sCD14-ST

A Novel Biomarker for Infection

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P/N:ENG-SCD14-ST–A Novel Biomarker for infection-210285X14P-20221201

healthcare within reach

Applications

sCD14-ST (the soluble subtype of CD14), or presepsin, is a glycoprotein fragment derived from monocytes and macrophages. It is an innate direct response biomarker of activation of immune cell responding towards an invading pathogen[1-3].

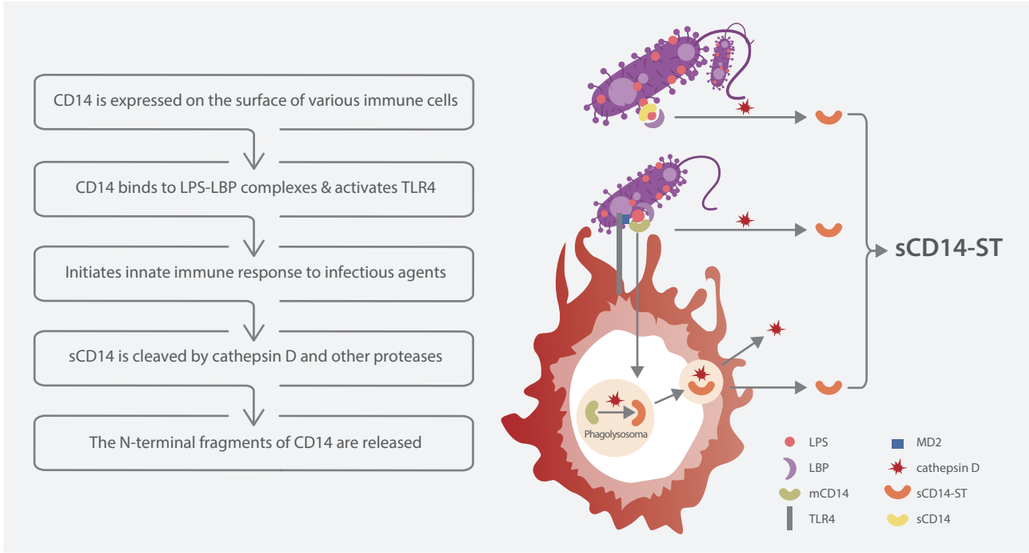


Fig. The physiological mechanism of sCD14-ST

sCD14-ST is an early diagnosis biomarker

Compared to PCT induced by cytokines after bacterial phagocytosis, sCD14-ST is a more direct infection biomarker, which is mediated by pathogens[4-5].

