PSP (PANCREATIC STONE PROTEIN) ON THE ABIOSCOPE® TRUE ENABLER OF EARLY SEPSIS DETECTION

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abionic

SEPSIS IS A MEDICAL EMERGENCY REQUIRING IMMEDIATE DIAGNOSIS & TREATMENT

Pancreatic Stone Protein (PSP) on the abioSCOPE® is the Earliest Marker of Sepsis

Sepsis is a major healthcare burden claiming more than 11 million lives per year, one death every 2.8 seconds[1].

It is caused by a dysregulated host response to infection which can progress to multiple organ dysfunction, septic shock and death.

It's a medical emergency that requires immediate diagnosis.
Unfortunately, current standards of care often lead to sepsis being diagnosed too late.

50m
sepsis cases every year[1]

Every hour antibiotic therapy is delayed, the chances of survival decrease by

8% [2]

The clinical signs and symptoms of sepsis are generic and non-specific, making it extremely challenging to timely identify.

The availability of an early and accurate biomarker at the patient's bedside is key to enabling faster treatment decisions, reduce mortality and lower sepsis-related healthcare costs.

EARLY SEPSIS DETECTION UP TO 72 HOURS BEFORE THE STANDARD OF CARE IN 5 MIN*

The PSP Test on the abioSCOPE® Can Save Millions of Lives

The **IVD CAPSULE PSP** on the **abioSCOPE®** is the first CE-marked *in vitro* diagnostic test to enable fast, reliable and early sepsis detection at the point-of-care from a single drop of blood in only 5 minutes*.

Get accurate results in
5min

A multicentric study published recently in *Critical Care*, proves that bedside measurement of PSP on the abioSCOPE® clearly correlates with the onset of sepsis, **enabling personalized clinical management of patients in the ICU[3].**

An increasing PSP concentration in the days preceding the clinical diagnosis of sepsis, offers a unique window of opportunity for clinicians to initiate timely the right treatment.

Reducing time to treatment by up to
72h
could dramatically improve patients' outcome

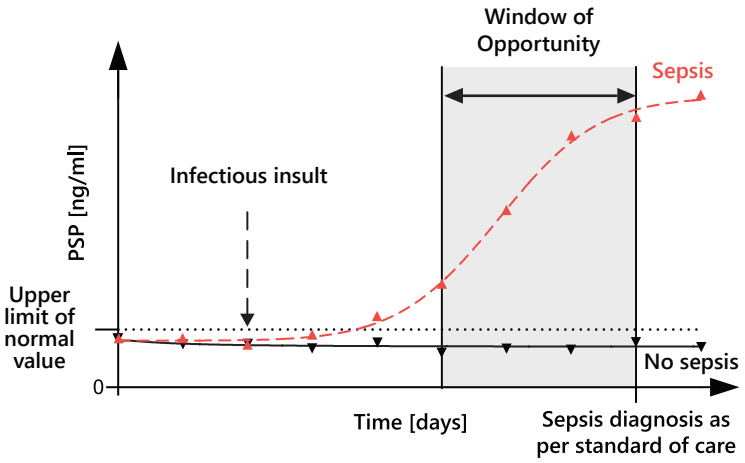

Figure 1. Schematized daily PSP biomarker readings in patients who develop nosocomial sepsis (dashed red line) or not (solid black line).

