



ASSOCIATION FOR MOLECULAR PATHOLOGY

Providing global expertise in molecular testing that drives patient care

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Dockets Management
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

Submitted electronically at <https://www.regulations.gov>

RE: Docket FDA-2023-D-5365, Consideration of Enforcement Policies for Tests During a Section 564 Declared Emergency

To Whom It May Concern:

On behalf of the Association for Molecular Pathology (AMP), thank you for the opportunity to submit these comments in response to “Consideration of Enforcement Policies for Tests During a Section 564 Declared Emergency.” 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. Many of AMP’s members are molecular laboratory professionals who were on the frontlines of responding to the COVID-19 pandemic and Mpox outbreak. AMP maintains that laboratory-developed tests (LDTs) are not medical devices and thus, should not be subject to FDA’s policies. However, we provide these comments to ensure that FDA’s thinking is supportive of robust and effective public health responses to chemical, biological, radiological, or nuclear (CBRN) agents as the conversation on LDT regulatory policy continues.

It is critical that the same policy failures that were experienced during the COVID-19 and Mpox public health emergencies are not repeated in future infectious disease outbreaks. To better inform policymaking efforts, AMP surveyed its members 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.¹ 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. This negatively affected

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

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 the virus continued to spread.

Additionally, our April 2020 data indicated that 50% of laboratories were solely using emergency use authorized commercial testing kits, 10% were using laboratory-developed testing procedures only, and 40% were using a combination of both. Regardless of which test types and methods were employed, laboratories were often using numerous testing approaches – for academic medical centers and community hospital laboratories, often 3 or more. The survey responses revealed that the reason for this was to provide testing continuously as supply chain shortages disrupted their testing efforts. In August 2020, over 80% of laboratories surveyed reported that supply interruptions delayed or decreased their ability to provide patient testing. The types of supply chain interruptions that laboratories experienced were vast and as you recall, included shortages of testing platforms, testing kits, reagents, swabs, viral transport medium, laboratory consumables, and personal protective equipment. Unfortunately, our survey findings also indicated that academic medical centers and community health laboratories were deprioritized with regard to accessing limited testing supplies despite the advantages they provide to local response efforts. AMP found that over 40% of those at academic medical center and community hospital laboratories at the time of the survey were experiencing testing kits supply interruptions, while only 13% of commercial laboratories were currently experiencing this issue. For these reasons, any future FDA enforcement discretion policy during a declared emergency should be used to allow labs to modify their tests or develop new LDTs without an EUA to allow them to rapidly adapt to supply shortages. **We strongly urge FDA to edit “Section III. Factors to Consider in Deciding Whether to Issue an Enforcement Policy for Unapproved Tests” to include the need for an enforcement discretion policy to address challenges stemming from supply chain disruptions.**

Thank you for the opportunity to provide these comments for your consideration. AMP appreciates your continued leadership and efforts to improve our nation’s preparedness for and response to public health emergencies and disasters. Should you have any questions or wish to discuss these issues further, please do not hesitate to contact Annie Scrimenti, AMP Associate Director, Public Policy and Advocacy at AScrimenti@amp.org. AMP looks forward to reviewing and providing additional feedback on the forthcoming guidance documents on this topic.

Sincerely,

Maria E. Arcila, MD

President, Association for Molecular Pathology