



**ASSOCIATION FOR MOLECULAR PATHOLOGY**  
*Providing global expertise in molecular testing that drives patient care*  
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October 19, 2020

The Honorable Richard Burr  
US Senate  
217 Russell Senate Office Building  
Washington, DC 20510

The Honorable Diana DeGette  
US House of Representatives  
2111 Rayburn House Office Building  
Washington, DC 20515

The Honorable Michael Bennet  
US Senate  
261 Russell Senate Office Building  
Washington, DC 20510

The Honorable Larry Bucshon  
US House of Representatives  
2313 Rayburn House Office Building  
Washington, DC 20515

Dear Senators Burr and Bennet and Representatives DeGette and Bucshon:

On behalf of the Association for Molecular Pathology (AMP), I would like to once again relay our appreciation for your dedication to modernizing the oversight of laboratory testing. It has come to AMP's attention that you are soliciting comments on the Verifying Accurate, Leading-edge IVCT Development (VALID) Act. Given the tremendous amount of information gleaned about the role of laboratory testing in our society during the COVID-19 pandemic, we believe that this is a prudent choice.

The public health emergency (PHE) revealed weaknesses in a laboratory testing regulatory system centered around the FDA, and our members witnessed this firsthand as they have served at the frontlines with other essential workers to provide care. Throughout the pandemic, our members have been providing SARS-CoV-2 RT-PCR, antibody, and antigen testing using a variety of platforms in a wide range of laboratory settings including commercial laboratories, academic medical center laboratories, community health laboratories, and more. Our members work in some of the earliest and hardest hit areas, such as Seattle and New York City, and can provide invaluable perspective on laboratory testing during the COVID-19 pandemic crisis.

We are disappointed that you did not reach out to AMP when soliciting comments on VALID. Over the past several years, our members have volunteered their time and expertise, using every opportunity to engage with you on this important topic, because they recognize it is their professional activities, services, and patients that would be significantly affected by your proposed framework. AMP maintains that it is critically important that the development of legislation that proposes to restructure the landscape of laboratory testing regulation should be done in a transparent and collaborative manner – one that involves all interested and impacted stakeholders, including those practicing in academic and community laboratories. We again urge you to engage all interested parties during your legislative development process.

We also write to share our recently released preliminary findings from the AMP August 2020 SARS-CoV-2 Diagnostic Testing Survey, as it is a valuable resource to better understand laboratory professionals' experiences during this pandemic and provides important data to consider as you work on legislation that will affect the ability of laboratory professionals to develop, validate, and offer testing procedures.<sup>1</sup> Throughout the pandemic, AMP has created a series of robust surveys that covered a range of topics related to molecular diagnostic testing for SARS-CoV-2, including how regulation by the Food and Drug Administration (FDA) has impacted laboratory activities. AMP found that once laboratories were able to develop SARS-CoV-2 tests, they responded rapidly. We invite you to explore all of our survey results. You can access the full survey results [here](#) or attend an upcoming town hall webinar on the survey that you can register for [here](#).

You likely recall that the declaration of the PHE effective January 31, 2020 required that all tests for SARS-CoV-2, regardless of whether they are boxed-and-shipped in vitro diagnostic test kits or laboratory developed testing procedures (LDPs), obtain emergency use authorization (EUA) from FDA prior to being used for clinical care. For molecular laboratory professionals designing and validating LDPs, this created duplicative and unnecessary regulatory requirements because, as you know, these services are part of medical practice and regulated under the Clinical Laboratory Improvement Amendments (CLIA). This drastic change in review requirements significantly slowed the ability of professionals to stand-up LDPs in the early days of the pandemic and greatly hampered the country's collective ability to stem the spread of SARS-CoV-2.

Unfortunately, even after the FDA drastically altered the EUA process after recognizing the testing delays, approximately 35% of the 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 more than four months ago and still had yet to receive an 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 said that they encountered hurdles in completing the EUA process. Laboratory professionals that participated in the survey noted FDA's lack of experience with certain kinds of technology, combined with inefficiencies in the submission and review process, compounded problems that led to unnecessary delays to launching tests. For example, review staff required repeating aspects of submissions that had already been authorized. AMP's survey reveals that the FDA's inability to efficiently and expertly review EUA submissions for COVID-19 tests delayed laboratories from offering testing during times with the country was far below meeting the test capacity needs. This not only delayed patient care, but potentially compromised the ability to utilize contact tracing and other measures in the response effort.

