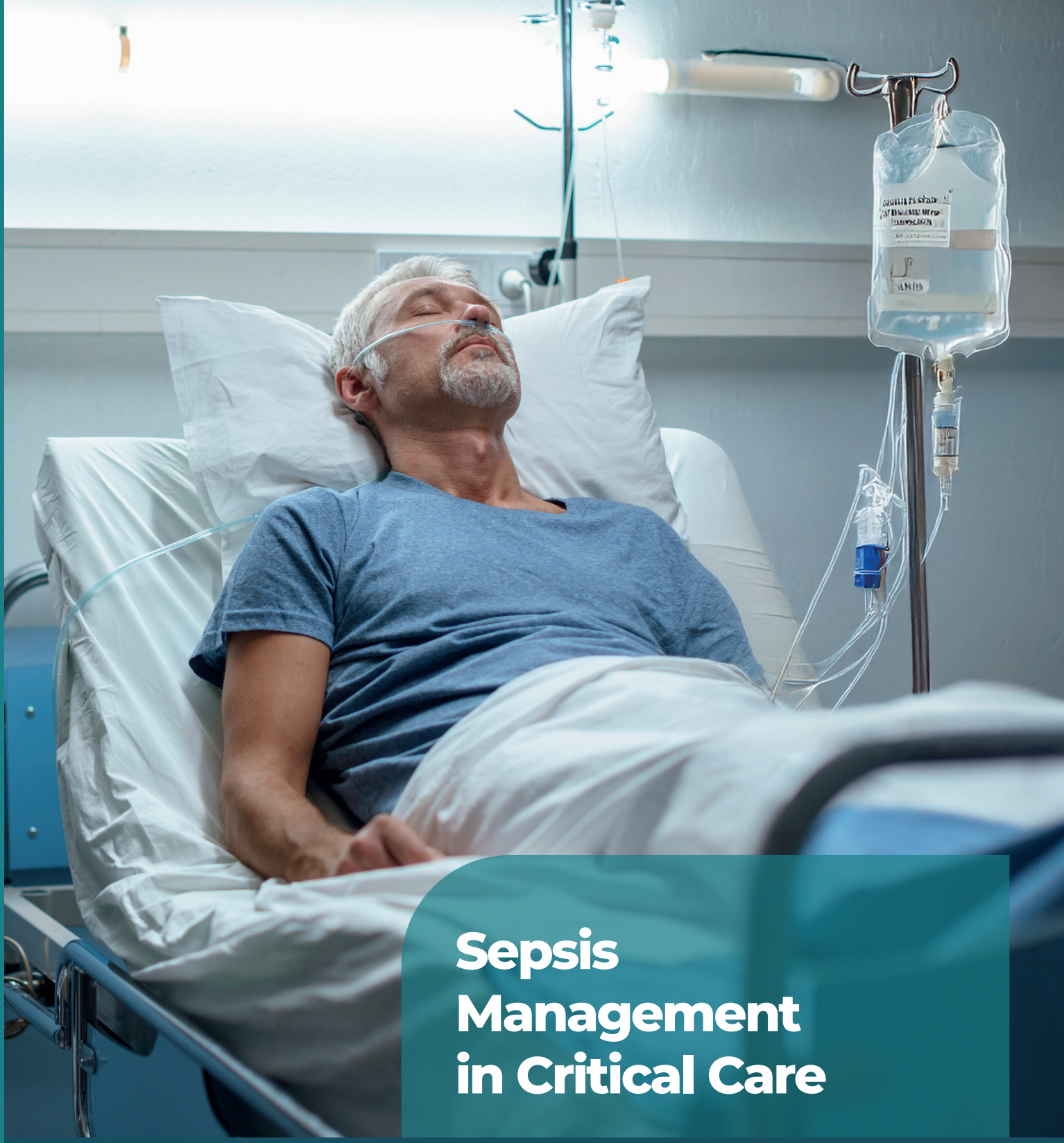
CRITICAL CARE



Sepsis Management in Critical Care

abionic
Early Sepsis Detection

7'
7 MINUTES

DETECT SEPSIS

ACTIVATE BUNDLE

Enabling Early Sepsis Detection

SEPSIS IS HARD TO DIAGNOSE

By the time sepsis is detected, the damage is done.