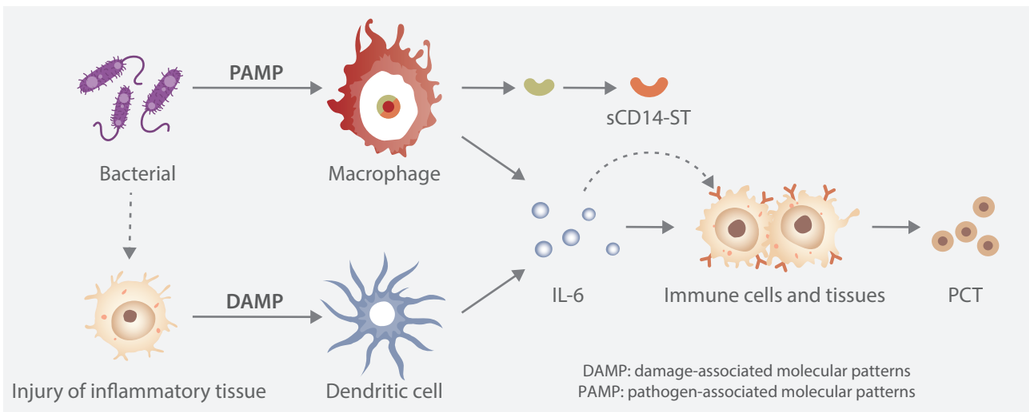
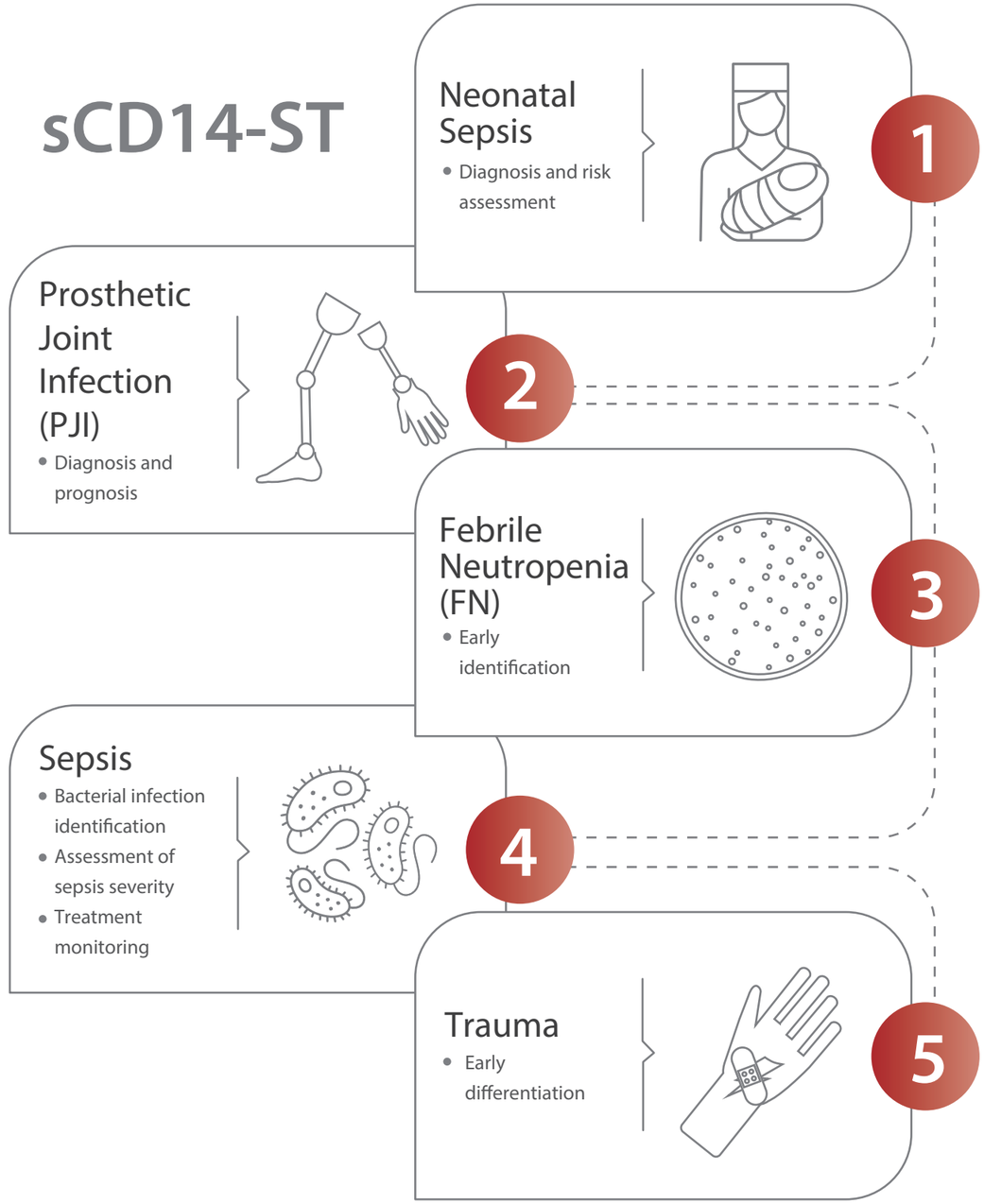


Fig. Production of sCD14-ST, PCT and IL-6

sCD14-ST has significant clinical value for infections

Studies on pathological mechanism and clinical trials have revealed that sCD14-ST is important for the clinical management of infectious diseases or related conditions, such as neonatal sepsis, prosthetic joint infection(PJI), febrile neutropenia(FN), sepsis and early infection in trauma.



