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AMP Publishes Recommendations for Clinical *CYP2C19* Genotyping Allele Selection

New report defines a two-tier categorization of alleles as part of ongoing effort to continuously improve professional pharmacogenetics practice and patient care

BETHESDA, Md. — Feb. 27, 2018 — The Association for Molecular Pathology (AMP), the premier global molecular diagnostics professional society, today published consensus, evidence-based recommendations to aid clinical laboratory professionals when designing and validating clinical *CYP2C19* assays, promote standardization of testing across different laboratories and complement existing clinical guidelines. The report, "Recommendations for Clinical CYP2C19 Genotyping Allele Selection: A Report of the Association for Molecular Pathology," was released online ahead of publication in *The Journal of Molecular Diagnostics*.

The cytochrome P450 2C19 (*CYP2C19*) gene is one of the most frequently tested pharmacogenetics (PGx) genes because it is involved in the phase I metabolism of many commonly prescribed medications. However, currently available *CYP2C19* tests can produce variable results due to factors such as the choice of tested alleles, targeted testing of populations with varying ethnic backgrounds, as well as the technical performance of the various platforms. The AMP PGx Working Group was established to help standardize this process by recommending variants for inclusion in clinical *CYP2C19* genotyping panels.

"Considering the complex nature of clinical PGx testing and interpretation, and its impact on patient care, there is a clear, practical need for standardizing these transformative assays," said Victoria M. Pratt, PhD, Associate Professor of Medical and Molecular Genetics at Indiana University School of Medicine and AMP PGx Working Group Chair. "The AMP PGx Working Group started with *CYP2C19* genotyping panels due to the widespread adoption of these tests and our desire to help physicians, pharmacists, researchers, and other stakeholders better understand what these panels include and what the test results mean."

This new report offers a two-tier categorization of *CYP2C19* alleles as an aid for designing *CYP2C19* genotyping assays. Using criteria such as allele function, population frequency and availability of reference materials, the AMP PGx Working Group recommended a minimum set of alleles and their defining variants that should be included in all clinical *CYP2C19* PGx tests (Tier 1). The team also defined a Tier 2 list of optional *CYP2C19* alleles that do not currently meet one or more of the criteria for inclusion in Tier 1. These recommendations are intended to facilitate testing by laboratories and improve genotyping concordance across laboratories.

"Pharmacogenetics is a rapidly changing field and molecular diagnostic laboratories must have updated resources and reference materials to guide them in their efforts to offer high-quality testing," said Karen E. Weck, MD, Director of the Medical Genetics Laboratory at University of North Carolina School of Medicine and AMP PGx Working Group Member. "AMP members are among the early adopters of PGx testing in clinical settings and we are committed to publishing and updating a series of recommendations for informative PGx genes beyond *CYP2C19,* as part of our ongoing quest to continuously improve professional practice and patient care."

To read the full manuscript, please visit https://doi.org/10.1016/j.jmoldx.2018.01.011.

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 2,300+ members practice in the various disciplines of molecular diagnostics, including bioinformatics, infectious diseases, inherited conditions, and oncology. They include individuals from academic and community medical centers, government, and industry; including pathologist and doctoral scientist laboratory directors; basic and translational scientists; technologists; and trainees. 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. Follow AMP on Twitter: @AMPath.

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