sector of the laboratory testing system may not have been fully utilized to respond to the pandemic. 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. Nonetheless, our 2020 surveys found that academic medical centers and community

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

health laboratories were underutilized and deprioritized throughout the pandemic with regard 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, but are frequently remote to the actual location of patients. All of the sectors of the clinical testing landscape need to be supported to ensure a complete laboratory response effort during a pandemic.

Created in 1999, the Laboratory Response Network coordinated by the Centers for Disease Control and Prevention (CDC) and the Association of Public Health Laboratories consists mainly of federal laboratories and state and local public health laboratories.² Its mission is to develop, maintain, and strengthen an integrated domestic and international network of laboratories to respond quickly to biological and chemical threats and other high-priority public health emergencies through training, rapid testing, timely notification, and secure messaging of laboratory results. To leverage the full clinical testing capacity of the US to respond to future pandemics, we strongly recommend that the PAHPA reauthorization bill include a provision that formally authorizes this program and also includes the participation of hospital-based and other clinical laboratories in the Laboratory Response Network.

Improve Processes for Supply Allocations and Laboratory Coordination

In its surveys, AMP also found that testing supply distribution was a significant limiting factor for providing diagnostic testing to the public, with over 80% of laboratories reporting that supply interruptions delayed or decreased their testing capacity during the pandemic. The types of supply chain interruptions that laboratories experienced were vast and included shortages of testing platforms, testing kits, reagents, swabs, viral transport medium, laboratory consumables, and personal protective equipment. Collection swabs were reported as being the most significant limitation across laboratories, especially early in the pandemic. Viral transport media was the second most problematic supply chain limitation. Moreover, we found that not all categories of laboratories were being supported with access to supplies to the same degree, regardless of their ability to contribute significantly to testing demands. AMP was alarmed by the lack of a coordinated approach to distributing testing supplies, as it hampered the ability to meet the testing demands observed in the United States. When laboratories made efforts to address shortages, approximately half of the laboratory professionals that participated in our COVID-19 survey reported that the federal government was a barrier. Thus, AMP urges you to ensure that for future pandemics, the legislation directs HHS to implement a national testing strategy that better coordinates supplies across laboratories.

In particular, we urge that a strategy is developed to be flexible enough to reprioritize supply allocations based on clinical testing needs, which could change over time. Depending on the rapidly shifting needs during a public health emergency, there may be a shift in testing methodology and related supplies. The demand for testing supplies designed for acute care, surveillance, high-throughput, and other clinical needs should be monitored widely to provide real-time feedback to agencies to support data-driven supply allocations. Ideally these monitoring systems would be proactively established, not require additional processes for laboratories, be rapidly activated following novel pathogen identification, and maintained throughout the course of response.

² <https://emergency.cdc.gov/lrn/>

Secondly, a national testing strategy should include real-time coordination amongst laboratories to leverage moments of excess capacity. Based on data regarding testing capacity and demand, there may be an opportunity to coordinate regionally to ensure that any excess test capacity is leveraged to ensure samples are processed as quickly as possible (e.g., a dashboard consisting of laboratories, manufacturers, and government representatives would allow real time supply chain understanding and help to prevent communication and resource bottlenecks).

Hazard Pay for Clinical Laboratory Professionals

We recommend that you include provisions that extend hazard pay provisions to the professionals working in clinical laboratories during future public health emergencies. The Department of Labor defines hazard pay as “additional pay for performing hazardous duty or work involving physical hardship. Work duty that causes extreme physical discomfort and distress which is not adequately alleviated by protective devices is deemed to impose a physical hardship.”³ During the COVID-19 pandemic, clinical laboratory professionals faced major challenges due to the shortage of personal protective equipment (PPE) and the danger of being exposed to COVID-19 during sample collection, transport, and processing. This high risk of exposure caused significant emotional hardship on these essential, frontline workers and was further compounded by staffing issues as technicians, scientists, and providers operated around the clock to provide timely COVID-19 test results to patients. For these reasons, we encourage you to include provisions to provide hazard pay to health professionals as well as their support staff, and that this provision is extended appropriately to include the full range of staff and providers within pathology and laboratory medicine.