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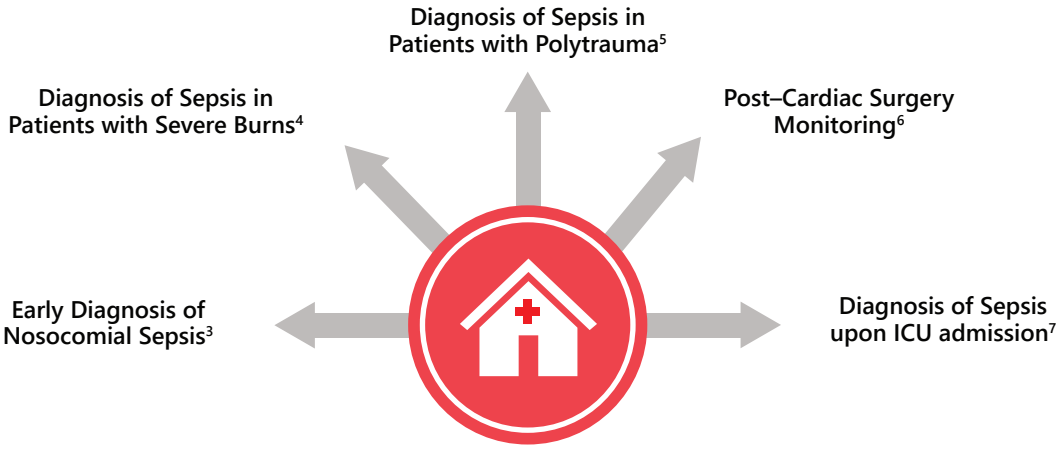
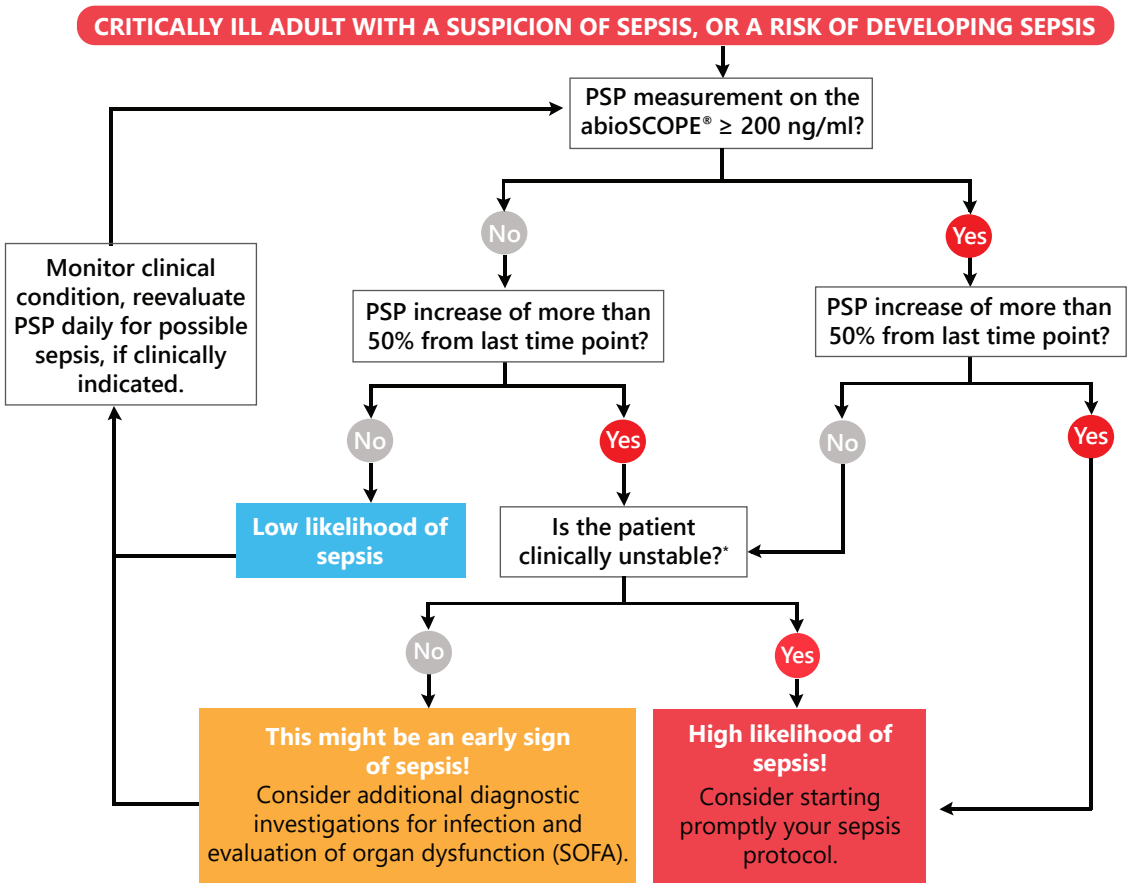
IVD CAPSULE PSP ON THE ABIOSCOPE DESIGNED FOR ON-DEMAND USE IN THE ICU

