Put It on the Board

FDA clears 2 of 3 ePlex blood culture ID panels

January 2019—GenMark Diagnostics announced in December that it received FDA market clearance for its ePlex Blood Culture Identification Gram-Positive (BCID-GP) and Fungal Pathogen (BCID-FP) panels.

GenMark's third panel, ePlex Blood Culture Identification Gram-Negative (BCID-GN), was submitted to the FDA in September 2018 and is still under review.

The fungal pathogens panel has broad coverage and includes many resistant and emerging strains, among them *Candida auris*, GenMark said in its statement.

The company says that by coupling BCID panels with the ePlex Templated Comments software module, hospitals can enable immediate intervention linked to a diagnostic result and improve the effectiveness of antimicrobial stewardship initiatives.

12 assays for Atellica Solution

Siemens Healthineers achieved 12 pre-market approvals from the FDA for its Atellica Solution infectious disease and oncology testing menu.

The infectious disease tests approved last year for the Atellica Solution are for HIV (HIV Ag/Ab Combo and HIV 1/O/2 Enhanced) and hepatitis B and C (Anti-HBs 2, HBsAg II, HBsII Confirmatory, HBc IgM, HBc Total, HBeAg, and HCV). Also approved last year: PSA, cPSA, and AFP assays.

"These 12 PMA assays, combined with recently released high-sensitivity troponin I and procalcitonin assays, provide a comprehensive menu on the Atellica Solution," Deepak Nath, PhD, president, laboratory diagnostics, Siemens Healthineers, said in a statement.

Qiagen to develop companion Dx for *PIK3CA*-mutated advanced breast cancer

Qiagen reported that it has a clinical development program underway with Novartis to bring to market a molecular test to guide the use of the investigational compound BYL719 (alpelisib) in combination with fulvestrant for men and postmenopausal women living with *PIK3CA*-mutated hormone-receptor–positive/HER2-negative advanced or metastatic breast cancer.

The Novartis drug candidate is in late-stage development.

Qiagen says its companion diagnostic for *PIK3CA* mutations will provide a Sample to Insight workflow, from DNA extraction to detection of the clinically relevant mutations and final reporting. The test will be clinically validated for analysis of FFPE tissue and liquid biopsy samples using plasma. It will run on the Rotor-Gene Q MDx cycler.

"Currently, no FDA-approved drugs are available on the U.S. market to specifically target this mutation in breast cancer. Under our master collaboration agreement with Novartis, we are fast-tracking the development of a companion diagnostic for BYL719 to help close this gap," Jonathan Arnold, vice president and head of oncology and precision diagnostics for Qiagen, said in a statement.

Roche to develop companion Dx for use with Keytruda

Roche has entered into a collaboration with Merck to develop a pan-cancer companion diagnostic to detect mismatch repair deficiency in solid tumors.

The companion diagnostic is under development now. It is an immunohistochemical test for use on the Roche

BenchMark Ultra instrument.

Qiagen introduces new workflow, panel at ASH 2018

Qiagen launched late last year, at the ASH 2018 meeting, a new workflow for its Clinical Insight Interpret bioinformatics solution for hematological malignancies. It also launched its new QIAact Myeloid DNA UMI Panel for use in myeloid neoplasm research as a Sample to Insight workflow on the GeneReader NGS System.

The myeloid panel provides an integrated Sample to Insight workflow targeting the genes and variants of most relevance to onco-hematology research. It is integrated with bioinformatics for analysis and interpretation, and it became available for research use only in December 2018.

The panel covers 25 genes and their variants, including single nucleotide variants and insertions/deletions of known significance to clonal myeloid malignancy. The genes targeted are *JAK2, CALR, IDH1/2, FLT3, KIT, SRSF2, TP53,* and others.

The new workflow for QCI Interpret was designed to consider the heterogeneous nature of myeloid malignancies and provides actionable information for the subclassification and prognostic assessment of hematological malignancies. QCI Interpret is a web-based clinical decision support platform.

New test ordering module

A module on colorectal cancer biomarkers is the latest to be added to the CAP Test Ordering Program, which provides CAP members with information about commonly misapplied lab tests so optimal ordering can be addressed with clinicians and others.

The new module covers *BRAF* testing as a follow-up to microsatellite instability in the exclusion of Lynch syndrome.

The CRC biomarker module is the program's fifth module. The others are on HCV infection, BNP and NT-proBNP, red blood cell folate testing, and cardiac markers. The program, which became available in 2017, is free to all members. For the modules, go to www.cap.org/member-resources/test-ordering-program.