Clinical scenario 1 - Neonatal Sepsis

sCD14-ST is a valuable biomarker for neonatal sepsis and allows for rapid assessment of the severity of sepsis in neonates. sCD14-ST levels are significantly higher in neonates with sepsis than in the non-infective systemic inflammatory response syndrome (SIRS) and normal control groups, suggesting that they can be an indicator for the identification of infective and non-infective SIRS[6].

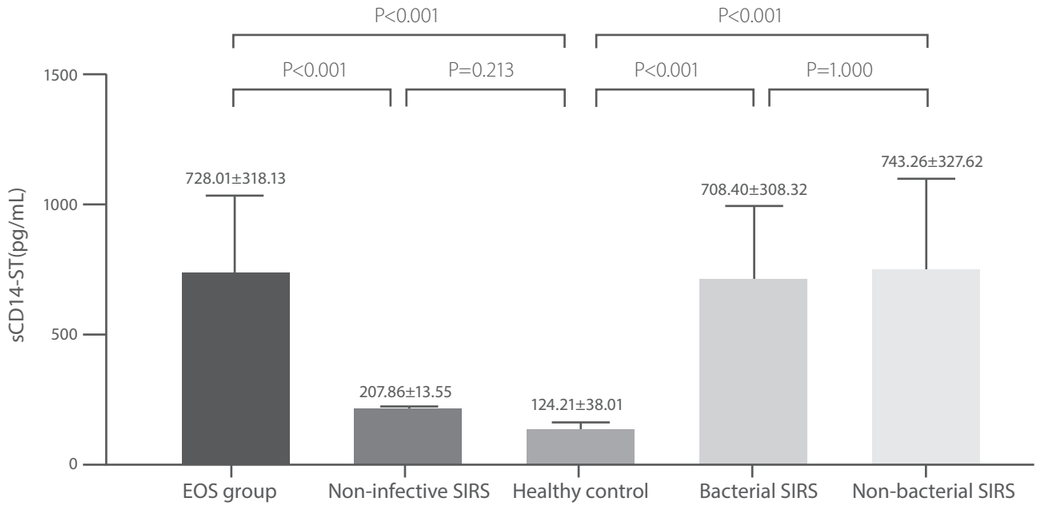


Fig. sCD14-ST in early-onset sepsis (EOS), bacterial SIRS, non-bacterial SIRS, non-infective SIRS and healthy control groups before treatment.

sCD14-ST levels at T0 were significantly higher in neonates with sepsis and sepsis shock compared to those with infection. During the first 48h from the onset of symptoms, sCD14-ST progressively increased in neonates with septic shock, while it remained stable or decreased in neonates with sepsis or infection[7].

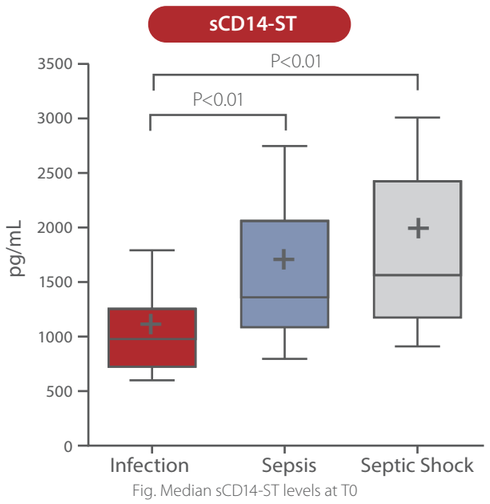


Fig. Median sCD14-ST levels at T0

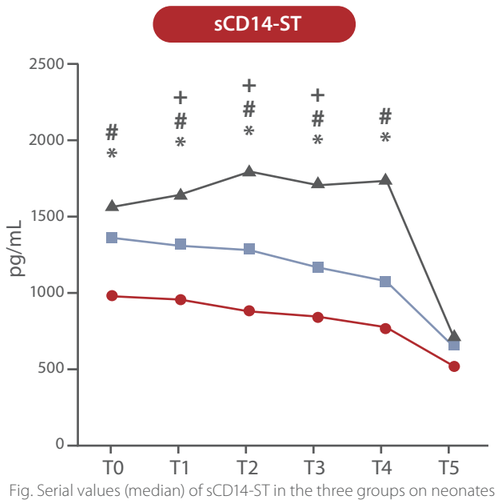


Fig. Serial values (median) of sCD14-ST in the three groups on neonates

P<0.01 marked as follow: *, infection vs. sepsis; #, infection vs. septic shock; +, sepsis vs. septic shock
T0: onset of symptoms. T1: 12h, T2: 24h, T3: 36h, T4: 48h, T5: end of antibiotic therapy

