NEWS RELEASE

Contact:

Angie Habis-Marchetti
Beckman Coulter Brand and Public Relations
714-961-4082 › ahhabismarchetti@beckman.com

FOR IMMEDIATE RELEASE

Beckman Coulter Files a 510(k) Submission with the FDA for Its Early Sepsis Indicator*

Offered as part of a routine CBC with differential test, the hematology-based solution is intended to alert emergency department clinicians to sepsis or the possibility of sepsis earlier than any other indicator

BREA, CALIF. — (June 25, 2018) — Beckman Coulter announced that it has filed a submission for 510(k) clearance with the U.S. Food and Drug Administration (FDA) for its Early Sepsis Indicator. The first-of-its-kind hematology-based solution is designed to give clinicians insight into the possibility of sepsis or risk of developing sepsis in patients in acute-care settings. The Early Sepsis Indicator is offered as part of a standard CBC with differential test. As such, test results can be available in less than one hour without additional workflow burden for clinicians or clinical laboratories. The Early Sepsis Indicator, which recently achieved European CE Mark, is commercially available in select countries for use with the company's newly released DxH 900 hematology analyzer.

Sepsis is a global healthcare crisis, affecting 26 million people worldwide every year[1] and increasing at a rate of 1.5% annually.[2] Sepsis not only significantly affects patients and their loved ones, but also it places considerable clinical and economic burden on the healthcare system at large.[3] The availability of timely, accurate detection solutions in the emergency department where treatment can be initiated, is critical to stopping the progression of this life-threatening condition. Patients with less severe sepsis can progress to severe sepsis or septic shock within 72 hours,[4] and up to half of patients with sepsis die.[2,5] A clear link exists between the timeliness of treatment and mortality.[6]

"We want to give clinicians in the emergency department a simple tool to help them identify sepsis quickly, shortening time to treatment for these critical patients," said Peter Soltani, Ph.D., senior vice president

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and general manager of the hematology business at Beckman Coulter. “Getting actionable clinical information to emergency department physicians sooner can speed critical treatment decisions.”

The Early Sepsis Indicator uses the DxH 900 hematology analyzer’s enhanced Coulter technology, which offers near native-state cellular characterization. The company’s powerful VCS 360 technology can uniquely detect morphological changes in monocytes, cells that play a role in the dysregulated immune response to sepsis. Identifying these monocyte morphological changes provides insight into possible sepsis earlier than other indicators.

About Beckman Coulter

Beckman Coulter Diagnostics helps healthcare and laboratory professionals provide better patient care by delivering the accurate diagnostic information they need, when they need it. For over 80 years, Beckman Coulter has been the partner of choice for healthcare organizations. Our scalable instruments, comprehensive diagnostic tests and business management services are trusted by hospitals, laboratories and other critical care settings around the world. We share in our customers' mission toward continuous improvement and quality patient care because we believe when efficiency and clinical outcomes are improved, patients benefit and we can move healthcare forward for every person.

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4. Glickman SW et al. “Disease Progression in Hemodynamically Stable Patients Presenting to the Emergency Department with Sepsis.” *Acad Emerg Med*, vol. 17. 2010, pp. 383–90.
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Disclaimer: *The Early Sepsis Indicator is CE Marked and is pending 510(k) clearance by the U.S. FDA. Not yet available for in vitro diagnostic use in the U.S.The DxH 900 analyzer is not available in all countries. The Early Sepsis Indicator is not available in all countries.*