IVD CAPSULE PSP

REF P02.00026

abionic

English

Intended use

The **IVD CAPSULE PSP** is a single use, rapid in vitro diagnostic test for the quantitative measurement of pancreatic stone protein (PSP) in human K_3-EDTA,K_2-EDTA and lithium heparin anticoagulated venous and capillary whole blood

The **IVD CAPSULE PSP** is to be used with the **abioSCOPE** 2.0 in vitro diagnostic test system. The system is intended for professional use in clinical laboratory settings or point of care (PoC) locations including near-patient testing.

The **IVD CAPSULE PSP** is used in conjunction with other clinical assessments and laboratory findings to aid in the early recognition of nosocomial sepsis in adults.

It is also used to assess the severity of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection in adults, the causative agent of the coronavirus disease 2019 (COVID-19).

Summary

Sepsis is a life-threatening organ dysfunction caused by a dysregulated host response to infection[1]. According to a recent study, an estimated **48.9 million incident cases of sepsis** were recorded worldwide in 2017, and **11.0 million sepsis-related deaths** were reported during the same period, accounting for approximately one death out of five.[2] Moreover, patients who survive sepsis often have long-term disabilities that result in impaired quality of life[3].

The pandemic COVID-19 caused by SARS CoV-2, identified for the first time in December 2019 in Wuhan, China, has been declared by the World Health Organization a Public Health Emergency of International Concern in January 2020 and a pandemic in March 2020. As of 12 November 2020, more than 52.1 million cases have been confirmed, with more than 1.28 million deaths attributed to COVID-19. This sudden massive increase in the need for hospitalisation, particularly in the intensive care unit, overcomes many healthcare systems' capacities worldwide. Therefore, rapid solutions to diagnose and predict the outcome of COVID-19 patients is highly needed.

PSP is a small protein mainly secreted by the acinar cells of the pancreas that activates neutrophil granulocytes[4]. PSP levels in adult at ICU admission discriminates well between sepsis and infection or inflammation whose aetiology is not related to infection[5]. Among septic patients PSP demonstrated a high correlation with the prognosis of mortality[6, 7]. Continuous increase of PSP for 3 days is associated with the development of sepsis.

Test principle

The blood sample is mixed with a solution composed of fluorescently labeled antibodies reactive to human PSP. The blood sample, now containing the PSP-antibody complex, is loaded onto the capsule of the kit.

Patient material is drawn through the capsule by capillary action and passes through a built-in separator that excludes particles from the measurement area.

After passing through the separator, the PSP-antibody complex is bound by antibodies immobilized on the capsule's read-out area.

The concentration of the captured PSP is proportional to the fluorescence generated by the fluorophore conjugated to the signal antibody. Therefore, the measured fluorescence signal is proportional to the concentration of PSP within the sample. The instrument automatically calculates the concentration of each sample and displays it on the instrument screen in ng/ml.

Reagents

Each assay contains one vial containing 50 µl of the **abioMIX** reagent. The **abioMIX** reagent is composed of the fluorescently labeled anti-human PSP antibody, dissolved in a phosphate buffered saline solution supplemented with bovine serum albumin and Tween-20. The **abioMIX** reagent contains a preservative (Table 1).

Material	Concentration
Fluorescently-labelled anti-human PSP antibody	4.00 µg/ml
Tween 20 (CAS number 005-64-5)	0.5% (v/v)
Bovine serum albumin	0.1% (w/v)
ProClin300 (CAS number 55965-84-9)	0.04% (v/v)

Table 1| Composition of the **abioMIX** reagent.

Materials included

- 1x PSP capsule
- 1x vial of **abioMIX** reagent
- 1x capillary blood collector (**abioPIPETTE**)
- 1x desiccant bag

Test procedures

1. Use the provided **abioPIPETTE** to collect 50 µl of whole blood.

2. Pick up the **abioMIX** vial and flick it to move the **abioMIX** down to the bottom before use. Pierce the cap with the filled **abioPIPETTE**, and completely insert it into the vial without pushing the plunger. Once fully inserted, turn the plunger one-quarter turn clockwise and push on the **abioPIPETTE**'s plunger to dispense the entire blood sample into the **abioMIX** reagent vial. Hold the pressure on the plunger of the **abioPIPETTE** then remove the **abioPIPETTE** and release the plunger outside of the vial.
3. Tap the vial at least 10 times on a hard surface to mix thoroughly the blood-**abioMIX** solution. A mixed sample will have a homogenous color. Immediately load the solution onto the capsule.
4. Outside the vial, push down the plunger completely and hold the pressure. Insert the **abioPIPETTE** in the vial. Release the plunger to completely fill the **abioPIPETTE** with the mix and remove the **abioPIPETTE**. Press the plunger gently to deposit the mixture evenly on the entire surface of the membrane (white area) in the center of the capsule. The mixture should be dispensed slowly to allow solution to wick into the capsule. Be careful not to scrape against the membrane with the pipette tip. The filled capsule should be measured immediately.
5. Fold the lid over to close the capsule. Hold the capsule only by the edges. Be careful not to touch the bottom side of the capsule.
6. To start the measurement, touch the button "measure" on the reader. The tray will open automatically.
7. Place the capsule onto the tray according to the guided capsule position on the screen, then touch the button "close tray".

To measure the sample, refer to the **abioSCOPE 2.0** User Manual.

Storage and stability

Stored at 2-8 °C until the expiration date printed on the label. The **abioMIX** reagent is ready-to-use. Allow the **abioMIX** reagent to warm up to room temperature before use. Use **abioMIX** reagent within 4 hours of warming.

The blood sample mixed with the **abioMIX** reagent should be immediately loaded onto the PSP capsule. The filled capsule should be immediately measured.

