

ASSOCIATION FOR MOLECULAR PATHOLOGY

Education. Innovation & Improved Patient Care. Advocacy.

9650 Rockville Pike. Bethesda, Maryland 20814

Tel: 301-634-7939 | Fax: 301-634-7995 | amp@amp.org | www.amp.org

AMP Issues Best Practice Guidelines for Next-Generation Sequencing-based Oncology Panel Validation

NGS testing experts publish consensus recommendations to help ensure high-quality sequencing results for better cancer patient care

BETHESDA, Md. — **March 22, 2017** — The Association for Molecular Pathology (AMP), the premier global, non-profit molecular diagnostics professional society, today published consensus recommendations to help clinical laboratory professionals achieve high-quality sequencing results and deliver better care for cancer patients. The report, "Guidelines for Validation of Next Generation Sequencing (NGS)-based Oncology Panels: A Joint Consensus Recommendation of the Association for Molecular Pathology and College of American Pathologists," was released online ahead of publication in *The Journal of Molecular Diagnostics*.

"In this era of precision medicine, NGS has quickly become the method of choice for detecting multiple somatic variants, diagnosing disease, and predicting response to targeted therapies. However, the required analytical validation process remains challenging," said Lawrence Jennings, MD, PhD, Attending Pathologist, Ann and Robert H. Lurie Children's Hospital of Chicago, Working Group Chair, and AMP Member. "AMP convened and led a multidisciplinary subject matter expert working group with liaison representation from CAP to summarize current knowledge, expose challenges, and provide guidance on how to best validate these tests to ultimately improve patient care."

AMP is in the process of providing a series of guidelines designed to improve the entire NGS workflow. The joint consensus recommendations are based on evidence from a review of published literature, empirical data, current laboratory practice surveys, feedback from multiple public meetings, and expert professional experiences. The latest report addresses NGS test development, optimization and familiarization, and best practices for establishing test performance characteristics. The recommendations emphasize the critical role of the molecular laboratory director in establishing and utilizing an error-based approach for patient risk management. Since these recommendations represent current best practice in a rapidly developing field, AMP anticipates a need for ongoing updates. The new report follows the previously published guidelines on interpreting oncology sequence variants. AMP plans on publishing the next companion paper in this series focusing on downstream NGS bioinformatics analysis later this year.

"With this series of guidelines, AMP continues to provide the cancer genomics community with the appropriate tools and guidance to better incorporate the latest scientific breakthroughs and technological innovations in molecular pathology," said Marina N. Nikiforova, MD, Professor of Pathology at University of Pittsburgh Medical Center, Working Group Member, and 2016 AMP Clinical Practice Committee Chair. "Our hope is that we will soon see the widespread adoption of these guidelines leading to improvements in how molecular pathologists validate and provide high-quality NGS results to support our oncologists, pathologists, and most importantly, patients."

To read the full manuscript, please visit http://dx.doi.org/10.1016/j.jmoldx.2017.01.011.

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 bioinformatics, infectious diseases, inherited conditions, and oncology. They include pathologists, doctoral scientist laboratory directors, basic and translational scientists, technologists, and trainees from 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. Follow AMP on Twitter: @AMPath.

MEDIA CONTACT:

Andrew Noble anoble@amp.org 415-722-2129

###