Clinical scenario 2 - Prosthetic Joint Infection (PJI)

sCD14-ST is a potential inflammation biomarker for the diagnosis and prognosis of PJI. Research showed that sCD14-ST levels were significantly higher in PJI patients than in controls. The post-operative sCD14-ST levels dropped significantly, which meant a longer recovery time, in PJI patients, but remained unchanged or were significantly lower in non-infected patients[8].

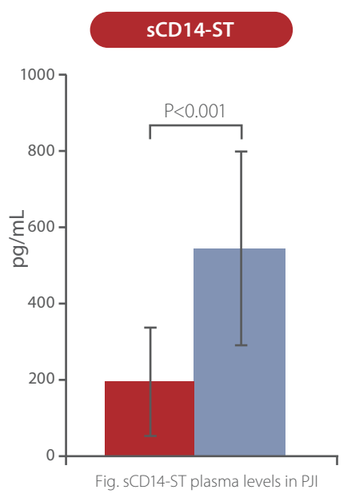


Fig. sCD14-ST plasma levels in PJI

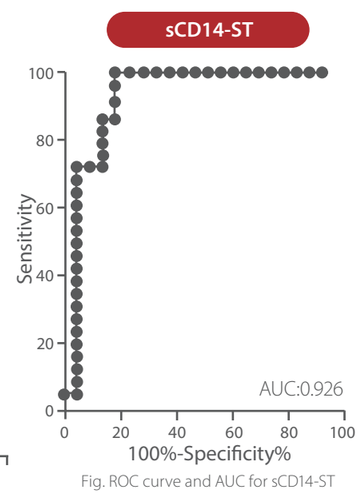


Fig. ROC curve and AUC for sCD14-ST

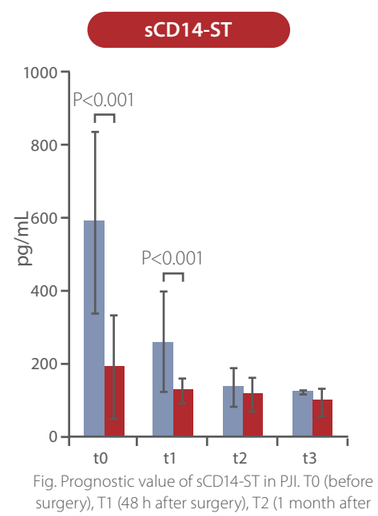


Fig. Prognostic value of sCD14-ST in PJI. T0 (before surgery), T1 (48 h after surgery), T2 (1 month after surgery), and T3 (3 months after surgery).

Red bars: non-infected patients; Blue bars: PJI patients.

Clinical scenario 3 - Febrile Neutropenia (FN)

sCD14-ST is an early diagnostic marker of FN in hematologic malignancy patients. In a related case study, elevated levels of sCD14-ST were observed one day prior to CRP. Plasma sCD14-ST levels are a reliable marker for FN even in cases with extremely low WBC counts. Further, evaluating the increase level can facilitate early diagnosis of FN in patients with myeloid and lymphoid disorders. Close monitoring of this molecule can prevent infection-associated death of patients with hematologic malignancy[9].