Traceability and calibration

IVD CAPSULE PSP is calibrated by the manufacturer using a purified preparation of recombinant human PSP based on the mass (concentration) of the analyte present in K_3-EDTA anticoagulated venous whole blood matrix. Each lot of IVD CAPSULE PSP is calibrated using a weighted 5 parameter logistic curve fit data reduction method. The instrument automatically reads in the lot-specific calibration data that are embedded within the capsule chip, eliminating the need for calibration by the user. PSP values assigned to controls and calibration materials are directly traceable to a master lot of calibrator.

Quality control

For quality control, use the **IVD CAPSULE PSP Control.** Follow the applicable local regulations and guidelines for quality control.

The control intervals should be adapted to each laboratory's individual requirements. Values obtained should fall within the defined target range. Each laboratory should establish corrective measures to be taken if values fall outside of the defined ranges.

Warnings and precautions

- For in vitro diagnostic use.
- The **IVD CAPSULE PSP** must be kept refrigerated until use.
- Do not freeze.
- Allow the **abioMIX** reagent vial to reach room temperature before use.
- The **IVD CAPSULE PSP** should be used within 4 hours after being removed from refrigeration.
- This product requires the handling of human specimens. It is recommended that all human-sourced material should be considered potentially infectious. Universal precautions that apply to your facility should be used for handling and disposal of materials during and after testing[8].
- Do not use reagents after the expiration date printed on the box.
- Incubation of the specimen in the abioMIX for more than 5 minutes may impact test results.
- The COVID-19 is a disease that only recently emerged, and limited understanding of its pathophysiology is available. Consequently, a PSP test result should be considered in the context of all available clinical and diagnostic information, including patient history and other tests. The PSP test is not intended to diagnose SARS-CoV-2 infection.

Reagent deterioration

The following observations indicate reagent deterioration:

- Presence of turbidity in the **abioMIX** vial.

- Consistently high or low values from assay kits from the same batch.

Limitations

- This assay uses antibodies of murine (mouse) origin. Patient material reactive to mouse proteins may give anomalous results. Heterophilic antibodies in human blood can interfere with in vitro immunoassays. Patients routinely exposed to animals or to animal blood products can be prone to this interference. The impact of heterophilic antibodies, human rheumatoid factors (RF) and of human anti-mouse antibodies (HAMA) on measurements have not been assessed.
- Test results should be interpreted within the complete clinical picture. Definitive diagnosis and/or clinical decision should not be based solely on the results of any single diagnostic test but made after all clinical and laboratory findings are evaluated.
- A high PSP test result in absence of detectable SARS-CoV-2 genetic material of antigen does not rule-out the presence of organ dysfunction or other infection.
- Grossly hemolytic, icteric or grossly lipemic specimen may interfere with test results at clinically elevated concentrations.
- All assay materials are single-use and cannot be re-used.

Expected values

The normal PSP concentration [ng/ml] range in adults was determined by the manufacturer on a U.S.-representative adult population. Results are provided in Table 2.

Mean	43.9 ng/ml
Median	41.7 ng/ml
5-95% percentiles	27.0 – 60.7 ng/ml
Lowest / Highest value	23.0 / 73.7 ng/ml

Table 2| Normal PSP value. Values are from 40 healthy donors (Male/Female (%): 50/50, Caucasian/African-American /Hispanic (%): 57/35/8).

PSP normal values are not influenced by age, gender or ethnicity/race.
It is recommended that each laboratory establish its own expected reference range for the population it serves.

Measuring range : 20 - 600 ng/ml

The linear assay range of the assay was determined by diluting a pool of samples with clinically elevated PSP level in a PSP-depleted sample to concentrations spanning the entire assay range (16.1 to 682.2 ng/ml of PSP). Regression analysis demonstrated that the assay response was linear with an R^2 value of 0.99, a slope of 0.97 and an intercept of 1.05 in this range. The analytic sensitivity study demonstrated a lower limit of detection of 3.2 ng/ml.

The **IVD CAPSULE PSP** is not affected by clinically elevated PSP concentration up to 5000 ng/ml.

Precision

The between-run and between-day variance components of **IVD CAPSULE PSP** on the **abioSCOPE** 2.0 have been determined with 8 PSP samples over 20 consecutive days, with four runs per sample per day (two in the morning, two in the afternoon). Total imprecision ('within laboratory') is depicted in Table 3.

PSP level	Mean value [ng/ml]	Standard deviation, [ng/ml]	Coefficient of variation, [%]
Level 1	38.9	2.5	6.3
Level 2	62.5	5.9	9.5
Level 3	125.0	15.7	12.6
Level 4	171.6	15.4	9.0
Level 5	218.3	14.6	6.7
Level 6	264.5	32.8	12.4
Level 7	252.7	25.8	10.2
Level 8	374.2	50.1	13.4

Table 3| Summary of the estimate of total imprecision of the **IVD CAPSULE PSP** on the **abioSCOPE** 2.0.

References

1. Singer, M., et *al*., JAMA. 2016;315(8):801-810
2. Kristina E Rudd., et *al*., Lancet 2020;395(10219) :200-211
3. Iwashyna, TJ., et *al*., JAMA. 2010;304(16):1787-1794.
4. Keel, M., et *al*., CCM 2009 ;37(5):1642-1648
5. Llewelyn, MJ., et al., Crit Care 2013;17(2):R60
6. Que, Y-A., et *al*., Crit. Care 2012;16(4):R114
7. Que, Y-A., et *al*., Chest 2015;148(3):674-682
8. Clinical and Laboratory Standards Institute (CLSI), M29-A4. Wayne, PA: CLSI; 2014.

CE marking

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Use a K_2- or K_3-EDTA or lithium heparin anticoagulated whole blood sample.