NON-SPECIFIC
Symptoms

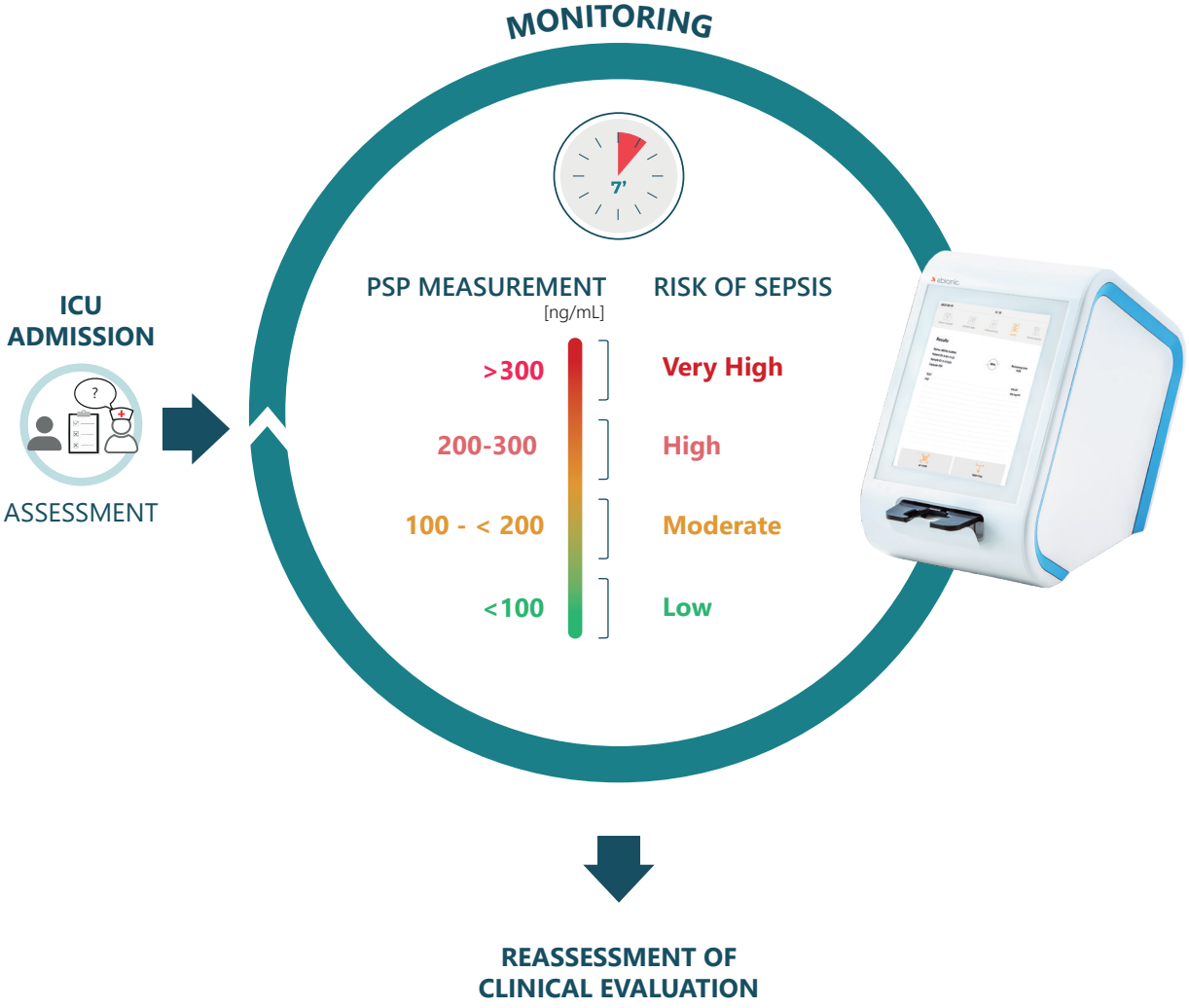
DELAYED
Decisions

INCREASED
Mortality Risks

Sepsis moves fast. Time waits for no one.

