Beckman Coulter’s Early Sepsis Indicator gets 510(k) clearance

April 22, 2019—Beckman Coulter announced that its Early Sepsis Indicator received 510(k) clearance from the U.S. Food and Drug Administration. The Early Sepsis Indicator is a hematology-based cellular biomarker designed to help emergency department physicians identify patients with sepsis or who are at an increased risk of developing sepsis and is reported automatically as part of a routine CBC with differential test.

The pivotal clinical trial findings for the Early Sepsis Indicator showed that Beckman Coulter’s monocyte distribution width biomarker “best discriminated sepsis from all other conditions when combined with the current standard of care,” the company reports. Derek Angus, MD, MPH, chair of the Department of Critical Care Medicine at University of Pittsburgh Medical Center, a collaborator in the study, said that the Early Sepsis Indicator is “a novel feature in that is exploiting the way in which white blood cell counts are already calculated.”

Compared with reviewing white blood cell count alone, the Early Sepsis Indicator strengthens a clinician’s suspicion of sepsis by 43 percent and, together with clinical signs and symptoms, improves their confidence in helping to rule out sepsis by 63 percent, Beckman Coulter said in a press release.