

Association for Molecular Pathology Leaders Publish Recommendations to Improve Diagnostic Testing Response for Current COVID-19 Pandemic and Future Emerging Outbreaks

JAMA Health Forum article lays the foundation for a comprehensive national testing strategy that will promote better collaboration between public health and diagnostic laboratories and test manufacturers

ROCKVILLE, Md. – Nov. 1, 2021 – The Association for Molecular Pathology (AMP), the premier global, molecular diagnostic professional society, today announced a new article in *JAMA Health Forum*. Authored by members of the AMP COVID Response Steering Committee, "<u>The Role of Clinical Laboratories in Emerging Pathogens: Insights</u> from the COVID-19 Pandemic," is a new viewpoint article that offers recommendations to improve the US' ability to respond to the current COVID-19 pandemic and prepare for future emerging infectious disease outbreaks.

"AMP members have been on the frontlines of this pandemic and have been managing the ever-increasing demand for testing despite numerous regulatory, reimbursement, supply-chain, logistical, and systems challenges," said Karen E. Weck, MD, Previous AMP President, Professor of Pathology and Laboratory Medicine, Professor of Genetics and Director of Molecular Genetics and Pharmacogenomics at the University of North Carolina Chapel Hill, and corresponding author of the *JAMA Health Forum* article. "Timely diagnostic and epidemiological testing are foundational to an effective response to any emerging infectious disease. AMP is committed to expanding our leadership role, sharing our expertise, and providing strategic recommendations to improve the US pandemic response and ensure more patients can benefit from timely access to high-quality testing procedures."

Throughout this pandemic, AMP has continuously focused on addressing key issues and enabling clinical laboratories to increase testing capacity. The new *JAMA Health Forum* article offers three important recommendations to improve the US reponse moving forward:

- 1. Clinical laboratories in response to the COVID-19 pandemic: Promote better collaboration and communication between public health and clinical laboratories and relevant government agencies in order to more effectively leverage capacities and capabilities to support testing needs.
- 2. Government regulation and clinical laboratories during the pandemic: Maintain the Centers for Medicare & Medicaid Services (CMS) via the Clinical Laboratory Improvement Amendments (CLIA) program as the regulatory agency responsible for oversight of laboratory developed testing procedures, enabling clinical laboratories to rapidly develop and deploy high-quality diagnostic tests during a public health emergency.
- **3. Supply chains to meet testing demands during the pandemic:** Ensure clinical laboratories have a stable chain of supplies and infrastructure to respond optimally to pandemic needs, as well as other critical clinical testing, including for cancer, inherited conditions, and infectious diseases. This will require early and better use of the Defense Production Act or similar support from the federal government.

Since 2009, AMP has been calling for a comprehensive national diagnostic testing response strategy for emerging outbreaks. The <u>AMP COVID Response Steering Committee</u> was formed to help coordinate and communicate the association's continued efforts to address clinical needs and engage key stakeholders. To help address the numerous regulatory, reimbursement, supply-chain, logistical, and systems challenges, AMP issued <u>seven</u> recommendations to federal, state, and local governments based on the preliminary results from the <u>April</u> and <u>August</u> 2020 surveys of laboratories conducting molecular testing for SARS-CoV-2. AMP members are committed to offer their expertise to help inform the Biden administration, guide healthcare providers, and educate the public.

In addition to Dr. Weck, the *JAMA Health Forum* article was co-authored by Eric Q. Konnick, MD, Co-Chair of the AMP Professional Relations Committee and Assistant Professor and Associate Director of the Genetics and Solid Tumor Laboratory at the University of Washington Department of Laboratory Medicine and Pathology and Jordan S. Laser, MD, Co-Chair of the AMP Professional Relations Committee.

View the full article <u>HERE</u>.

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.

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