

Minimum set of pharmacogenetic alleles to help standardize clinical genotyping testing for warfarin response

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The Association for Molecular Pathology (AMP), the premier global, molecular diagnostic professional society, today published consensus, evidence-based recommendations to aid in the design, validation and interpretation of clinical genotyping tests for the prediction of warfarin response. The manuscript, "Recommendations for Clinical Warfarin Sensitivity Genotyping Allele Selection: A Joint Recommendation of the Association for Molecular Pathology and College of American Pathologists," was released online ahead of publication in *The Journal of Molecular Diagnostics*.

The new guideline on clinical warfarin sensitivity genotyping allele selection completes a series of three reports that were intended to facilitate testing and promote standardization for frequently used pharmacogenetics (PGx) genotyping assays. Developed by the AMP PGx Working Group with organizational representation from the College of American Pathologists (CAP) and the Clinical Pharmacogenetics Implementation Consortium (CPIC), the latest report builds on the earlier recommendations for clinical CYP2C19 and CYP2C9 genotyping. The recommendations should be implemented together with other clinical guidelines such as those issued by the CPIC, which focus primarily on the interpretation of PGx test results and therapeutic recommendations for specific drug-gene pairs.

"Clinical genotyping assays that help predict warfarin response and

optimize a patient's dosage requirements have enabled some of the earliest success stories of this precision medicine era," said Victoria M. Pratt, Ph.D., FACMG, Professor and Director of Pharmacogenetics and Molecular Genetics Laboratories, Indiana University School of Medicine, and AMP PGx Working Group Chair. "Together, the AMP PGx Working Group defined a standard set of evidence-based recommendations that will help build on these past successes and improve phenotype prediction and test interpretation for all future warfarin sensitivity genotyping panels."

Similar to the previous reports in the series, this new warfarin genotyping guideline offers a two-tier categorization of alleles that are recommended for inclusion in clinical PGx genotyping assays. Using criteria such as allele frequencies in different populations and ethnicities, the availability of reference materials and other technical considerations, the AMP PGx Working Group recommended a minimum set of alleles and their defining variants that should be included in all clinical [warfarin](#) sensitivity genotyping tests (Tier 1). The team also defined a Tier 2 list of optional alleles that do not currently meet one or more of the criteria for inclusion in Tier 1. These recommendations are meant to be a reference guide and not to be interpreted as a restrictive list. AMP intends to update these recommendations as new data and/or reference materials become available.

"AMP members are among the earliest adopters of pharmacogenetic testing in clinical settings," said Karen E. Weck, MD, Professor of Pathology and Laboratory Medicine, Professor of Genetics and Director, Molecular Genetics and Pharmacogenomics at University of North Carolina Chapel Hill, and AMP President and PGx Working Group Member. "This series of guidelines for common clinical PGx [genotyping](#) tests is another example of AMP's ongoing commitment to sharing our collective expertise with the broader laboratory community in order to

improve professional practice and patient care.

More information: Victoria M. Pratt et al, Recommendations for Clinical Warfarin Sensitivity Genotyping Allele Selection: A Report of the Association for Molecular Pathology and College of American Pathologists, *The Journal of Molecular Diagnostics* (2020). [DOI: 10.1016/j.jmoldx.2020.04.204](https://doi.org/10.1016/j.jmoldx.2020.04.204)

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