Scope of Use for the PSP Biomarker in the Diagnosis of Sepsis in Adults



Compact, robust, and intuitive to use, Abionic's PSP test on the **abioSCOPE®** is fully compatible with hospital information systems and fits seamlessly into the workflow. When sepsis is suspected, an immediate access to reliable test results is essential. Serial bedside PSP measurements every 24 hours can aid the clinical management and early identification of sepsis in patients at risk. A constantly low PSP value is also a strong indicator of a patient's stability, supporting the decision to not start or withhold unnecessary antibacterial treatment.

DECISION TREE FOR THE INTERPRETATION OF SERIAL PSP MEASUREMENTS



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CLINICAL EVIDENCE

Early Diagnosis of Sepsis in Hospitalized Patients

It is important for intensive care physicians to be able to differentiate between patients suffering from a systemic inflammatory response without infection, compared to those suffering from sepsis. This differential diagnosis is imperative to administer the appropriate treatment.

The multicentric study on critically ill patients published in *Critical Care*, showed that PSP was the only biomarker able to identify sepsis 72 hours before clinical diagnosis according to an external adjudication committee (**Fig. 2**)[3]. Providing a large window of opportunity to adapt the patient's clinical management.

PSP shows similar performances that have been previously reported in studies looking at a variety of critically ill patients, including those with severe burns[4], polytrauma[5], post-cardiac surgery[6] and on admission to the intensive care unit (ICU)[7].

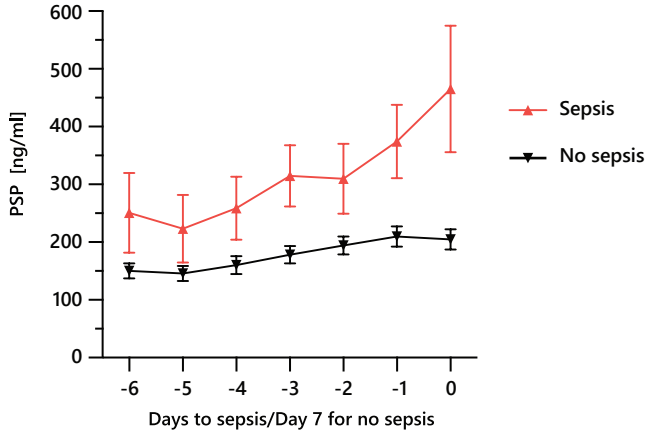


Figure 2. Average daily PSP concentration with standard error of the mean preceding the diagnosis of nosocomial sepsis (day 0; red line) or ICU discharge for patients who did not develop sepsis (black line).

