



**ASSOCIATION FOR MOLECULAR PATHOLOGY**

*Providing global expertise in molecular testing that drives patient care*

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September 10, 2020

The Honorable Alex Azar  
Secretary  
Department of Health and Human Services  
200 Independence Avenue SW  
Washington, DC 20201

RE: Coverage and reimbursement of COVID-19 laboratory developed testing procedures

Dear Secretary Azar,

The Association for Molecular Pathology (AMP), an international medical and professional association representing approximately 2,500 physicians, doctoral scientists, and medical technologists who perform or are involved with laboratory testing based on knowledge derived from molecular biology, genetics, and genomics, commends the Department of Health and Human Services (HHS) for recently rescinding all guidance and other informal issuances regarding laboratory developed tests, or what AMP refers to as laboratory developed testing procedures (LDPs).

**Thank you for your leadership on this very important issue and we write today to request a clarification that this policy will not inadvertently limit patient access to the COVID-19 testing being provided by our members as it is vital to the country's efforts to control the pandemic.** This change mandates the Food and Drug Administration (FDA) undergo notice and comment rulemaking prior to requiring premarket review of these procedures, including those for COVID-19. LDPs are designed and performed by molecular diagnostic professionals whose laboratories are already regulated by the Centers for Medicaid & Medicare Services (CMS) through the Clinical Laboratory Improvement Amendments (CLIA). This action by HHS reduces the duplicative regulatory burden placed on molecular diagnostic professionals wishing to use their expertise to provide high-quality SARS-CoV-2 molecular testing in the COVID-19 pandemic.

Section §6001(a) of division F of the Families First Coronavirus Response Act (Public Law 116-127), as amended by Section §3201 of the Coronavirus Aid, Recovery, and Economic Security (CARES) Act (Public Law 116-136), authorizes public and private insurance coverage for LDPs for COVID-19 including those with an EUA, those awaiting FDA authorization, those overseen by their individual state, and those that the Secretary determines appropriate in guidance. In light of this new HHS policy regarding FDA oversight of LDPs, it is critical that payers continue to understand that LDPs without an EUA, including LDPs that are no longer required to seek an EUA, are covered at no cost sharing under the CARES Act. We ask that HHS and CMS use the authority granted in this last provision of §3201 to ensure coverage for these LDPs continues to align with current regulatory policy. Based on this authority, we ask that HHS update the Frequently Asked Questions stating that in light of recent HHS announcement, all validated LDTs performed in high complexity CLIA laboratories, regardless of EUA authorization, are now covered.

On behalf of AMP's members, thank you for your consideration of this request. AMP looks forward to continuing to work with you to ensure all Americans have access to reliable COVID-19 testing. Please contact Tara Burke, Senior Director of Public Policy & Advocacy at [tburke@amp.org](mailto:tburke@amp.org) in case you have any questions.

Sincerely,

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

Samuel K. Caughron, MD FCAP  
Chair, Economic Affairs Committee  
Association for Molecular Pathology