Daily PSP Measurement Ensures Early Sepsis Detection

SOLUTION



PSP Indications

The PSP test, used with the abioSCOPE® system, enables the early recognition of sepsis. It is intended for professional use in clinical laboratory settings or near-patient testing locations, supporting the diagnosis and monitoring of sepsis in patients accross various clinical situations, such as polytrauma[1], post-cardiac surgery[2], severe burns[3], and pediatric care[4,5]:

- Polytrauma
- Post-cardiac Surgery
- Severe Burns
- *Pediatric* *Pending*

Sepsis Requires Rapid Diagnosis and Treatment

Pancreatic Stone Protein (PSP) for the Early Detection of Sepsis

Pancreatic Stone Protein (PSP) has emerged as a proven biomarker for the early detection of sepsis and for predicting patient outcomes[6]. PSP is a blood protein secreted by pancreatic acinar cells and plays a key role in the body's immune response, particularly in modulating neutrophil activation during sepsis[7].

An increase in PSP levels in the days preceding the clinical diagnosis of sepsis offers a unique window of opportunity for early intervention **(Figure 1)**.

PSP levels can be measured within minutes from a single drop of whole blood on the abioSCOPE®, enabling real-time monitoring of sepsis onset[8].

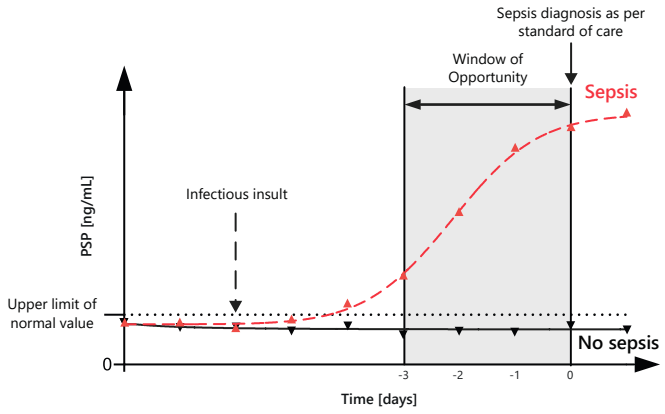


Figure 1. Schematized daily PSP biomarker readings in patients who develop nosocomial sepsis (dashed red line) or not (solid black line).

Clinical Evidence

Predictive Value of PSP for Sepsis in Critical Care

A 2021 prospective multicenter study[9] enrolling 243 patients demonstrated that PSP increases significantly in the days before sepsis onset, offering a proven early signal for timely clinical intervention (**Figure 2**). The predictive value of PSP has been validated across diverse critically ill populations within the intensive care (ICU) setting[1,2,3,10].

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 AUC of 0.81, outperforming conventional markers such as CRP and PCT.[11]

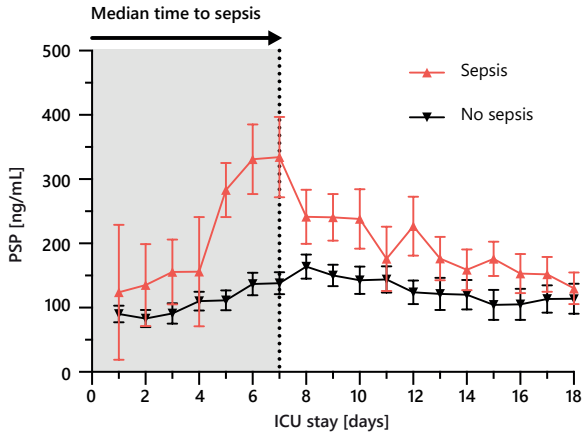


Figure 2. PSP trajectories of patients who did (red) or did not (black) develop sepsis. Data are median with SEM. Unpublished data from AB-PSP-001 (NCT: 03474809). SEM, standard error of the mean.

