



ASSOCIATION FOR MOLECULAR PATHOLOGY
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AMP Recommends Minimum Set of Pharmacogenetic Alleles to Guide Clinical *CYP2D6* Genotype Testing, Promote Standardization, and Improve Patient Care

Latest joint consensus guideline authored by representatives from AMP, CAP, Royal Dutch Pharmacists Association, and European Society for Pharmacogenomics and Personalized Therapy

ROCKVILLE, Md. – June 10, 2021 – The Association for Molecular Pathology (AMP), the premier global, molecular diagnostic professional society, today published consensus recommendations to aid in the design and validation of clinical *CYP2D6* assays, promote standardization of testing across different laboratories and improve patient care. The manuscript, "[Recommendations for Clinical *CYP2D6* Genotyping Allele Selection: A Joint Consensus Recommendation of the Association for Molecular Pathology, College of American Pathologists, Dutch Pharmacogenetics Working Group of the Royal Dutch Pharmacists Association, and European Society for Pharmacogenomics and Personalized Therapy,](#)" was released online ahead of publication in *The Journal of Molecular Diagnostics*.

The AMP Pharmacogenetics (PGx) Working Group is developing a series of guidelines designed to help standardize clinical testing for frequently used genotyping assays. The latest *CYP2D6* report builds on the earlier recommendations for clinical genotyping of [CYP2C19](#), [CYP2C9](#), and [genes important for warfarin testing](#). The recommendations should be implemented together with other relevant clinical guidelines such as those issued by the Clinical Pharmacogenetics Implementation Consortium (CPIC), Dutch Pharmacogenetics Working Group (DPWG), Canadian Pharmacogenomics Network for Drug Safety (CPNDS), and the American College of Medical Genetics and Genomics (ACMG), which mostly focus on the interpretation of PGx test results and therapeutic recommendations for specific drug-gene pairs.

"*CYP2D6* is known to be responsible for the metabolism of many commonly prescribed medications including some antidepressants, atypical and typical antipsychotics, beta-blockers, opioids, antiemetics, and atomoxetine," said Victoria M. Pratt, PhD, Professor and Director of Pharmacogenetics and Molecular Genetics Laboratories, Indiana University School of Medicine, and AMP PGx Working Group Chair. "The ultimate goal of the AMP PGx Working Group is to promote standardization of PGx gene/allele testing across clinical laboratories. While the *CYP2D6* gene is especially complex, with this latest report, we have been able to define a minimum set of variants that should be included in all future clinical *CYP2D6* PGx genotyping assays."

Similar to the previous reports in the series, the *CYP2D6* 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 *CYP2D6* 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 is committed to collaborating with the broader laboratory community to continuously improve professional PGx practices amidst a rapidly evolving molecular diagnostic landscape,” said Antonia R. Sepulveda, MD, PhD, AMP President and Professor and Chair of the George Washington School of Medicine Department of Pathology. “Standardizing clinical testing for frequently used PGx genotyping assays will improve concordance across laboratories and enable healthcare professionals to provide high-quality patient care.”

To read the full manuscript, please visit <https://doi.org/10.1016/j.jmoldx.2021.05.013>.

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 2,500+ 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 Twitter: [@AMPath](https://twitter.com/AMPath)

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