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AMP issues recommendations for clinical *CYP2C19* genotyping allele selection

To promote standardized testing across laboratories, the Association for Molecular Pathology published on Feb. 27 consensus, evidence-based recommendations for designing and validating clinical *CYP2C19* assays.

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* (doi:10.1016/j.jmoldx.2018.01.011).

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, and 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.

Victoria M. Pratt, PhD, associate professor of medical and molecular genetics at Indiana University School of Medicine and AMP PGx Working Group chair, said in a statement that the 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."

The 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 working group recommended a minimum set of alleles and their defining variants that should be included in all clinical CYP2C19 PGx tests (tier one). The team also defined a tier two list of optional *CYP2C19* alleles that do not currently meet one or more of the criteria for inclusion in tier one. The recommendations are intended to facilitate testing and improve genotyping concordance across laboratories.

Karen E. Weck, MD, director of the medical genetics laboratory at the University of North Carolina School of Medicine and AMP PGx Working Group member, said a series of recommendations for PGx genes beyond *CYP2C19* will be published.

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Phase 3 results for Tecentriq plus Avastin in mRCC

Roche announced last month the results from the phase three IMmotion151 study of Tecentriq (atezolizumab) and Avastin (bevacizumab) as a first-line treatment for advanced or metastatic renal cell carcinoma. The study met its

co-primary endpoint of investigator-assessed progression-free survival in people whose disease expressed the PD-L1 (expression ≥1 percent) protein.

Those who received Tecentriq plus Avastin had a 26 percent reduced risk of disease worsening or death compared with people treated with sunitinib (median PFS: 11.2 versus 7.7 months; HR=0.74; 95 percent CI: 0.57, 0.96; P=0.02). Initial observations from the co-primary endpoint of overall survival in the overall study population (intention-to-treat) were encouraging but are still immature, Roche said in a statement.

Observations of a pre-specified subgroup analysis of the Tecentriq and Avastin combination indicated that in people whose disease expressed PD-L1, a numerical difference in progression-free survival favoring Tecentriq was seen across all patient risk factor groups (favorable, intermediate, and poor) compared with sunitinib.

In addition, a predefined analysis of patient-reported outcomes revealed that the combination of Tecentriq and Avastin markedly delayed the time to a worsening of disease symptoms that interfere with day-to-day life compared with sunitinib (median time to deterioration: 11.3 versus 4.3 months; HR=0.56; 95 percent CI: 0.46, 0.68) in the intention-to-treat population.

The IMmotion151 data were presented Feb. 10 at the 2018 Genitourinary Cancers Symposium.
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SeraCare's CNV-specific reference material for NGS

SeraCare Life Sciences launched its Seraseq Breast CNV and Seraseq Lung and Brain CNV Mix, which are copy number variation reference materials for next-generation sequencing assays. Reference materials that analyze for CNVs allow for variant assessment of DNA-based tumor profiling and diagnostic molecular assays beyond SNVs and indels.

SeraCare's products were quantified using digital PCR assays to analyze amplifications of *EGFR, MET, FGFR3, MYC, ERBB2*, and *MYCN* genes at +3, +6, and +12 copies against a single well-characterized genomic background (GM24385).
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Qiagen launches Therascreen PITX2 in Europe

Qiagen launched last month in Europe its Therascreen PITX2 RGQ PCR Kit, the first clinically validated DNA methylation assay that helps predict the response of certain high-risk breast cancer patients to anthracycline-based chemotherapy. The CE-IVD marked assay is Qiagen's first epigenetic test in breast cancer and the latest addition to its portfolio of Therascreen tests.

"This reliable, clinically validated assay determines the PITX2 DNA methylation ratio to differentiate between patients who are more likely, or less likely, to show beneficial response to anthracyclines," Thierry Bernard, senior VP of the molecular diagnostics business area, said in a statement. "The simple workflow of the Therascreen PITX2 assay provides automated processing from sample to insight in less than 48 hours." It runs on the QIAsymphony platform.
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Aptima HBV Quant assay receives PMA approval

The FDA granted PMA approval for the Aptima HBV Quant assay for quantitation of hepatitis B viral load on the fully automated Panther system.

The Aptima HBV Quant assay is the newest addition to the Panther system's viral load menu. Also approved are

the Aptima HIV-1 Quant assay and Aptima HCV Quant Dx assay. All three assays use Hologic's real-time transcription-mediated amplification. The HBV Quant assay quantitates HBV DNA across all major genotypes A-H.

"We now have available on a single system the three major viral load assays that most laboratories are asked to run for patients," Tom West, president of Hologic's diagnostic solutions division, said in a statement.
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Alcor's iSED used at Olympics

Alcor Scientific's iSED analyzer was used by the laboratory at the Pyeongchang Olympic Winter Games and Paralympic Winter Games medical center. The medical center was constructed by a task force from South Korea's major hospitals to care for injured athletes. The iSED is a fully automated erythrocyte sedimentation rate analyzer.
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George Lundberg joins Self Care Catalysts

George D. Lundberg, MD, of Los Gatos, Calif., has been appointed chief medical officer and chair of medical and scientific advisors for Self Care Catalysts, a patient solutions, intelligence, and analytics company. Dr. Lundberg joins the company after eight years as editor in chief and chief medical officer of CollabRx.

Dr. Lundberg, a CAP member, is also currently president and chair of the board of directors of the Lundberg Institute, a consulting professor at Stanford University, executive adviser of Cureus, editor in chief of Cancer Commons, and editor at large for Medscape from WebMD. [hr]