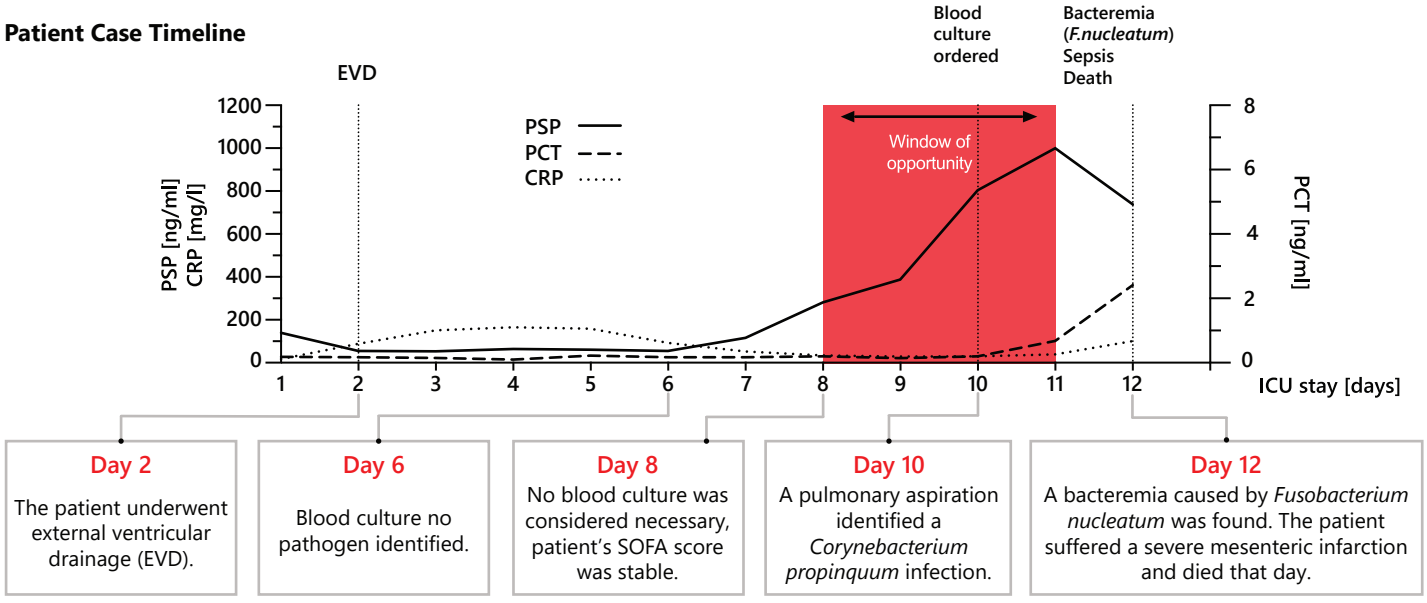
In addition to individual studies, a large meta-analysis including more than 600 patients also confirms the high diagnostic performance of PSP for diagnosing infection in the ICU and emergency department (ED), with an accuracy of 81%[8].

Patient Case Report

Patient history

A 71-year-old male patient was hospitalized for a traumatic brain injury, which required immediate ICU admission with invasive mechanical ventilation.

Patient Case Timeline



Day 2
The patient underwent external ventricular drainage (EVD).

Day 6
Blood culture no pathogen identified.

Day 8
No blood culture was considered necessary, patient's SOFA score was stable.

Day 10
A pulmonary aspiration identified a *Corynebacterium propinquum* infection.

Day 12
A bacteremia caused by *Fusobacterium nucleatum* was found. The patient suffered a severe mesenteric infarction and died that day.

Biomarkers

The patient's PSP, CRP, and PCT levels were relatively low on admission. The CRP level was non-specifically elevated from day 2 onward, peaking on day 4. The PCT level was <0.2 ng/ml through day 10, then only increased later on day 11 and on day 12.

PSP remained stable and low until day 7, after which, it began to increase and eventually surpassed the 200 ng/ml cut-off. The continuous increase in the PSP concentration between days 7 and 10 was associated with the development of bacteremia, and anticipated the **diagnosis of sepsis by >72h.**

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UNIQUE NANOTECHNOLOGY-BASED PLATFORM

Abionic's Patented Nanofluidic Immunoassay Revolutionizes Point-of-Care Diagnostics

Abionic's technology enables quantitative results for up to 14 specific parameters in a single capsule.

Molecules are forced into a nanochannel, limiting their travel distance to a few hundred nanometers and reducing incubation time to 2 minutes[9].

A washing step is not needed as the surface-to-volume ratio is extremely high, and non-specific background is negligible[9].

PSP level can thus be efficiently quantified within an ultra short assay time, with high precision and accuracy on a closed, small, easy-to-operate platform, providing lab quality results at the point-of-care.

