



**ASSOCIATION FOR MOLECULAR PATHOLOGY**

*Education. Innovation & Improved Patient Care. Advocacy.*

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Mary Denigan-Macauley  
Director of Health Care  
Government Accountability Office  
441 G St., NW  
Washington, DC 20548

Re: GAO report on “COVID-19: FDA Took Steps to Help Make Tests Available; Policy for Future Public Health Emergencies Needed”

Delivered electronically

Dr. Denigan-Macauley:

On behalf of the Association for Molecular Pathology (AMP), thank you for the work of you and your colleagues to study and report on the impact of FDA policy on the COVID-19 pandemic. As an international medical and professional association, we represent 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, who have served at the frontlines of this pandemic working with other essential healthcare professionals. AMP took note of the recent report from the Government Accountability Office (GAO) on “COVID-19: FDA Took Steps to Help Make Tests Available; Policy for Future Public Health Emergencies Needed” and would like to take the opportunity to offer our perspective.

AMP members have developed, validated, and performed molecular testing for SARS-CoV-2 since the earliest days of the pandemic, and they will similarly serve a critical and valuable role in any future infectious disease outbreaks. Given the considerable expertise and experience of AMP members, our organization has continuously solicited and obtained qualitative and quantitative data from its members with the objectives of creating professional resources and informing policymaking. You will find that our comments below are informed by this work which includes two surveys of laboratory professionals in 2020 on many important aspects of SARS-CoV-2 molecular diagnostic testing. You can find the full findings from these surveys here: <https://www.amp.org/advocacy/sars-cov-2-survey/>

Our analysis found many Food and Drug Administration (FDA) regulatory actions and policies negatively affected the ability of laboratories and test developers to offer timely SARS-CoV-2 tests to meet needed clinical testing capacity throughout the pandemic. Under non-emergency circumstances, laboratories accredited by the Clinical Laboratory Improvement Amendments (CLIA) program under the Centers for Medicare and Medicaid Services (CMS) are authorized to develop, validate, and offer laboratory developed testing procedures (LDPs) as medical services for clinical care without notifying FDA or seeking review and approval/authorization by the agency. However, early in the pandemic, FDA made the decision to require laboratories to obtain an emergency use authorization (EUA) regardless of whether a test was boxed-and-shipped as an in vitro diagnostic test kit or a LDP. This drastic change in review requirements for laboratories using LDPs created a duplicative process that

ultimately became a barrier for professionals to implement testing services in the early days of the pandemic, greatly hampering the country's collective ability to stem the spread of SARS-CoV-2 in spring 2020 when the country was without testing for weeks. We are concerned that the report does not fully describe the purpose of the CLIA program or acknowledge that high-complexity laboratories are required to comply with stringent validation requirements as part of it.

Unfortunately, even after the FDA modified its guidance in early spring to simplify the EUA process in an attempt to mitigate testing delays, 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. Several individuals reported that their laboratory submitted their application and even after four months, had yet to receive authorization. One individual reported that FDA did not respond to their application for six weeks, and then when the agency finally did answer, staff asked questions that could have easily been answered up front. 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 implementing tests for clinical care. AMP's survey revealed that the FDA's inability to efficiently and expertly review EUA submissions for COVID-19 tests delayed the ability of laboratories to offer testing during times when the country was far below meeting test capacity needs. 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. Therefore, we agree that 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 medical services and regulated by CMS.

Further, we are deeply concerned by the Department of Health and Human Services' response to the GAO's recommendations indicating that they prefer that a smaller number of high capacity tests be authorized in future outbreaks. The benefits of robust and diverse testing in our response efforts were articulated by molecular professionals in 2021 after it became clear that the United States could be doing more to support the efforts of clinical laboratories.<sup>1</sup> Laboratory developed tests were instrumental in being able to overcome the many challenges that we confronted, and the authors state that an "overreliance on a small number of tests would continue to threaten laboratories' ability to conduct swift and accurate testing in unpredictable circumstances." For instance, diversity in testing allowed the United States to adapt rather than be crippled by missteps early on when only the test kit that was available proved to be faulty. Moreover, we found in our surveys that laboratory professionals simultaneously employed multiple SARS-CoV-2 testing methods, including those developed by their own laboratories, to address supply-chain disruptions and ensure that access to testing and patient care was maintained despite problems with procuring certain materials and components. Innovation that has led to alternative testing options has brought about methods that allow patients to collect their own specimens, thus circumventing the need for scarce PPE early in the pandemic. Further, laboratories validated use of saline instead of extremely limited viral transport media or used saliva as a specimen type to alleviate the swab shortage. Diversity in testing led to the ability to identify different viral strains, which has been critically important for understanding how the United States' responses should be adapted and evolve over time.

We are pleased that the laboratory community is involved in the efforts to detect monkeypox virus. In June, the Centers for Disease Control and Prevention published a Real-Time PCR test procedure to detect monkeypox

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<sup>1</sup> Konnick EQ, Laser J, Weck KE. The Role of Clinical Laboratories in Emerging Pathogens—Insights From the COVID-19 Pandemic. *JAMA Health Forum*. 2021;2(10):e213154. doi:10.1001/jamahealthforum.2021.3154

virus for any laboratories interested in developing a laboratory developed test. However, we are very concerned that the FDA is currently limiting the use of the CDC's authorized test kit to only five clinical laboratories. While this does expand the capacity beyond the public health laboratories' capabilities, it is still woefully short of the volume of testing services that will be needed if the outbreak continues to spread in the US. Restricting academic and small clinical laboratories from testing in combination with the very narrow testing criteria are exactly the same mistakes made in early 2020. It is extremely concerning to observe the same policy failures occurring once again, knowing that it likely means that the monkeypox virus is spreading undetected through our communities. We must continue to work to ensure that these lessons are not forgotten and that clinical laboratories are supported in their efforts to provide patient care.

As the GAO continues its work to aid federal departments and agencies in their pursuit to prepare better for infectious disease outbreaks, we urge you to factor in the considerations detailed above. Additionally, I hope you will consider AMP and its members as a resource for these critically important issues. If we can provide any assistance, please contact Sarah Thibault-Sennett, PhD, Director of Public Policy and Advocacy at [sthibaultsennett@amp.org](mailto:sthibaultsennett@amp.org).

Sincerely,

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