PEDIATRICS

Sepsis Management in Pediatric Care

abionic
Early Sepsis Detection

7 MINUTES

DETECT SEPSIS

ACTIVATE BUNDLE

Reveal Sepsis up to 72h
Before Clinical Recognition

Sepsis Requires Immediate Diagnosis and Treatment

Sepsis in Pediatric Population

Sepsis is a life-threatening organ dysfunction caused by a dysregulated host response to infection. The newly developed "Phoenix Sepsis Score" aims to enhance early detection and support effective risk assessment in pediatric patients[1].

In 2017, an estimated
25 Million
CHILDREN
were affected by sepsis worldwide[2]

Leading to more than
3.4 Million
DEATHS

The Surviving Sepsis Campaign[3] recommends implementing systematic screening in children who present as acutely unwell, to enable timely recognition of septic shock and other sepsis-associated organ dysfunction.

Pancreatic Stone Protein (PSP) for the Early Sepsis Detection

What is PSP?

Pancreatic stone protein (PSP) has emerged as a proven biomarker for the early detection of sepsis and for predicting patient outcomes[4]. 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[5].

Why PSP?

In adult, PSP levels allow to identify severe infection[6]. PSP efficiently discriminates patients with sepsis from those with a non-infective systemic inflammatory response and is able to reflect the severity of illness[7]. Among septic patients, PSP demonstrates a high correlation with the prognosis of mortality[8-10]. PSP levels begin to rise up to 3 days before sepsis is clinically diagnosed, earlier than current biomarkers such as CRP and PCT, providing clinicians with a valuable early warning to initiate treatment at the right time **(Figure 1)**[11]. This early detection is also applicable to newborns born at 37 weeks of gestational age (GA), supporting timely diagnosis in neonatal care[12].

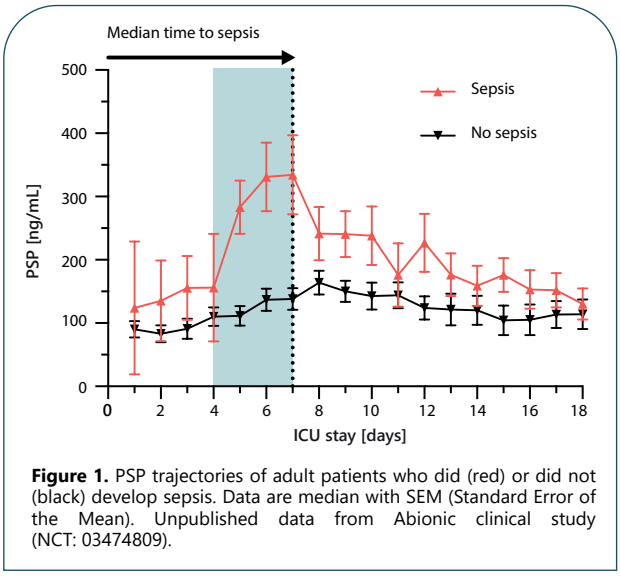

Figure 1. PSP trajectories of adult patients who did (red) or did not (black) develop sepsis. Data are median with SEM (Standard Error of the Mean). Unpublished data from Abionic clinical study (NCT: 03474809).

How to measure PSP?

PSP is measured on the abioSCOPE® platform, delivering a quantitative result in 7 minutes from a drop of whole blood. The test requires 50 µL of capillary blood (e.g. via a heel/finger prick), or venous/arterial whole blood, collected from K_2-EDTA, K_3-EDTA, or lithium heparin tubes according to the local standard practices for neonates/children. This fast and easy-to-use solution supports early sepsis detection and enables close monitoring of at-risk patients, complementing clinical evaluation and other laboratory findings. Abionic's PSP test for adults in critical care is both CE-marked under the EU IVDR (2017/746) in July 2022 and FDA-cleared in September 2024.

Early Sepsis Detection Within Minutes

abioSCOPE®

50 µL

Reducing Time-To-Treatment
by up to
72h
can dramatically improve
patient outcomes

Clinical Evidence

Normal Values of PSP in Neonates and Children

The study by Schlapbach *et al.*[13] assessed PSP concentrations in 234 healthy pediatric donors using an ELISA method. PSP concentrations varied with age: they were lowest in preterm newborns, increased steadily through childhood and adolescence, then slightly declined in adulthood. These reference values provide a solid basis for establishing optimal PSP cut-off levels in future clinical studies **(Table 1).** A comparative study was conducted to establish a conversion factor between ELISA-based values and those measured on the abioSCOPE® platform.

