ASSOCIATION FOR MOLECULAR PATHOLOGY
Education. Innovation & Improved Patient Care. Advocacy.
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AMP Recommends Minimum Set of Pharmacogenetic Alleles to Guide Design, Development, and Validation of Clinical *TPMT* and *NUDT15* Genotyping Assays

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

ROCKVILLE, Md. – Aug. 25, 2022 – 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 *TPMT and NUDT15* genotyping assays, promote standardization of testing across different laboratories and improve patient care. The manuscript, "*TPMT* and *NUDT15* Genotyping Recommendations: A Joint Consensus Recommendation of the Association for Molecular Pathology, Clinical Pharmacogenetics Implementation Consortium, College of American Pathologists, Dutch Pharmacogenetics Working Group of the Royal Dutch Pharmacists Association, European Society for Pharmacogenomics and Personalized Therapy, and Pharmacogenomics Knowledgebase," 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 *TPMT and NUDT15* report builds on the earlier recommendations for clinical genotyping of *CYP2C19*, *CYP2C9*, *CYP2D6*, 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 French National Network of Pharmacogenetics, all of which focus primarily on the interpretation of PGx test results and therapeutic recommendations for specific drug–gene pairs.

"Clinical tests for genetic variants in *TPMT* and *NUDT15* can identify individuals who are at increased risk of adverse drug toxicity with standard doses of thiopurine medications," said Victoria M. Pratt, PhD, Co-Chair of the AMP PGx Working Group, Vice President of Molecular Diagnostics Quality Assessments at Optum Genomics, and Adjunct Professor of Medical and Molecular Genetics at Indiana University School of Medicine. "The AMP PGx Working Group was established to help standardize clinical testing across laboratories. This series of reports for *TPMT*, *NUDT15*, and many other frequently used PGx genotyping assays are designed to ensure the assays investigate the most clinically relevant variant alleles and enable healthcare professionals to provide high-quality patient care."

Similar to the previous reports in the series, the new *TPMT and NUDT15* report offers a two-tier categorization of alleles that are recommended for inclusion in clinical PGx genotyping assays. Using criteria such as allele frequencies in people of different genetic ancestries, 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 *TPMT and NUDT15* 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.

"PGx testing has become an important tool to help clinicians select medications and prescribe an appropriate dose for certain patients," said Karen E. Weck, MD, Co-Chair of the AMP PGx Working Group and Director of Molecular Genetics and Pharmacogenomics and Professor of Pathology & Laboratory Medicine and Genetics at the University of North Carolina at Chapel Hill. "AMP is committed to collaborating with the broader laboratory community to continuously improve professional PGx practices amidst this rapidly evolving molecular diagnostic landscape."

To read the full manuscript, please visit https://www.jmdjournal.org/action/showPdf?pii=S1525-1578%2822%2900194-5.

***TPMT* and *NUDT15* Genotyping Recommendations Webinar**

AMP members will present the recommendations and share more information from this new PGx report during a live webinar.

Time / Date: 1:00 pm ET on Tuesday, Aug. 30, 2022

Presenter: Makenzie L. Fulmer, PhD, Department of Pathology and ARUP Laboratories at University of Utah School of Medicine

Moderator: Reynold C. Ly, PhD, Department of Medical and Molecular Genetics at Indiana University School of Medicine

To register, please visit https://register.gotowebinar.com/register/4598302088248626956.

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 2,600+ 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.

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