Revolutionary Diagnostic SeptiCyte™ LAB Cleared By FDA for Suspected Sepsis Patients

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SEATTLE, Feb. 22, 2017 – Immunexpress, Inc., a molecular diagnostic company committed to improving outcomes for suspected sepsis patients and healthcare providers, today announced it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) 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.

"Sepsis is a medical emergency. When recognized and treated early, lives are saved and costs are reduced," said Dr. Roy Davis Immunexpress Chief Medical Officer. "Standardized, rapid and objective diagnostics are needed for better clinical agreement in these patients. The SeptiCyte™ LAB blood test aids in differentiating infection in 100% of suspected sepsis patients in as few as 4.5 hours from sample draw."

Sepsis is a complication caused by a patient's overwhelming and life-threatening immune response to infection and can lead to tissue damage, organ failure and death. It is the most expensive in-patient cost in U.S. hospitals, totaling over $20 billion each year. Currently, confirmation of a clinical diagnosis of sepsis relies on pathogen detection, which can take up to several days.

Immunexpress's Dr. Roslyn Brandon, President and CEO states: "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% of suspected sepsis patients".

Immunexpress is aiming to revolutionize clinical diagnostics for suspected sepsis patients by facilitating earlier, faster and more specific infection recognition using the patient's own inflammatory response. By identifying four blood biomarkers, clinicians can access objective information to aid providers in diagnostic and targeted treatment decisions. This revolutionary technology will also aid clinical decisions in patients without infection where de-escalation of care and reducing antimicrobial treatment are appropriate".

Dr. Brandon adds that “the company is in advanced discussions with potential IVD and point of care instrument partners for the development of automated versions of the test which will be submitted to the FDA. The company also continues discussions with a key IVD partner in respect of a staged commercial launch of SeptiCyte™ LAB in the second half of 2017.”

Any customers seeking early access to the assay can send enquiries to http://www.immunexpress.com/corporate/contact-us/.

Immunexpress is currently developing and planning further SeptiCyte™ assays to enhance the quality and power of clinical information, as well as increase the speed of result.

About Immunexpress

Immunexpress is a Seattle-based molecular diagnostic company committed to improving outcomes for patients suspected of sepsis. Immunexpress’s SeptiCyte™ technology rapidly quantifies, directly from whole blood, specific molecular markers from the patient’s own immune system – the “host response”. Detecting the host’s response to infection has the potential to differentiate infection earlier, faster and more accurately than finding the invading pathogen because it is independent of whether or not the pathogen is present in the sample. Immunexpress’s pipeline includes several assays for readily available instruments, including random access, point-of-care (POC) and sample-to-answer.