sCD14-ST elevates one day prior to CRP

WBC	2400	7300	8300	1900	200	100
CRP	0.13	0.46	0.18	0.2	0.36	7.25
sCD14-ST	187		243	279	558	

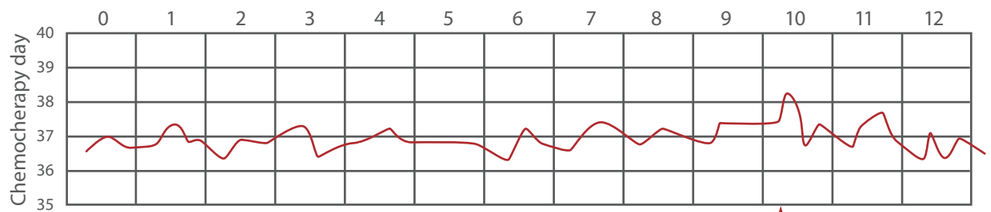


Fig. Plasma sCD14-ST levels in representative case

Clinical scenario 4 - Sepsis

sCD14-ST is an accurate biomarker for bacterial infection. The concentration levels of Mindray sCD14-ST in bacterial infection disease group are significantly higher than those in non-bacterial infectious disease and healthy groups[10].

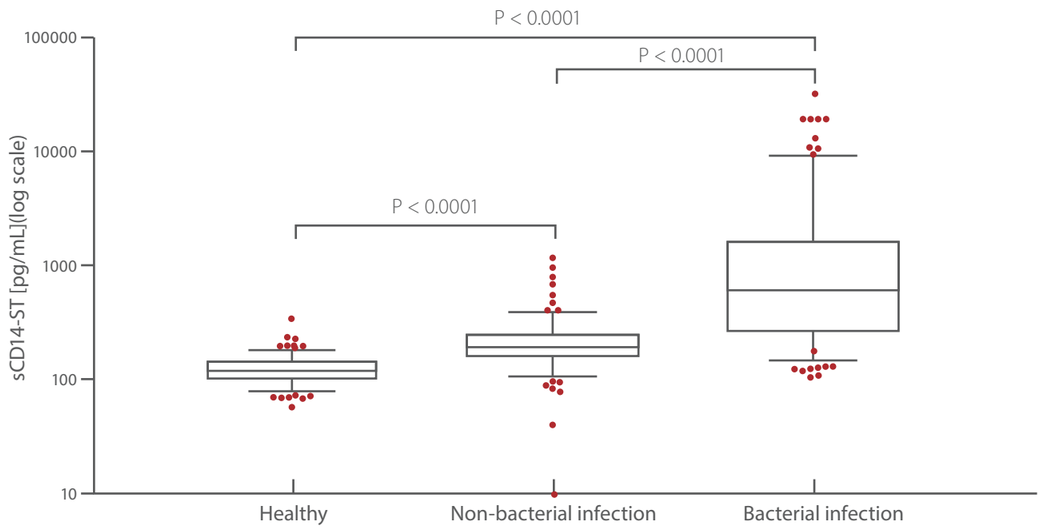


Fig. Distribution of -ST in healthy individuals (n=181), and patients with non-bacterial infection (n=163), and patients with bacterial infection disease (n=188)

