ASSOCIATION FOR MOLECULAR PATHOLOGY
Education. Innovation & Improved Patient Care. Advocacy.
6120 Executive Boulevard, Suite 700, Rockville, Maryland, 20852
Tel: 301-634-7987 | Fax: 301-634-7995 | amp@amp.org | www.amp.org

Association for Molecular Pathology Commends Senator Rand Paul for Introducing the Verified Innovative Testing in American Laboratories (VITAL) Act of 2020

Coronavirus pandemic underscores need for streamlined approach that clarifies regulatory authority, enhances transparency, preserves innovation, and ensures broad patient access to essential laboratory developed testing procedures

ROCKVILLE, Md. – March 18, 2020 - The Association for Molecular Pathology (AMP), the premier global, molecular diagnostics professional society, applauds US Senator Rand Paul (R-KY) for introducing new legislation to allow molecular pathology professionals to continue advancing and offering laboratory developed testing procedures (LDPs) for patient care. The Verified Innovative Testing in American Laboratories (VITAL) Act of 2020 clarifies the federal regulatory authority over LDPs and encourages the modernization of the existing Clinical Laboratory Improvement Amendments (CLIA), which are administered by the Centers for Medicare and Medicaid Services (CMS). The legislation was designed to enhance transparency, preserve innovation and ensure widespread patient access to essential medical services.

The current coronavirus pandemic highlights the inefficient FDA oversight processes and, at the same time, underscores the integral role that public health, local academic and community laboratories play to both patient care and public health surveillance. The public health emergency declaration retroactive to January 27, 2020, triggered a requirement that all tests for SARS-CoV-2, regardless of whether they are boxed and shipped testing kits or medical procedures, obtain emergency use authorization (EUA) from the FDA prior to use. This decision, since modified by the FDA, prevented many laboratories from fixing the flaw in the first test kit provided by the Centers for Disease Control and Prevention (CDC). This regulatory process imposed by the FDA was duplicative with CLIA regulations and impeded the ability of private laboratories, including many academic medical centers, reference laboratories and community health systems across the country, to rapidly develop, validate and offer high-quality LDPs for use on their local patient populations.

"We are pleased that Senator Rand Paul introduced this legislation that will provide clinical laboratories with clarity and predictability in federal oversight of testing programs," said Karen E. Weck, MD, President of the Association for Molecular Pathology. "The delayed response to the current coronavirus pandemic perfectly illustrates the importance of clinical laboratories in being able to develop and provide novel testing services. AMP members welcome the opportunity to share our collective expertise and engage with key stakeholders to modernize the current CLIA oversight system in order to ensure high-quality testing without jeopardizing innovation or compromising patient access to potentially lifesaving procedures."

AMP has long maintained that the involvement of appropriately trained and qualified laboratory professionals is critical to the development of accurate and reliable LDPs, as well as for correct utilization, precise interpretation, and appropriate application of molecular test results. The professional association also recognizes the need to update existing CLIA regulations to better reflect the current state of the field of clinical laboratory testing. The VITAL Act correctly differentiates LDPs, which are medical services that are developed, validated and performed within a laboratory, from the boxed and shipped *in vitro* diagnostic test kits. It is a first step in the right direction to establish a more efficient regulatory framework that ensures high-quality patient care while continuing to foster the rapid innovation and promise of new diagnostic technologies.

To view the full-text version of the VITAL Act of 2020, visit www.amp.org/VITAL

ABOUT AMP

The Association for Molecular Pathology (AMP) was founded in 1995 to provide structure and leadership to the emerging field of molecular diagnostics. AMP's 2,500+ members practice various disciplines of molecular diagnostics, including bioinformatics, infectious diseases, inherited conditions, and oncology. Our members are pathologists, clinical laboratory directors, basic and translational scientists, technologists, and trainees that practice in a variety of settings, including academic and community medical centers, government, and industry. Through the efforts of its Board of Directors, Committees, Working Groups, and Members, AMP is the primary resource for expertise, education, and collaboration in one of the fastest growing fields in healthcare. AMP members influence policy and regulation on the national and international levels, ultimately serving to advance innovation in the field and protect patient access to high quality, appropriate testing. For more information, visit www.amp.org and follow AMP on Twitter: @AMPath

MEDIA CONTACT:
Andrew Noble
anoble@amp.org
415-722-2129

###