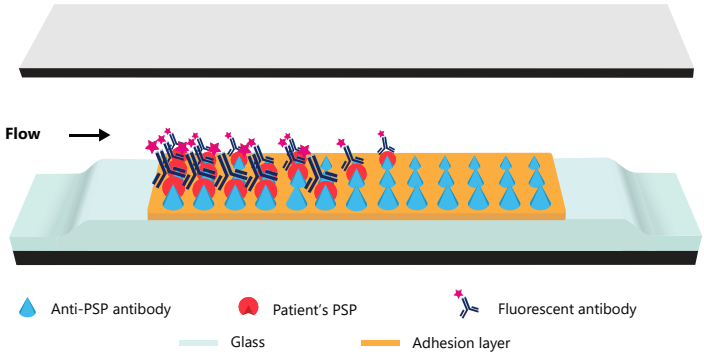


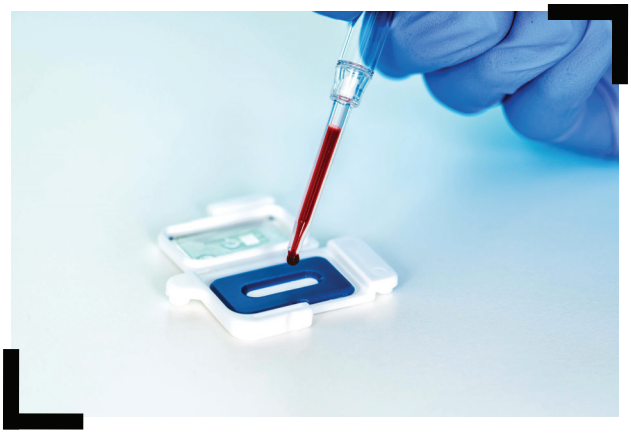
Figure 3. Cross-section through a nanofluidic biosensor

The abioSCOPE®: True Game Changer for the Future of Diagnostics

Rapid results
5-minute measuring time to get accurate actionable results

Easy to use
4 simple steps with 50 µl of blood from a fingerstick or venous blood

No maintenance
Contamination-free device, no washing step required



Laboratory quality results
Performances equivalent to those obtained in a laboratory

Connectivity options
Input: Barcode scanner, remote software upgrade
Output: HL7, ethernet to HIS/LIS, QR code

Complementary menu in development
Available tests: cSOFA test, a severity score for COVID-19 patients
Coming soon: CRP, D-Dimer

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References

1. Global Sepsis Alliance; https://www.global-sepsis-alliance.org/sepsis
2. Improving time to antibiotics and implementing the "Sepsis 6". McGregor C. et al., BMJ Open Quality. 2014
3. Serial measurement of pancreatic stone protein for the early detection of sepsis in intensive care unit patients: a prospective multicentric study. Pugin et al., Crit Care. 2021 Apr 20
4. Pancreatic Stone Protein Predicts Sepsis in Severely Burned Patients Irrespective of Trauma Severity: A Monocentric Observational Study. Klein et al., Annals of Surgery. 2020
5. Pancreatic stone protein is highly increased during posttraumatic sepsis and activates neutrophil granulocytes. Keel et al., Crit Care Med. 2009
6. Pancreatic stone protein predicts postoperative infection in cardiac surgery patients irrespective of cardiopulmonary bypass or surgical technique. Klein et al., PloS one, 2015
7. Sepsis biomarkers in unselected patients on admission to intensive or high-dependency care. Llewelyn et al., Crit Care. 2013
8. Pancreatic Stone Protein for the Diagnostic of Infection. Individual Patient Level Meta-analysis. Prazak et al., Crit Care. 2021
9. Nanofluidics Drives Point-of-care Technology for on the Spot Protein Marker Analysis with Rapid Actionable Results. Putallaz, L., Bogaard, P. V. D., Laub, P. & Rebeaud, F. Journal of Nanomedicine & Nanotechnology 2019

* **IVD CAPSULE PSP** on the **abioSCOPE®** measurment time: 5 minutes; Total Assay time: 7.5 minutes.

IVD

CE 2797

The abioSCOPE® and the IVD CAPSULE are CE marked.

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