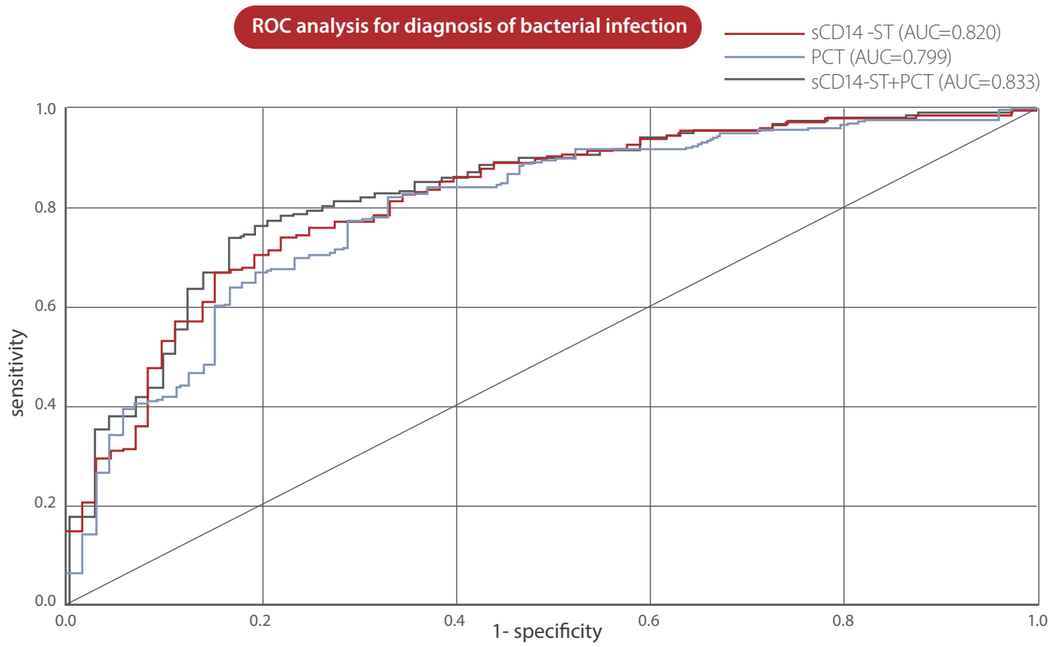


Fig. ROC analysis of the biomarker's performance in the diagnosis of non-bacterial infection (n=73) and bacterial infection (n=204)
Data source: Mindray clinical validation study

sCD14-ST is a predictive marker for adult sepsis. The levels of Mindray sCD14-ST are significantly increased in patients with sepsis and septic shock compared to bacterial infection and healthy groups. According to ROC analysis results, sCD14-ST provides an accurate indicator for the diagnosis of ICU patients without sepsis and those with sepsis[10].

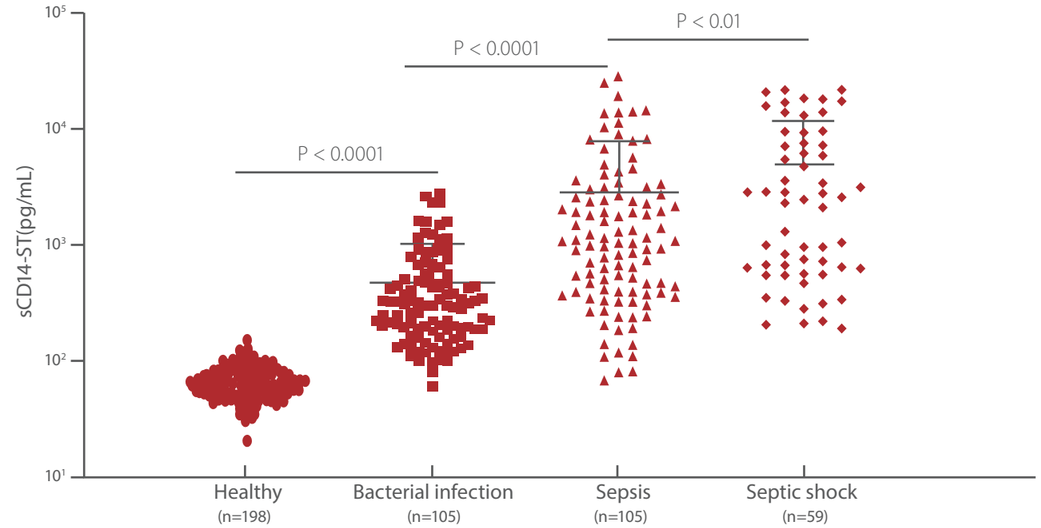


Fig. Concentration distribution of sCD14-ST in different pathological situations .

