Presepsin:

analytical performances, reference values and early pattern of release of a new sepsis biomarker.

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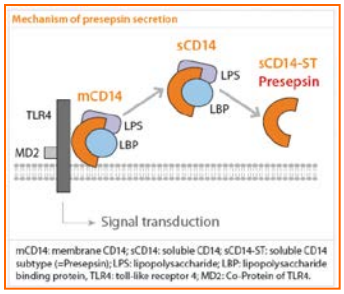
BACKGROUND: Binding of bacterial antigens (such as lipopolysaccharides or LPS) to the specific membrane receptor CD14 of monocytes/macrophages induces the release of presepsin (soluble CD14 sub-type or sCD14-ST). Circulating concentrations of presepsin are increased in sepsis. We aimed to:
(1) evaluate main analytical performances of presepsin immunoassay on the Pathfast™ analyser (Mitsubishi Chemical, Tokyo, Japan),
(2) verify plasmatic presepsin concentrations in a reference population,
(3) study presepsin release from circulating white blood cells (WBC) after in vitro-stimulation with LPS.



Pathfast™

METHODS: Pathfast™ Presepsin method is a point-of-care chemiluminescent one-step immunoassay (measuring rang from 20 to 20,000 ng/L; 95th percentile = 327 ng/L).
(1) Analytical evaluation was performed according to French protocole for method validation (Société Française de Biologie Clinique, SFBC). Imprecision was evaluated using quality controls provided by the manufacturer (CTL-1 and CTL-2), and an heparinized-plasma PP1 obtained from a healthy donor.
(2) Heparinized samples from 50 healthy donors were also analyzed.
(3) Study of presepsin release was performed on heparin-whole blood from 4 healthy donors; circulating white blood cells (WBC) were in contact with 10 ng/mL LPS during the 3 hours of the in-vitro experiment.

RESULTS:

(1) Presepsin analytical performances:

- **Imprecision coefficients of variation (CV) were <5% (Table 1).**
- **Linearity of the measuring range was verified from 20 to 4,800 ng/L (sloape=0.991; r^2=0,999; recovery: 89 to 111%).**
- **Neither haemolysis (<400 mg/dL) nor LPS (<100 ng/mL) influenced presepsin concentrations.**

Table 1:

	PP1	CTL-1	CTL-2
Target (range), ng/L		1003 (702-1304)	3098 (2169-4027)
Mean, ng/L	282	820	2550
Standar deviation, ng/L	11	49	97
CV, %	4.1	4.8	3.8

(3) Presepsin release

Plasmatic presepsin increases early after LPS contact with WBC (+32% at 1 hour), and reaches 44% at 2 hours (Figure 1).

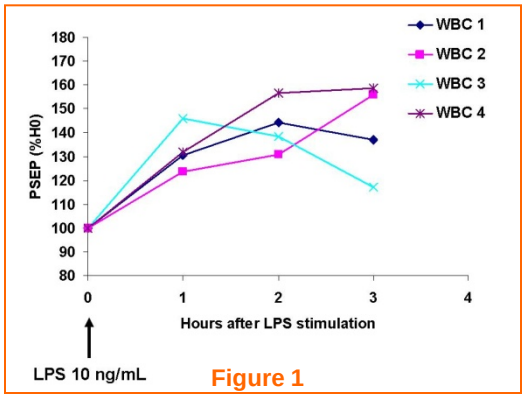


Figure 1

(2) Presepsin reference range

Median plasmatic concentration of presepsin obtained on samples from 50 healthy volunteers was 214 ng/L (Table 2).

Table 2:

n	50
Men, n (%)	14 (28)
Age, in years, mean (IQR)	27 (24-31)
Temperature, °C, mean (IQR)	36.9 (36.7-37.2)
Systolic blood pressure, mm Hg, mean (IQR)	119 (110-128)
Diastolic blood pressure, mm Hg , mean (IQR)	74 (66-79)
Heart rate, bpm, mean (IQR)	78 (68-85)
Presepsin plasmatic concentrations : - mean (IQR), ng/L - 95th percentile, ng/L	 214 (153-258) 346

CONCLUSION: PathfastTM Presepsin assay presents satisfying analytical performances. Manufacturer's references values are confirmed. In addition, early release of presepsin after LPS stimulation is promising for the use of this new point-of-care sepsis biomarker in clinical practice.