Put It on the Board

Minimum set of alleles recommended for clinical *CYP2C9* genotyping

June 2019—A joint report from the CAP and the Association for Molecular Pathology was published last month to aid in the design and validation of clinical *CYP2C9* assays, promote standardization of testing across different laboratories, and improve patient care. The report, "Recommendations for Clinical *CYP2C9* 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* (doi:10.1016/j.jmoldx.2019.04.003).

The AMP Pharmacogenetics Working Group is developing a series of guidelines to help standardize clinical testing for frequently used genotyping assays. Developed with organizational representation from the CAP and the Clinical Pharmacogenetics Implementation Consortium, the latest report follows a set of recommendations for clinical *CYP2C19* genotyping allele selection published in May 2018. These reports define a minimum set of alleles/variants that should be included in clinical genotyping panels for two of the most important PGx genes.

"The AMP PGx Working Group started with *CYP2C19* and *CYP2C9* 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," Victoria Pratt, PhD, associate professor and director of pharmacogenetics and molecular genetics laboratories, Indiana University School of Medicine, said in an AMP statement. Dr. Pratt is AMP president and PGx Working Group chair.

The new report offers a two-tier categorization of *CYP2C9* alleles as an aid for designing *CYP2C9* genotyping assays.

FDA clears Aperio AT2 DX for clinical diagnosis

Leica Biosystems received clearance from the Food and Drug Administration to market its Aperio AT2 DX System for clinical diagnosis in the United States.

A multicenter study supporting this clearance was conducted at five clinical study sites: University of California Davis, Pacific Rim Pathology, Dignity Health, TriCore Reference Laboratories, and Intermountain Healthcare. The participating pathologists read approximately 16,000 cases.

The Aperio AT2 DX is a high-throughput automated scanning and viewing platform. It will be launched commercially with clinical image management software for an integrated digital pathology workflow solution.

Qiagen launches QIAstat-Dx

Qiagen launched in the U.S. its FDA-cleared QIAstat-Dx syndromic testing system with a respiratory panel that detects more than 20 pathogens.

The QIAstat-Dx (formerly Stat-Dx DiagCore) received CE-IVD marking in January 2018.

Qiagen says the respiratory panel is the first test in a deep and broad pipeline of planned assays for QIAstat-Dx in the U.S. It plans to launch a gastrointestinal panel later this year.

The following pathogens and subtypes are identified using the QIAstat-Dx respiratory panel: adenovirus; coronaviruses 229E, HKU1, NL63, OC43; human metapneumovirus A+B; influenza A, A H1, A H3, A H1N1/pdm09, B; parainfluenza viruses 1, 2, 3, 4; rhinovirus/enterovirus; RSV A+B; and *Bordetella pertussis*, *Chlamydophila pneumoniae*, and *Mycoplasma pneumoniae*.

TV/MG test added to Cobas 6800/8800 menu

The Food and Drug Administration cleared the Cobas TV/MG test for use on the Cobas 6800/8800 systems for the detection of *Trichomonas vaginalis* and/or *Mycoplasma genitalium* DNA in symptomatic and asymptomatic patients. Laboratories can now simultaneously process from a single sample a combination of *Chlamydia trachomatis, Neisseria gonorrhoeae, Trichomonas vaginalis*, and *Mycoplasma genitalium*.

In other news, Roche announced the CE-IVD launch of the Cobas MTB-RIF/INH test to detect resistance to antibiotics within tuberculosis DNA. This assay is part of the mycobacteria test menu that includes the Cobas MTB and Cobas MAI tests for use on the 6800/8800 systems.

Abbott, DoD, and TRACK-TBI study point-of-care blood test for concussions

Abbott announced the next phase of a partnership with the U.S. Department of Defense and researchers from the Transforming Research and Clinical Knowledge in Traumatic Brain Injury (TRACK-TBI) Network. Together the groups will conduct a clinical trial to evaluate the effectiveness of an Abbott point-of-care blood test technology that is under development to help clinicians assess brain injuries within minutes.

Abbott and the DoD began their work in 2014 to develop a portable blood test that helps assess concussions at a person's side. Abbott has more than 120 scientists who are researching and developing its concussion assessment test for the next-generation i-Stat Alinity system. The blood test under development would measure two types of proteins—GFAP and UCH-L1—that are released from the brain and into the blood when the brain is injured.

A critical part of the TRACK-TBI research initiative is to evaluate the effectiveness of blood-based biomarkers to detect brain injury. Abbott and the DoD will work with researchers from TRACK-TBI for this clinical trial to analyze data collected from patients who come to top trauma centers across the country.

TRACK-TBI Network is a collaborative research effort funded by the National Institute of Neurological Disorders and Stroke and the DoD through U.S. Army Medical Research and Materiel Command and U.S. Army Medical Materiel Development Activity, with support from private and philanthropic partners.