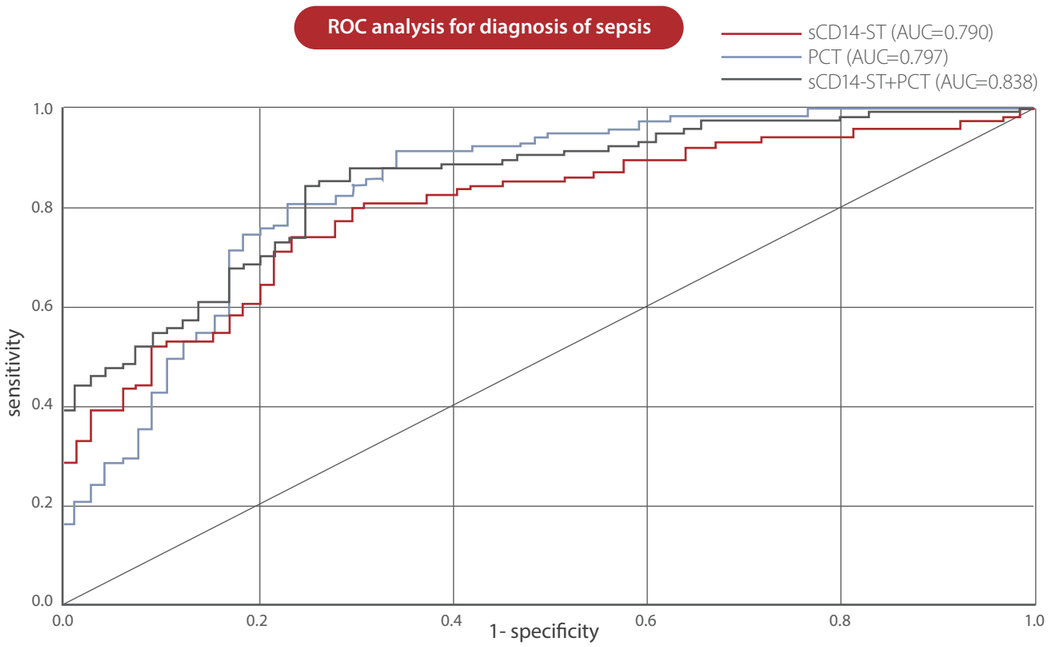


Fig. ROC analysis of the biomarker's performance in the diagnosis of ICU patients without sepsis (n=64) and those with sepsis (n=115)

sCD14-ST is a sensitive biomarker for the assessment of sepsis severity in ICU patients. In this study, sCD14-ST levels showed significant differences in severely ill (APACHE II≤15) and critically ill (APACHE II >15) groups, and PCT and IL-6 levels showed no statistically significant difference between these two groups[10].

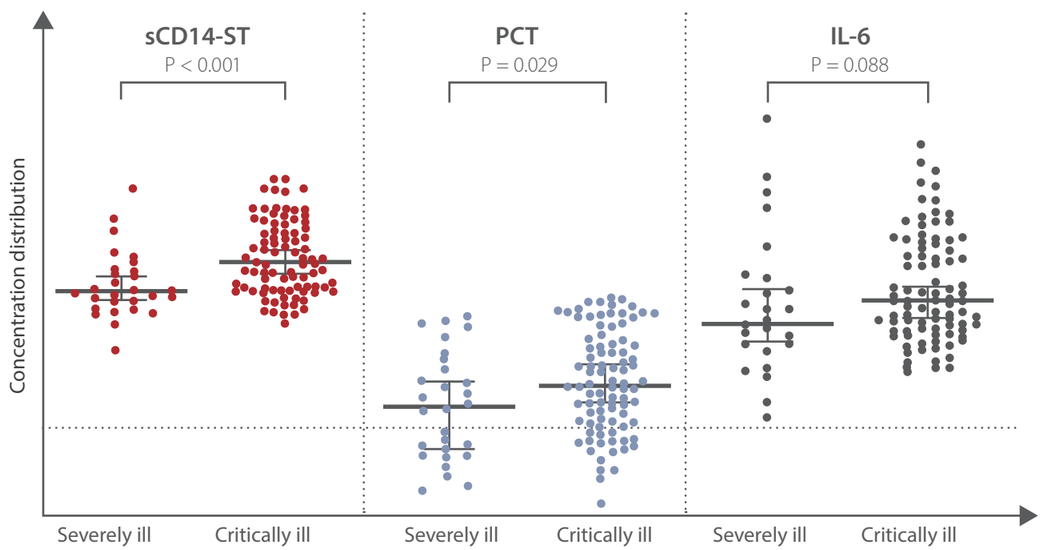


Fig. Scatter plots showing differences in the biomarker's levels between severely ill group (n=28, APACHE II≤15) and critically ill group (n=92, APACHE II>15).

sCD14-ST is a powerful monitoring tool for the treatment of sepsis. In the SOFA and APACHE II favorable group, sCD14-ST levels on D3 and D7 were significantly lower than levels measured at the time of admission. Meanwhile, in SOFA and APACHE II unfavorable group, sCD14-ST levels on D7 were not significantly lower than the levels measured at the time of admission[11].