Age Group	PSP value [ng/mL]
Neonates/Infants (≥37 weeks GA and <1 year)	48.2 (P10: 25.1; P90: 96.6)
Children (≥1 year and <16 years old)	94.5 (P10: 63.8; P90: 141.7)
Children (≥16 years old and <18 years old)	80.5* (P10: 56.6; P90: 113.8)

Table 1. Normal PSP values stratified by age. Values are from 234 healthy pediatric donors. GA: gestational age.

*This value was obtained by interpolation between data from children (74 healthy donors; ≥1 year and <16 years old; 94.5 ng/mL) and the adult reference population (61 healthy adults; 66.4 ng/mL).

Diagnostic Performance of PSP for Detecting Pediatric Sepsis

Several studies have highlighted the clinical value of PSP in detecting sepsis in neonates and children. In a pilot study by Bottari *et al.*[14], 40 patients aged between >1 month to <18 years were enrolled across pediatric intensive care units, high-dependency units, and general pediatric wards. The results showed that serial PSP measurements using the abioSCOPE® platform can effectively differentiate sepsis from non-infectious inflammation, with PSP (AUC 0.74) performing better than CRP (AUC 0.47) and showing similar performance to PCT (AUC 0.75).

A second study by Bottari *et al.*[15] in a larger cohort of 99 children confirmed the diagnostic value of PSP. The study showed an area under the curve (AUC) of 0.82 for PSP, with higher accuray than CRP (AUC 0.64), PCT (AUC 0.61), and white blood cell count (AUC 0.49) **(Figure 2)**. The combination of PSP and CRP demonstrated a robust diagnostic performance, with an area under the curve (AUC) of 0.84. PSP alone showed a comparable AUC, highlighting its potential as a promising biomarker. Based on the Phoenix Criteria, the optimal PSP cut-off value for sepsis diagnosis was identified as 116 ng/mL, with a sensitivity of 66% (95% CI, 48%–81%) and a specificity of 89% (95% CI, 77%–95%).

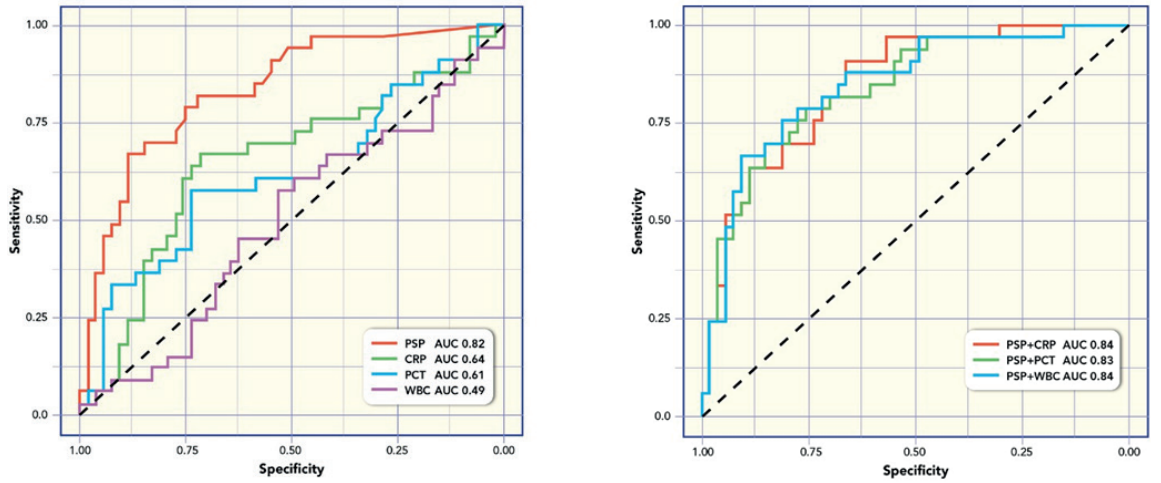

Figure 2. AUROC analysis of PSP, CRP, PCT, and WBC, as well as combinations of PSP with PCT, CRP, and WBC, was performed for the diagnosis of sepsis according to the Phoenix criteria. CRP= C-reactive protein, PCT = Procalcitonin and WBC = White Blood Cells.

