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Association for Molecular Pathology Publishes Evidence-based Recommendations for Tumor Mutational Burden Testing

New joint consensus guideline authored by representatives from AMP, ASCO, CAP, and SITC

ROCKVILLE, Md. – June 6, 2024 – The Association for Molecular Pathology (AMP), the premier global molecular diagnostic professional society, today published a set of evidence-based recommendations for the analytical validation and reporting of tumor mutational burden (TMB) testing as a potential predictive biomarker for immune checkpoint inhibitor (ICI) therapies. These recommendations encompass pre-analytical, analytical, and post-analytical factors of TMB analysis, and emphasize the importance of comprehensive methodological descriptions in publications to allow comparability between assays. The manuscript, "Recommendations for Tumor Mutational Burden Assay Validation and Reporting: A Joint Consensus Recommendation of the Association for Molecular Pathology, College of American Pathologists, and Society for Immunotherapy of Cancer," was released online ahead of publication in *The Journal of Molecular Diagnostics*.

ICI therapies have transformed patient care for a subset of individuals with multiple cancer types. As a result, there continues to be significant interest in predictive biomarkers, such as TMB, that can identify the patients more likely to benefit from these treatments. However, the calculation, reporting, and interpretation of TMB may vary across different laboratories. The AMP TMB Working Group was established to assess existing laboratory practices and develop evidence-based standards for the analytical validation and reporting of clinical TMB testing. These recommendations are intended to be a reference guide based on scientific literature, observational survey data, and the professional experience of the Working Group's subject matter experts.

"While TMB has emerged as a potential predictive biomarker for ICI therapy, the variety of approaches for calculating and reporting TMB, and few comprehensive methodological descriptions regarding clinical assay validation, pose significant challenges to adoption," said Larissa V. Furtado, MD, Chair of the AMP TMB Working Group and Molecular Pathologist at St. Jude Children's Research Hospital. "This new report not only summarizes the existing knowledge and challenges related to TMB testing, but also provides our consensus recommendations on how to best validate and report these assays in the clinical setting."

"AMP is committed to helping laboratories overcome challenges and improve current test and interpretation practices," said Susan Hsiao, MD, PhD, Chair of the 2024 AMP Clinical Practice Committee, Member of the AMP TMB Working Group, and Associate Professor of Pathology and Cell Biology at Columbia University Vagelos College of Physicians and Surgeons. "As with all our evidence-based guidelines, the AMP Clinical Practice Committee will continue to reassess and modify these TMB recommendations as new technological and scientific advances become available."

To read the full manuscript, please visit https://doi.org/10.1016/j.jmoldx.2024.05.002.

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 2,900+ 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 X: @AMPath.

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