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The Association for Molecular Pathology Establishes New Standard for Clinical Utility of Molecular Diagnostics for Inherited Diseases and Cancer

The Journal of Molecular Diagnostics report recognizes value of testing procedures and promotes paradigm corrections to drive widespread adoption of a more proactive, patient-centered approach to modern healthcare

BETHESDA, Md. – Aug. 17, 2016 – The Association for Molecular Pathology (AMP), the premier global, non-profit organization serving molecular diagnostic professionals, today announced a new report that addresses the challenges in defining the clinical utility of molecular diagnostics for inherited diseases and cancer. The manuscript titled "The Spectrum of Clinical Utilities in Molecular Pathology Testing Procedures for Inherited Conditions and Cancer: A Report of the Association for Molecular Pathology" has been released online ahead of publication in the September 2016 issue of The Journal of Molecular Diagnostics.

Molecular diagnostic procedures are used for a myriad of purposes including diagnosis, prognosis, risk assessment, prediction of future disease, and monitoring and selection of therapies of disease in patients. Future advancements in precision medicine are threatened by drastic shifts in evidence demands and the adoption of very narrow clinical utility definitions that do not address all the important applications of molecular diagnostic testing. Without a correction, treating clinicians could be left to make decisions without an accurate molecular diagnostic result and the clinically valuable information needed for patient management.

In the manuscript, the AMP Framework for the Evidence Needed to Demonstrate (FEND) Clinical Utility Task Force recommends clinical utility definitions that appropriately recognize the full contribution and value of molecular diagnostic testing to improve patient care. This approach emphasizes that a clinical test result's utility depends on the context in which it is used to classify a patient's disease or disorder and/or guide management. The authors also note that the recommendations can be extended to additional applications of molecular testing.

"Patient access to clinically useful and appropriate molecular diagnostic testing based upon realistic evidence levels is paramount and clinical utilities beyond therapeutic selection are valuable to patients, providers, and family members," said Elaine Lyon, PhD, 2014 AMP President and FEND Task Force Co-chair. "Ultimately, we need to capture evidence for the clinical utility of molecular pathology procedures outside of a traditional randomized control trial setting, recognizing that any individual test result is an intermediate outcome that relies on proper clinical interpretation and utilization in context for that specific patient to achieve maximum benefit."

"Molecular pathology testing procedures are vital tools for insight and analysis into various aspects of clinical practice," said Roger D. Klein, MD, JD, AMP Professional Relations Chair. "However, we need a more practical and patient-centered approach for evaluating clinical usefulness before we can truly deliver the promise of precision medicine."

To read the full manuscript, please visit: http://dx.doi.org/10.1016/j.jmoldx.2016.05.007

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 2,300+ members practice in the various disciplines of molecular diagnostics, including infectious diseases, inherited conditions and oncology. They include individuals from academic and community medical centers, government, and industry; including pathologist and doctoral scientist laboratory directors; basic and translational scientists; technologists; and trainees. 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.

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