

Association for Molecular Pathology Publishes Best Practice Recommendations for Clinical HRD Testing

Joint consensus report includes organizational representation from AMP, ASCO, ACCC and the CAP

ROCKVILLE, Md. – June 24, 2025 – The Association for Molecular Pathology, the premier global molecular diagnostic professional society, today announced the publication of best practice recommendations for clinical laboratories developing and performing homologous recombination deficiency (HRD) testing. The manuscript, titled "<u>Recommendations for Clinical Molecular Laboratories for Detection of Homologous Recombination</u> <u>Deficiency in Cancer</u>: A Joint Consensus Recommendation of the Association of Molecular Pathology, Association of Cancer Care Centers and College of American Pathologists," was published online ahead of print, and the full text is freely available in *The Journal of Molecular Diagnostics*.

HRD testing identifies tumors that are unable to effectively repair DNA damage through the homologous recombination repair pathway. This deficiency is often linked to increased genomic instability and serves as a potential biomarker for predicting response to certain cancer therapies. Although multiple HRD assays are currently available, they differ in their definitions of HRD, the biomarkers they assess, and the algorithms they employ. These variations can impact treatment decisions, especially for patients who may benefit from poly (ADP-ribose) polymerase (PARP) inhibitor therapies.

To develop these recommendations, AMP's Clinical Practice Committee assembled an expert panel to review current practices and assess the medical literature related to the molecular detection of HRD in clinical settings. The AMP Detection of HRD in Cancer Working Group included organizational representation from the Association of Community Cancer Centers, the American Society of Clinical Oncology and the College of American Pathologists.

Alanna J. Church, M.D., is the chair of AMP's 2025 Clinical Practice Committee and associate director of the Laboratory for Molecular Pediatric Pathology at Dana-Farber/Boston Children's Cancer Center. "As part of our assessment, we identified considerable variability in many aspects of HRD testing, including sample requirements, tumor types, molecular methodologies and the biomarkers evaluated," said Church. "This new report offers evidence-based recommendations for HRD diagnostic assays to help improve standardization, transparency, quality across laboratories and care for our cancer patients."

The AMP HRD Working Group developed 12 recommendations focused on the design and validation of HRD assays. These guidelines are based on survey data, a review of more than 4,300 peer-reviewed scientific publications, professional experience and consensus of the subject matter experts. The recommendations address technical aspects of genomic instability and HRD analysis, including interpretation of genomic scars from tumor and germline next-generation sequencing results and the clinical relevance of HRD biomarkers.

Susan Hsiao, M.D., Ph.D., is the chair of the AMP Detection of HRD in Cancer Working Group and associate professor of pathology and cell biology at Columbia University Vagelos College of Physicians and Surgeons. "These recommendations are intended to guide clinical laboratories offering HRD testing and highlight areas where further research and validation are needed," said Hsiao. "AMP remains committed to refining these recommendations as scientific knowledge and technology continue to evolve."

To read the full manuscript, please visit <u>www.jmdjournal.org/article/S1525-1578(25)00136-9/fulltext</u>.

About AMP

Association for Molecular Pathology was founded in 1995 to provide structure and leadership to the emerging field of molecular diagnostics. AMP's 3,100+ 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 who 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: <u>@AMPath</u>.

MEDIA CONTACT: Andrew Noble anoble@amp.org 415-722-2129