ASSOCIATION FOR MOLECULAR PATHOLOGY
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Association for Molecular Pathology Publishes Best Practice Recommendations for Liquid Biopsy Assay Validations

New joint consensus manuscript from AMP developed in collaboration with ASCO and CAP

ROCKVILLE, Md. – Oct. 12, 2023 – The Association for Molecular Pathology (AMP), the premier global molecular diagnostic professional society, today published a set of 13 best practice recommendations for validating and reporting clinical circulating tumor DNA (ctDNA) or liquid biopsy assays and their related scientific publications. The manuscript, "Recommendations for Cell-free DNA Assay Validations: A Joint Consensus Recommendation of the Association for Molecular Pathology and College of American Pathologists (CAP)," was released online ahead of publication in *The Journal of Molecular Diagnostics*.

"One of the most important technological advances in molecular diagnostics over the past decade has been the ability to accurately detect and measure low abundance ctDNA in blood and body fluids," said Christina Lockwood, PhD, Chair of the AMP Liquid Biopsy Working Group and Professor and Division Head of Laboratory Genetics at the University of Washington School of Medicine. "As with any emerging technology or methodology, the way these liquid biopsy assays are developed, validated, and reported can vary. This new report provides a set of evidence-based recommendations that can help promote standardization, transparency, and quality improvement among laboratories."

The AMP Clinical Practice Committee's Liquid Biopsy Working Group, including organizational representation from the American Society of Clinical Oncology (ASCO) and CAP, developed a set of recommendations for validating, reporting, and publishing clinical ctDNA assays. The recommendations are based on a review of more than 1,200 publications that describe ctDNA assay performance in patients with lymphoma and solid tumor malignancies and subject matter expert professional experience. The recommendations include reporting key pre-analytical considerations and assay performance metrics.

"This new report was meant to summarize the current collective state of knowledge and assist clinical laboratory professionals with liquid biopsy assay validation," said Susan Hsiao, MD, PhD, 2023 AMP Clinical Practice Committee Chair and Associate Professor of Pathology and Cell Biology at Columbia University Irving Medical Center. "As part of our ongoing commitment to improving clinical practice and patient care, AMP will continue to reassess and modify our recommendations as these technologies become more sensitive and additional trials are available to evaluate assay performance and clinical utility."

To read the full manuscript, please visit https://doi.org/10.1016/j.jmoldx.2023.09.004.

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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