COLLEGE of AMERICAN PATHOLOGISTS

Statement to the Clinical Laboratory Improvements Advisory Committee on the Clinical Laboratory Perspectives on Laboratory Developed Tests

The College of American Pathologists (CAP) appreciates the opportunity to provide comments to the Clinical Laboratory Improvements Advisory Committee (CLIAC) on the topic of Clinical Laboratory Perspectives on Laboratory-Developed Tests (LDTs). As the world's largest organization of board-certified pathologists and leading provider of laboratory accreditation and proficiency testing programs, the CAP serves patients, pathologists, and the public by fostering and advocating for excellence in the practice of pathology and laboratory medicine worldwide. LDTs have been integrally involved in direct mitigation of the COVID-19 crisis by increasing patient access to testing for accurate and timely diagnosis.

Appropriate processes and infrastructure should be in place to ensure that patients have timely access to diagnostic testing and laboratories have the resources and support to provide testing. Specifically, this should include quick deployment of the emergency use of LDTs. The process of having uniform standards and guidelines made the ramp up process more effective; but timely consistent communication from federal agencies is essential. While the Food and Drug Administration (FDA) and the Centers for Medicare and Medicaid Services (CMS) have made recent improvements in this area, initial delays and shortcomings affected the prevalence of testing in the United States.

As physicians providing diagnostic services during this unprecedented public health crisis, pathologists have seen firsthand the role LDTs have contributed to help manage and address this crisis. As documented by the media, the initial delays in testing contributed to the spread of COVID-19 within our communities, impacted our most vulnerable communities and frontline health workers, and strained health care resources. As such, pathologists are in a unique position to provide our perspective on lessons learned. When LDTs quickly become available for clinical use, the volume of LDTs exceeds the FDA's capabilities to directly manage and review. Established standards are needed to allow for third-parties to assume some of the oversight responsibilities. In addition, flexibility in the regulatory structure is needed to respond to health crises.

Once the FDA granted emergency use authorizations (EUA) for COVID-19 LDTs, academic medical centers and clinical laboratories were able to quickly offer testing to meet the clinical needs. During the initial stages of the pandemic, LDTs were only available to identify COVID-19 patients that required isolation and/or treatment. Over the past few months, the FDA changed its policies and approach to allow states to authorize LDTs to detect COVID-19 for use within their state without an EUA from FDA. This move was needed because of the volume of LDTs being submitted to the FDA for EUA created a significant backlog, related to the agency's inability to review each LDT, that prevented LDTs and commercial kits from being offered. To assist these state programs and laboratories, the FDA focused its efforts on establishing a standard for analytical performance since clinical validity of COVID-19 testing was well-established.

While pathologists and clinical laboratories are still facing challenges throughout the testing process, supply chain issues remain of high concern. Laboratories, for example, have documented persistent problems obtaining the necessary supplies needed for testing. Our own research shows 45% of laboratories testing for COVID-19 have difficulties obtaining the testing supplies they needed in recent months. While this represents an improvement since last summer, shortages still represent a substantial burden on those laboratories diagnosing coronavirus disease and require national attention to mitigate disruptions. Laboratory directors cite problems acquiring necessary reagents, test kits, plastic pipette

tips, and specimen acquisition swabs and transport media as the greatest barriers to COVID-19 testing. LDTs have made it possible for clinical laboratories to minimize these disruptions by offering testing using multiple platforms. From our most recent survey, laboratories have reported using different testing platforms to keep up with the demand and ensure that testing is available in their communities. To have multiple testing platforms, laboratory directors will have multiple versions of both high throughput and non-high throughput testing platforms. In fact, over 80% of laboratories used two or more platforms, and about one-half of the respondents reported using three or more unique testing platforms.

Finally, the pandemic also brings into focus the need for consistent policy and regulatory guidance. In August 2020, the directives by the Department of Health and Human Services that allowed only LDT-oversight by regulation that has gone through a comment period caused confusion and liability concerns since clinical laboratories that developed or modified tests because of various challenges were no longer afforded liability protections. The COVID-19 pandemic shined a light on the importance of diagnostic tests and how important they are to help track and trace the virus and identify those who need to be quarantined and treated. It also backs up the CAP's belief that a regulatory approach for the oversight of LDTs should be flexible and build on existing framework and institutional knowledge, while limiting intrusions and compliance burdens on laboratories.

Thank you for the opportunity to comment and the CAP looks forward to working with CLIAC, federal officials, and the clinical laboratory community to develop solutions for COVID-19 and any future pandemics.