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

SEE EARLIER - ACT FASTER
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.

**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*.

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**

TRUE ENabler OF EARLY SEPSIS DETECTION

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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

CRITICALLY ILL ADULT WITH A SUSPICION OF SEPSIS, OR A RISK OF DEVELOPING SEPSIS

Monitor clinical condition, reevaluate PSP daily for possible sepsis, if clinically indicated.

PSP measurement on the abioSCOPE® ≥ 200 ng/ml?

- Yes
  - PSP increase of more than 50% from last time point?
    - No
      - Low likelihood of sepsis
      - Is the patient clinically unstable?
        - No
          - This might be an early sign of sepsis! Consider additional diagnostic investigations for infection and evaluation of organ dysfunction (SOFA).
        - Yes
          - High likelihood of sepsis! Consider starting promptly your sepsis protocol.
    - Yes
      - Yes

- No
  - Monitor clinical condition, reevaluate PSP daily for possible sepsis, if clinically indicated.
**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^.

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**

**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.
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 minutes⁹.

A washing step is not needed as the surface-to-volume ratio is extremely high, and non-specific background is negligible⁹.

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.

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

Figure 3. Cross-section through a nanofluidic biosensor
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; https://bmjopenquality.bmj.com/content/2/2/u202548.w1443

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