ICU MANAGEMENT & PRACTICE

FDA Clears Abionic's IVD CAPSULE PSP for the Early Detection of Sepsis

abionic
Early Sepsis Detection

Abionic, an emerging medical diagnostics company focused on rapid early detection technologies, announced today that its **IVD CAPSULE PSP** test has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) to accelerate the *Time-to-Detection* of Sepsis. Already certified under the EU IVDR as of July 2022, this FDA clearance marks a pivotal moment for Abionic's expansion into the U.S. market.

Sepsis is a global health threat affecting 50M patients worldwide and responsible for 11M deaths, or 20% of all global deaths. In the United States, it strikes 1.7M patients and costs $38B annually, making it a major public health challenge. Sepsis is a time-sensitive emergency and according to the Sepsis Alliance, 80% of sepsis-related deaths could be prevented, but it remains notoriously difficult to diagnose due to the non-specific nature of its symptoms, which often resemble those of other common conditions. The timely and early detection of sepsis is critical to initiate optimal treatment protocols and increase the odds of patient survival.

Pancreatic Stone Protein **(PSP)** is an emerging sepsis biomarker used by clinicians as a screening tool for the early-detection of sepsis 24-48h earlier than current standards to support critical time-sensitive decisions. Produced by the pancreas and immune cells, **PSP** levels increase in response to infections and inflammation and has demonstrated significant sensitivity and specificity in detecting sepsis, particularly in critically ill patients. Clinical studies have shown that elevated **PSP** levels correlate closely with the progression of sepsis, allowing healthcare professionals to activate sepsis bundles earlier and improve outcomes.

The **IVD CAPSULE PSP** runs exclusively on the **abioSCOPE®**, an award-winning rapid diagnostics platform that leverages nanofluidics to deliver lab-quality results from a drop of blood within minutes. Seamlessly integrated into routine clinical workflows, the test delivers fast, accurate, and user-friendly results in critical care settings. By measuring PSP levels, which are directly linked to a patient's risk of sepsis, the test enables clinicians to make informed decisions and initiate appropriate treatments earlier, improving outcomes.

"Achieving FDA 510(k) clearance for **IVD CAPSULE PSP** marks a significant milestone for Abionic and confirms our ability to meet the need for quick & reliable sepsis testing," said Patrick Pestalozzi, CEO at Abionic. "This clearance will allow us to deploy our solutions across the United States and provide clinicians in acute care settings with a proven solution to accelerate the Time-To-Detection of sepsis."

For more information about **IVD CAPSULE PSP** and its role in early sepsis detection, please visit www.abionic.com or contact Patrick Pestalozzi.

Source & Image Credit: Abionic

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