Put It on the Board

Early Sepsis Indicator receives 510(k) clearance

May 2019—Beckman Coulter's Early Sepsis Indicator received 510(k) clearance from the Food and Drug Administration.

Beckman Coulter says clinical trial findings showed that its monocyte distribution width biomarker best discriminated sepsis from all other conditions when combined with the current standard of care.

The Early Sepsis Indicator is automatically reported as part of a routine complete blood count with differential for adult emergency department patients. A positive Early Sepsis Indicator result signals a higher probability of sepsis. Compared with reviewing WBC count alone, Beckman Coulter says the Early Sepsis Indicator strengthens a clinician's suspicion of sepsis by 43 percent and, together with clinical signs and symptoms, improves confidence in helping to rule out sepsis by 63 percent.

The indicator can be used in conjunction with the company's Multidiscipline Reflex Rules in Remisol Advance middleware.

Qiagen launches CDx to help guide metastatic urothelial cancer treatment

Qiagen announced the U.S. launch of its Therascreen FGFR RGQ RT-PCR Kit as a companion diagnostic to help guide the use of newly approved FGFR kinase inhibitor Balversa (erdafitinib), developed by Janssen Biotech. The test will aid in identifying patients with urothelial cancer whose tumors have certain alterations in the fibroblast growth factor receptor 3 (FGFR3) gene. The Food and Drug Administration co-approved the new test with Balversa.

The Therascreen FGFR Kit will run on Qiagen's Rotor-Gene Q MDx.

An updated list of laboratories offering the new Therascreen FGFR Kit under Qiagen's Day-One Lab Readiness program is available at www.qiagen.com/fgfr-lab-finder.

FDA clears GenMark ePlex BCID-GN panel

GenMark Diagnostics received FDA 510(k) market clearance from the Food and Drug Administration for its ePlex Blood Culture Identification Gram-Negative Panel.

This is the third ePlex BCID Panel to receive FDA clearance in recent months. The other two are the Gram-Positive and Fungal Pathogen panels, developed on the company's ePlex system for the diagnosis and management of bloodstream infections.

Beckman Coulter expands portfolio of ClearLLab IVD reagents for flow cyto

Beckman Coulter is launching the ClearLLab 10C System for the clinical flow cytometry laboratory. It is a 10-color IVD panel of immunophenotyping reagents cleared by the Food and Drug Administration for lymphoid and myeloid lineages.

The four dry premixed antibody tubes use the company's Dura Innovations technology, eliminating the need to pipette antibodies.

The integrated ClearLLab 10C System consists of ClearLLab Control Cells, a liquid preparation of stabilized human erythrocytes and leukocytes. They include assay values for the 27 markers on the four ClearLLab10C panels, available for normal and abnormal controls. Also part of the system are Clear-LLab Compensation Beads for

establishing compensation using the ClearLLab compensation kit, which includes 10 single-color tubes for each compensation setup, and Kaluza C analysis software v 1.1 or higher.

The four ClearLLab 10C panels are designed to run on Beckman Coulter's Navios and Navios EX flow cytometers. When using the ClearLLab 10C System, compensation is required only on initial setup of the application, when daily QC fails, after instrument service as needed, or when switching to a new lot of Flow-Set Pro.

Roche launches Ventana HER2 Dual ISH CDx

Roche launched its Ventana HER2 Dual ISH DNA Probe Cocktail assay for the detection of the HER2 biomarker in breast and gastric cancer.

The assay is being launched in Europe, the Middle East, Africa, Latin America, and Asia Pacific. It will be submitted to the Food and Drug Administration for approval.
The new assay is designed to be completed within the same day. Results can be read using light microscopy.

Prescient Medicine acquires AutoGenomics

Prescient Medicine Holdings has acquired AutoGenomics, developer of the Infiniti platform. Prescient says the acquisition will enable it to advance the development and commercialization of the Infiniti Neural Response Panel, a diagnostic test for identifying patients who may be at risk for opioid use disorder.

The Food and Drug Administration granted the panel a breakthrough device designation. Prescient and AutoGenomics intend to pursue a de novo premarket submission.