Ensure that Regulatory Requirements for Clinical Laboratories Are Not Duplicative or Burdensome, Especially During a Pandemic

With the declaration of the public health emergency, FDA issued a policy requiring emergency use authorization (EUA) for laboratory-developed testing procedures (LDPs) prior to using them clinically. This regulatory barrier led to a dearth of clinical testing in the United States during the critical first few weeks of the pandemic, despite laboratories at academic medical centers throughout the country having tests validated and ready to deploy.⁴ Community spread of COVID-19 was rampant and our healthcare system had no diagnostic tools available to stem its spread in those early days due to this policy.⁵

The initial FDA policy 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 adequate capacity in diagnostics to adequately respond. As a result, the United States was without testing for the first few months of the PHE, and in numerous instances, this country was unable to meet the surging clinical need for patient testing which was compounded by the emerging supply chain challenges. After the FDA provided more flexibility in its guidance,⁶ laboratories were better able to quickly offer validated tests for clinical use and provide innovative solutions to respond to the disrupted supply chain (such

³ <https://www.dol.gov/general/topic/wages/hazardpay>

⁴ <https://www.gq.com/story/inside-americas-coronavirus-testing-crisis>

⁵ <https://www.nytimes.com/2020/03/10/us/coronavirus-testing-delays.html>

⁶ <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-new-policy-help-expedite-availability-diagnostics>

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 is sensitive and specific for that particular region.

However, even after the FDA modified its guidance in early spring 2020 to simplify the EUA process in an attempt to mitigate diagnostic shortages, approximately 35% of the laboratory professionals surveyed (both AMP members and non-members) noted that it took more than a month for their laboratory to receive an EUA.⁷ In response to AMP surveys, several individuals reported that their laboratory submitted their application and even after four months, had yet to receive authorization. One individual laboratory reported that the FDA did not respond to their application for six weeks. In fact, 32% of the respondents in one of our 2020 surveys said that they encountered hurdles in completing the EUA process. Laboratory professionals who participated in the survey noted FDA's lack of experience with certain kinds of technology, which combined with inefficiencies in the submission and review process, led to unnecessary delays in implementing tests for clinical care. AMP's survey revealed that the FDA's inability to efficiently and expertly review EUA submissions for SARS-CoV-2 tests delayed the ability of laboratories to offer testing during times when the country was struggling to meet testing demands. This not only delayed patient care but potentially compromised the ability to utilize contact tracing and other measures in the effort to stem the spread of COVID-19. Moreover, this additional regulatory review by FDA was unnecessary, as laboratories already adhere to the validation requirements in place under CLIA, third-party organizations, and certain states' regulations.

AMP believes it is imperative that FDA establish clear and consistent policy for IVD kit manufacturers to ensure that the United States can respond promptly to infectious disease outbreaks in the future. However, this policy should not apply to laboratory developed tests, which are professional medical services, and are already regulated by CMS. In order to provide laboratories with the flexibility to use LDPs in a public health emergency, LDPs should not be treated as medical devices or the same as manufactured and shipped test kits that require Emergency Use Authorizations (EUAs). Instead, AMP encourages you to make use of the successful regulatory system under Centers for Medicare and Medicaid Services developed in response to the CLIA, which oversees laboratory examinations and processes including LDPs.

Thank you for the opportunity to submit these recommendations as you consider the reauthorization of the PAHPA. If AMP may be of further assistance, please do not hesitate to contact Monika Franco, Policy Analyst, Public Policy & Advocacy at mfranco@amp.org.

Sincerely,
Laura J. Tafe, MD
President, Association for Molecular Pathology

⁷ <https://www.amp.org/advocacy/sars-cov-2-survey/>