Access PCT cleared by the FDA

Feb. 13, 2020—Beckman Coulter's Access PCT assay has received FDA 510(k) clearance and is available for sale in the United States. The assay enables health care providers to integrate procalcitonin testing analysis into their routine sepsis workups on core laboratory analyzers, as a primary or reflex test programmed through Beckman Coulter's Remisol Advance middleware. Test results are available in less than 20 minutes.

"Bringing the Access PCT assay into our core laboratory automated workflow makes it possible to streamline procalcitonin testing into our routine service to clinical teams," Bernard C. Cook, PhD, chemistry division head and director of automated core laboratory operations at Henry Ford Hospital in Detroit, said in a press stament from Beckman Coulter. "In addition, our early evaluations confirmed that the assay has the accuracy and low-end sensitivity needed to help clinicians determine the best treatment options for patients with sepsis and other infections."

Access PCT is available for use on the company's Access family of immunoassay systems, including the Access 2, UniCel DxI 600, and UniCel DxI 800.