Recently, FDA officials published an opinion piece where they discuss their perspective on issues encountered during the pandemic that may be applied to future circumstances.<sup>2</sup> While AMP agrees that the United States government should develop international collaborations to rapidly share clinical specimens in future pandemics, we find significant issues with the remaining recommendations presented by the authors. Specifically, the recommendation calling for consolidation of testing to a limited number of assays would have further exacerbated the supply chain shortages in the current

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

<sup>2</sup> <https://www.nejm.org/doi/full/10.1056/NEJMp2023830>

pandemic. Based on the real-world experience of our members, such consolidation would have further prolonged test turnaround times due to testing not being performed locally. It is critically important to highlight that local testing, particularly in the hospital setting, is a critical factor to achieve clinically meaningful turnaround times for inpatients and patient triage. The authors also claim that assay validation approaches should be standardized, which neglects the fact that CLIA currently requires that laboratory directors must evaluate standard metrics of all assays before patient samples can be tested. How those parameters are assessed may vary based on local conditions, patient populations, equipment, and a myriad of other factors. Restricting experts from applying their expertise is unlikely to have positive outcomes for patients.

We find FDA's current response to the pandemic-testing needs inadequate, and it stands in sharp contrast to previous outbreaks like the 2009 H1N1 influenza pandemic. During the first month of the 2009 H1N1 outbreak, 62% of the patients screened for H1N1 influenza in Chicago were tested by community molecular diagnostics laboratories, with a turnaround time of 24 hours. Further, a previously conducted survey of AMP members focused on H1N1 testing revealed that 93% of respondents had a molecular assay that could distinguish between influenza type A and influenza type B with the ability to expand their aggregate testing capacity to 12,000 specimens per day within one month, easily accommodating the testing needs of the entire country during that pandemic outbreak. We hope that policymakers will conclude that creating new barriers to accessing accurate and reliable testing is not in the best interest of Americans' health.

The COVID-19 pandemic serves as a case study of what an influx of laboratory-developed testing reviews could mean for FDA. More than 70,000 unique genetic tests are currently offered to patients to inform clinical care.<sup>3</sup> During this pandemic, FDA has demonstrated that they lack the resources to review the several hundred submissions it received for COVID-19 testing, raising concern about the Agency's ability to perform oversight over tens of thousands of these tests. In November of last year when you asked for each stakeholder's top three priorities, we asked that the added regulatory burden within the VALID Act for medical laboratories using LDPs be justified. AMP believes that the introduced version of the VALID Act, similar to previous versions of VALID, outlines a regulatory system that is inappropriate for LDPs and would significantly diminish patient access to critically important laboratory tests.

AMP maintains that the most efficient way to both ensure the safety of patients and protect innovation is to modernize CLIA for LDPs. This can be most simply accomplished by using the VALID Act as a starting place for discussion on how to modernize FDA regulation for boxed-and-shipped in vitro diagnostics test kits. Additionally, AMP urges you to include a section to modernize CLIA by incorporating the Verified Innovative Testing in American Laboratories (VITAL) Act (S. 3512) into your legislation. The VITAL Act correctly differentiates LDPs, which are medical services, from the boxed-and-shipped in vitro diagnostic test kits, and it initiates a process for modernizing CLIA involving all stakeholders. Importantly, it also directs the Secretary of the Department of Health and Human Services to report to the Senate Health, Education, Labor and Pensions Committee and the House Energy and Commerce Committee providing an assessment of the availability and utilization of LDPs during 2020 COVID-19 pandemic response. We believe a study of this kind will find that LDPs have been a crucial component in the response efforts.

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<sup>3</sup> [https://www.concertgenetics.com/wp-content/uploads/2017/05/10\\_ConcertGenetics\\_CurrentLandscapeofGeneticTesting\\_2017Update.pdf](https://www.concertgenetics.com/wp-content/uploads/2017/05/10_ConcertGenetics_CurrentLandscapeofGeneticTesting_2017Update.pdf)

We would greatly appreciate the opportunity to engage in a transparent process once again and further discuss these ideas at your convenience. If you have any questions or would like to schedule a meeting, to reach out to Tara Burke at [tburke@amp.org](mailto:tburke@amp.org).

Sincerely,

Karen E. Weck, MD FCAP  
President, Association for Molecular Pathology