FDA-approved sepsis test, 6/16

June 2017—Immunexpress received FDA 510(k) clearance for the use of SeptiCyte Lab as an aid in differentiating infection-positive (sepsis) from infection-negative (SIRS) systemic inflammation in critically ill patients on their first day of ICU admission. It is the first RNA-based clinical diagnostic tool, direct from whole blood, to aid medical providers in the early identification of infection in suspected sepsis patients, according to a company statement.

The SeptiCyte Lab blood test aids in differentiating infection in 100 percent of suspected sepsis patients in as few as 4.5 hours from sample draw, Roy Davis, MD, PhD, chief medical officer of Immunexpress, said in the statement.

“In 447 suspected sepsis patients, SeptiCyte Lab predicted all patients with a positive blood culture in a matter of a few hours. This is a major advance over the currently available technology that delivers a result in days, not hours, and in only 10 to 20 percent of suspected sepsis patients,” Roslyn Brandon, DVM, PhD, president and CEO of Immunexpress, said.

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