PSP as a Biomarker for Predicting Outcomes Admitted to the ICU

A prospective observational cohort study[12] conducted in Greece enrolled 40 patients with intra-abdominal infections admitted to the ICU. PSP was measured using the abioSCOPE to assess its prognostic value.

PSP outperformed ferritin, CRP, and fibrinogen in predicting key clinical outcomes. For treatment escalation, PSP achieved an AUC of 0.862, significantly higher than the other biomarkers. In predicting sepsis, PSP demonstrated strong predictive ability, with an AUC of 0.698, whereas ferritin, CRP, and fibrinogen showed lower values. Finally, for readmission prediction, PSP showed an AUC of 0.899, significantly higher than the other biomarkers. Overall, PSP is very promising for predicting unfavorable outcomes (**Table 1**).

Biomarkers	Treatment Escalation	Sepsis	Readmission
PSP (ng/dL)	0.862	0.698	0.899
Ferritin (mg/dL)	0.678	0.541	0.718
CRP (mg/dL)	0.575	0.533	0.628
Fibrinogen (mg/dL)	0.566	0.630	0.670

Adapted from Michailides, C. et al.[12]

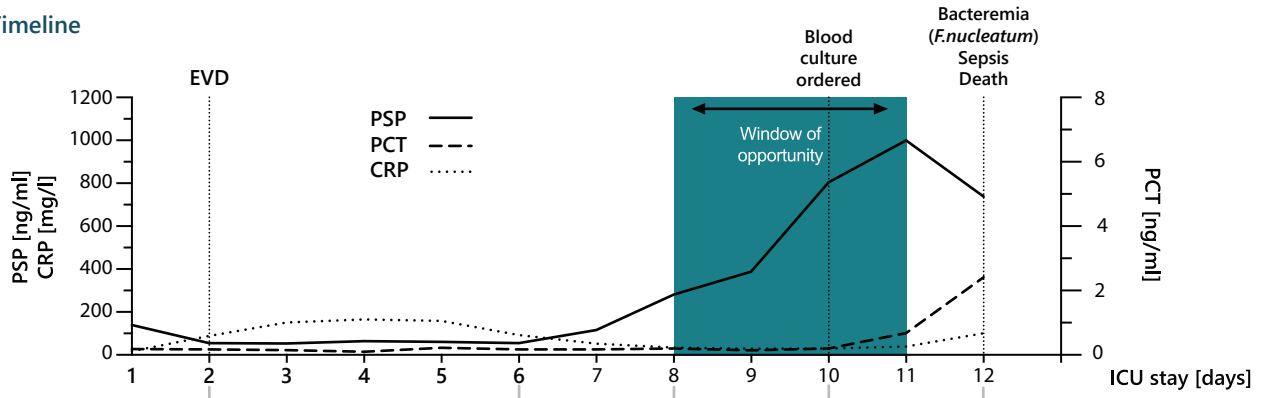
Table 1. Comparison of the AUC of PSP with other biomarkers (ferritin, CRP and fibrinogen).

Study Case

Patient history

A 71-year-old male patient was hospitalized for a traumatic brain injury, which required immediate ICU admission with invasive mechanical ventilation. Unpublished data from AB-PSP-001 (NCT: 03474809).

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.