Early-Onset Neonatal Sepsis (EONS): Promising Diagnostic Perforance of PSP

A prospective clinical study by Rass *et al.*[16] demonstrated that Pancreatic Stone Protein (PSP) is a highly reliable biomarker for detecting early-onset neonatal sepsis (EONS), defined as infection within the first 72 hours of life. In this study, PSP levels were measured using a specific ELISA kit. Among 104 newborns admitted to the Neonatal Intensive Care Unit (NICU) with suspected sepsis, PSP significantly outperformed CRP at its conventional threshold.

Notably, PSP achieved a high negative predictive value (NPV) (89.3%), enabling clinicians to safely rule out sepsis, reduce unnecessary antibiotic treatment, and potentially shorten hospital stays. These findings highlight the value of PSP in enhancing early clinical decisions, delivering fast, actionable insights for safer care in neonates **(Table 2)**.

Performances	PSP	CRP
Sensitivity	96.2%	84%
Specificity	88.5%	65%
Positive Predictive Value (PPV)	95.8%	81%
Negative Predictive Value (NPV)	89.3%	71%
AUC (95% CI)	0.87 (0.78–0.97) p < 0.001	0.81 (0.72–0.91) p = 0.023

Table 2. Comparative Performance of PSP and CRP in Suspected Neonatal Sepsis

Overview of Studies supporting the role of PSP in Sepsis Diagnosis and Prognosis

The **Table 3** summarizes pediatric studies for sepsis detection evaluating the prognostic value of PSP for mortality or diagnosing sepsis.

Study	Endpoints	PSP measurement device	Pediatric patient population	Cut-off	Sensitivity	Specificity	Sepsis diagnosis criteria
Bottari *et al.*[14]	Prognostic	abioSCOPE device	n = 40 Age > 1 month and < 18 years	166 ng/mL	54%	83%	Goldstein criteria
Bottari *et al.*[15]	Diagnostic	abioSCOPE device	n = 99 Age > 1 month and < 18 years	116 ng/mL	66%	89%	Phoenix criteria
Dündar *et al.*[17]	Prognostic	abioSCOPE device	n = 48 Age > 1 month and < 18 years	≥50 ng/mL	95%	45%	SIRS symptoms, fever, and positive blood culture
Antari *et al.*[18]	Diagnostic	abioSCOPE device	n = 70 Age < 18 years	120 ng/mL	84%	82%	Goldstein criteria

Table 3. Summary of studies in pediatric population for sepsis detection conducted with the abioSCOPE®

Timely Intervention for Neonates and Children at Risk of Developing Sepsis

The **Table 4** summarizes PSP thresholds associated with sepsis-related risk factors in neonates/infants (≥37 weeks GA and <1 year) and children (≥1 year and <18 years old)*. The association of PSP with the development of sepsis has been demonstrated in five independent European single-center, prospective clinical studies: 1 in neonates[12] and 4 in children[14,15,17,18] **(Table 4).**

	PSP Concentration [ng/ml]	Risk Level
Neonates/Infants (≥37 weeks GA and <1 year)	≥ 60	Moderate to High risk of sepsis
	< 60	Low risk of sepsis
Children (≥1 year and <18 years old)	≥ 100	Moderate to High risk of sepsis
	< 100	Low risk of sepsis

Table 4. PSP thresholds related to risk factors in neonates/infants (≥37 weeks GA and <1 year) and children (≥1 year and <18 years old).
*It is recommended that each laboratory determines its own cut-offs based on the desired balance between sensitivity and specificity in clinical practice as well as based on the population it serves.

Customer Story

As a pediatrician, I've seen how quickly a child's condition can change when facing sepsis. Having access to a test like PSP, which delivers accurate results within minutes makes a real difference. It allows me to detect sepsis earlier. I can act sooner and more confidently. This solution is not just helpful, it's essential!

Prof. Athanasios Tragiannidis, MD, PhD
Pediatric Hematology-Oncology, Aristotle University of Thessaloniki

abioSCOPE® - Benchtop Rapid Diagnostic Platform

Lab-Quality Results, From A Drop Of Blood, Within Minutes

1

COLLECT
50 µL from capillary, venous or arterial whole blood

2

TRANSFER
Sample into the capsule

3

MEASURE
Quantitative results within minutes

Rapid Results
Accurate quantitative results within minutes

Laboratory Quality Results
Performances equivalent to those obtained in a laboratory

Easy To Use
3 simple steps with 1 drop of blood (50 µL) from capillary, venous or arterial whole blood

Easy Device Handling
Low-maintenance
No sample-to-device contamination

abionic
Early Sepsis Detection

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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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*FDA clearance does not cover pediatric use nor capillary and lithium-heparin anticoagulated sample types.