Content Director: Victoria Pratt, PhD, FACMG; *Indiana University Medical Center*
Faculty:

- Karen Weck, MD, FACMG; *University of North Carolina* (Planning committee)
- Yuan Ji, PhD, MBA, FACMG; *University of Utah School of Medicine/ARUP Laboratories* (Planning committee)
- Reynold C. Ly, PhD; Indiana *University School of Medicine* (Planning committee)
- Jeffrey Kleinberger, MD, PhD: *University of Pittsburgh School of Medicine* (Planning committee)
- Stuart A. Scott, PhD, FACMG; *Stanford University*
- Ann Moyer, MD, PhD; *Mayo Clinic*

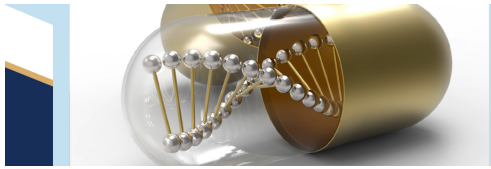
With thanks to the AMP Training & Education Committee for their support and careful review

Course Description: Pharmacogenomics is an important and evolving area of medical testing that combines pharmacology and genomics to identify genomic variability that can affect individual drug response. There is a need in the general medical and laboratory communities to understand the fundamentals of pharmacogenomics and the impacts of molecular testing on optimizing drug selection. This certificate program is intended to provide an introduction to pharmacogenomics and to review AMP expert consensus recommendations for standardization of alleles for clinical pharmacogenomic genotyping assays.

Course Learning Objective:

1. Use appropriate nomenclature when describing genes and variants involved in Pharmacogenomics (PGx).
2. Describe the application of Association for Molecular Pathology (AMP) PGx Working Group clinical guidelines.
3. Outline the importance of standardizing PGx testing across clinical laboratories
4. Discuss the key considerations of clinical PGx test development, including gene contents, testing methods, and reference materials.
5. Describe and discuss AMP PGx Working Group 'Tier 1 and 2' recommended alleles for CYP2C19, CYP2C9, warfarin sensitivity genes, and CYP2D6.

Target Audience: Molecular pathologists, residents, laboratory directors, technologists, and others who have some prior exposure to molecular diagnostic testing. Secondary audiences include oncologists, genetic counselors, primary care clinicians, and other health care professionals.



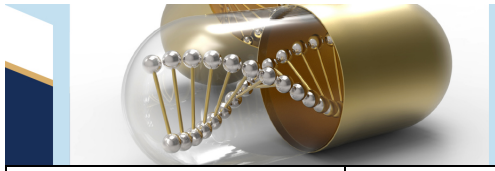
PHARMACOGENOMICS Genes, Drugs, and Genotyping: AMP Pharmacogenomics Guidelines

An Online Learning Experience

AMP Association for Molecular Pathology

CERTIFICATE PROGRAM OUTLINE:

Title	Speaker(s)	Description	Learning Objectives	Duration
Welcome Remarks from Content Director	**Speaker:** Victoria Pratt, PhD, FACMG			5 min
Pre-test measuring baseline knowledge				30 min
Introduction to Pharmacogenetics	**Speaker:** Reynold Ly, PhD	This presentation introduces key concepts and terms used in pharmacogenetics including pharmacogenetic star-allele nomenclature and metabolizer status. **RECORDED: September 23, 2021**	• Describe how pharmacogenetics relates to genes involved in drug pharmacokinetics and pharmacodynamics • Define basic pharmacogenetic terms • Describe pharmacogenetic star-allele nomenclature • Differentiate between various metabolizer statuses based on allele function	20- 30 min
Knowledge Check – Introduction to Pharmacogenetics (A score of 80% correct or better is required to obtain the AMP's Certificate of Completion)				~5 min
Recommendations for Clinical *CYP2C19* Genotyping Allele Selection	**Speaker:** Karen E. Weck, MD, FACMG **Moderator:** Joshua Deignan, PhD	A presentation on the recommendations of the AMP Pharmacogenomics (PGx) Working Group of the Clinical Practice Committee for inclusion of variants in *CYP2C19* genotyping panels. The working group has published consensus, evidence-based recommendations using criteria such as allele function, population frequency, and availability of reference materials. The recommendations include a Tier 1 minimum set of alleles and defining variants that should be included in all clinical *CYP2C19* PGx tests, and a Tier 2 list of additional optional alleles that do not currently meet all of the criteria for inclusion in Tier 1. These recommendations are intended to aid clinical laboratory professionals when designing and validating *CYP2C19* genotyping assays, promote standardization of testing across different laboratories, and complement existing clinical guidelines for PGx testing. **RECORDED: March 21, 2018**	• List the three most common alleles associated with *CYP2C19* altered metabolism and their respective effects on enzymatic function. • Give examples of key drugs in clinical use that are affected by *CYP2C19* genetic variability affecting enzymatic activity. • Describe the key characteristics of PGx alleles that are recommended for inclusion in clinical testing platforms by the AMP PGx working group.	60 min
Knowledge Check –*CYP2C19* (A score of 80% correct or better is required to obtain the AMP's Certificate of Completion)				~5 min
Recommendations for Clinical *CYP2C9* Genotyping Allele Selection	**Speaker:** Stuart A. Scott, PhD, FACMG **Moderator:** Yuan Ji, PhD, MBA, FACMG	The goals of the AMP PGx Working Group of the AMP Clinical Practice Committee are to define the key attributes of PGx alleles recommended for clinical testing and a minimum set of variants that should be included in clinical PGx genotyping assays. The *CYP2C9* project and manuscript provides recommendations for a minimum panel of variant alleles (Tier 1) and an extended panel of variant alleles (Tier 2) that will aid clinical laboratories when designing assays for *CYP2C9* testing. **RECORDED: September 5, 2019**	• Identify sequence variants that define *CYP2C9* star (*) allele haplotypes. • Describe *CYP2C9* PGx and list clinically relevant medications that are metabolized by CYP2C9. • Describe the reported *CYP2C9* 'Tier 1 and 2' recommended alleles.	60 min
Knowledge Check – *CYP2C9* (A score of 80% correct or better is required to obtain the AMP's Certificate of Completion)				~5 min



PHARMACOGENOMICS Genes, Drugs, and Genotyping: AMP Pharmacogenomics Guidelines

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Recommendations for Clinical Warfarin Genotyping Allele Selection	**Speaker** Yuan Ji, PhD, MBA, FACMG **Moderator** Andria L. Del Tredici, PhD	This is a 2020 update from the AMP PGx Working Group on clinical warfarin sensitivity testing. Building on recommendations on CYP2C19 and CYP2C9 allele selections in the previous two manuscripts/presentations, the speaker now addresses Warfarin sensitivity genotyping allele selection for clinical laboratories to use as guidelines when designing and developing these PGx assays. Healthcare providers may also find these documents useful in comparing and contrasting PGx tests across clinical laboratories when they are familiar with a "must-test" list for each of the pharmacogenes. **RECORDED: March 10, 2020**	• Describe Warfarin PGx and the importance of standardization of clinical PGx and its implications to patient care. • Describe the AMP PGx Working Group 'Tier' system of PGx sequence variants/alleles recommendation. • Explain the key attributes of Tier 1 and Tier 2 recommended alleles for clinical warfarin sensitivity genotyping.	60 min
Knowledge Check – *Warfarin* (A score of 80% correct or better is required to obtain the AMP's Certificate of Completion)				~5 min
Recommendations for Clinical *CYP2D6* Genotyping Allele Selection	**Speaker**: Ann Moyer, MD, PhD **Moderator**: Andria del Tredici, PhD	This is a presentation on updating clinical CYP2D6 testing. As with the previous presentations, clinical laboratories can use these guidelines when designing and developing PGx assays, thus promoting the standardization of clinical PGx testing across different clinical laboratories. This is the final of four genes covered in this series on pharmacogenetics in the molecular laboratory. **RECORDED: June 8, 2021**	• Describe *CYP2D6* PGx and the importance of standardization of clinical PGx and its implications to patient care. • Describe the AMP PGx Working Group 'Tier' system of PGx sequence variants/alleles recommendation. • Explain the key attributes of Tier 1 and Tier 2 recommended alleles for *CYP2D6* genotyping.	60 min
Knowledge Check – *CYP2D6* (A score of 80% correct or better is required to obtain the AMP's Certificate of Completion)				~5 min
Additional Useful Resources	• Resource document • Molecular in My Pocket™ Card			
Case Study Questions				15 min
Closing Remarks	**Speaker:** Victoria Pratt, PhD, FACMG			1 min
Course Evaluation				10 min
Claiming CME, CMLE, and AMP Certificate of Completion				