From Sample To Result: As Easy as 1·2·3

COLLECT
50 µL from capillary, venous or arterial whole blood

TRANSFER
Sample into the capsule

MEASURE
Quantitative results within minutes

PSP Levels for Sepsis Risk Assessment

PSP Concentrations	Interpretations	Suggested Measures
> 300 ng/mL	Very High risk of sepsis	Urgent reassessment to establish sepsis diagnosis or to confirm treatment adequacy
Cut-off: 300 ng/ml	Sensitivity: 45% Specificity: 84%	
200 - 300 ng/mL	High risk of sepsis	Close monitoring and reassess clinical evaluation
Cut-off: 200 ng/ml	Sensitivity: 55% Specificity: 77%	
100 - < 200 ng/mL	Moderate risk of Sepsis	Maintain clinical observation and reassess as needed
Cut-off: 100 ng/ml	Sensitivity: 83% Specificity: 53%	
< 100 ng/mL	Low risk of sepsis	Evaluate alternative diagnoses to sepsis

The absolute values and relative changes of PSP should always be evaluated in the context of the patient's overall clinical picture.

Table 2. PSP level interpretation for Sepsis Risk Assessment based on clinical data from intensive care unit.

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Early Sepsis Detection

PSP is a reliable biomarker for the early diagnosis! Even more important than just the absolute PSP value is the increasing trend between two or more consecutive measurements. Up until now PSP measurements supported our clinicians in the decision-making process and in some cases assisted them to take action early and proceed with empirical therapy initiation while in some other cases led them to PSP guided therapy discontinuation. All cases were evaluated afterwards based on clinical outcomes reinforcing the fact that PSP guidance led them towards the right direction.

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References

1. Keel, M. *et al.* Pancreatic stone protein is highly increased during posttraumatic sepsis and activates neutrophil granulocytes*. Critical Care Medicine (2009).
2. Klein, H. J. *et al.* Pancreatic Stone Protein Predicts Postoperative Infection in Cardiac Surgery Patients Irrespective of Cardiopulmonary Bypass or Surgical Technique. PLOS ONE (2015).
3. Klein, H. J. *et al.* Pancreatic Stone Protein Predicts Sepsis in Severely Burned Patients Irrespective of Trauma Severity: A Monocentric Observational Study. Annals of Surgery (2021).
4. Schlapbach, L. J. *et al.* Pancreatic stone protein as a novel marker for neonatal sepsis. Intensive Care Med (2013).
5. Bottari, G. *et al.* Pancreatic Stone Protein in the Diagnosis of Sepsis in Children Admitted to High-Dependency Care: A Single-Center Prospective Cohort Study. Pediatr Crit Care Med (2024).
6. Fidalgo, P. *et al.* Pancreatic Stone Protein: Review of a New Biomarker in Sepsis. Journal of Clinical Medicine (2022).
7. Eggimann, P. *et al.* Measurement of Pancreatic Stone Protein in the Identification and Management of Sepsis. Biomark. Med. (2019).
8. Putallaz, L. *et al.* Measurement of Pancreatic Stone Protein in the Identification and Management of Sepsis. Biomark. Med. 13, 135–145 (2019).
9. Pugin, J. *et al.* Serial measurement of pancreatic stone protein for the early detection of sepsis in intensive care unit patients: a prospective multicentric study. Crit Care (2021).
10. Llewelyn, M. J. *et al.* Sepsis biomarkers in unselected patients on admission to intensive or high-dependency care. Crit Care (2013).
11. Prazak, J. *et al.* Accuracy of pancreatic stone protein for the diagnosis of infection in hospitalized adults: a systematic review and individual patient level meta-analysis. Crit Care (2021).
12. Michailides, C. *et al.* The Role of the Pancreatic Stone Protein in Predicting Intra-Abdominal Infection-Related Complications: A Prospective Observational Single-Center Cohort Study. Microorganisms (2023).

IVD
FDA CLEARED
CE 2797

The IVD CAPSULE PSP and the abioSCOPE® devices are compliant with the EU IVD Regulation 2017/746 and have received FDA clearance.

The abioSCOPE® and the IVD CAPSULE are CE marked.

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