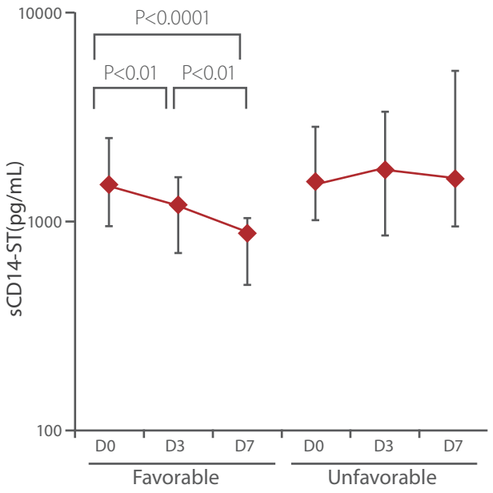


Fig. Time courses of sCD14-ST levels in patients who showed favorability (n=27) and unfavorability (n=26) according to SOFA scores on day 0(D0),day 3(D3), and day 7(D7) after admission. SOFA, Sequential Organ Failure Assessment

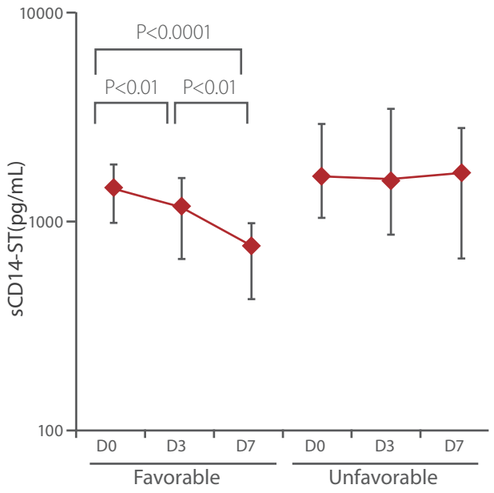


Fig. Time courses of sCD14-ST levels in patients who showed favorability (n=20) and unfavorability (n=31) according to APACHE II scores on 0 (D0), day 3 (D3), and day 7 (D7) after admission. APACHE II, Acute Physiology and Health Evaluation II.

Clinical scenario 5 - Trauma

sCD14-ST is a superior biomarker for early differentiation of infection in trauma patients. Plasma sCD14-ST levels within the first 3 days of admission were only significantly increased in the infected trauma group, but not in the noninfected trauma and sterile groups. sCD14-ST is also specified in the presence of infection in trauma patients[12].

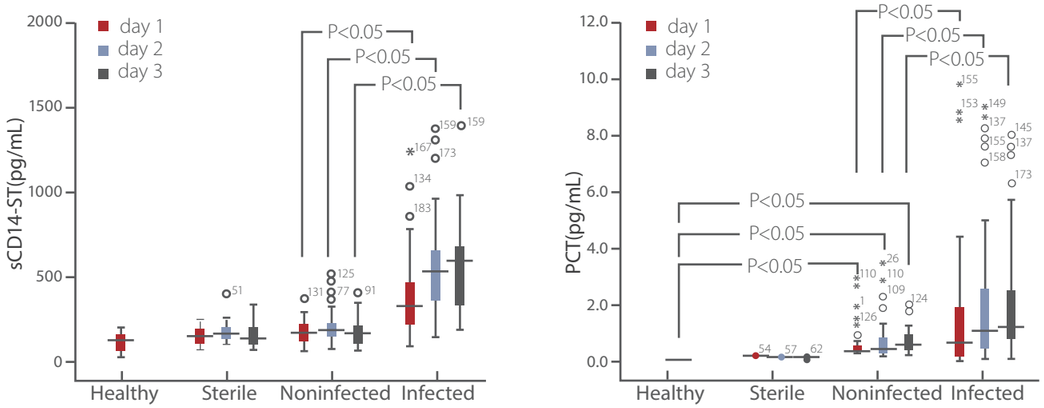
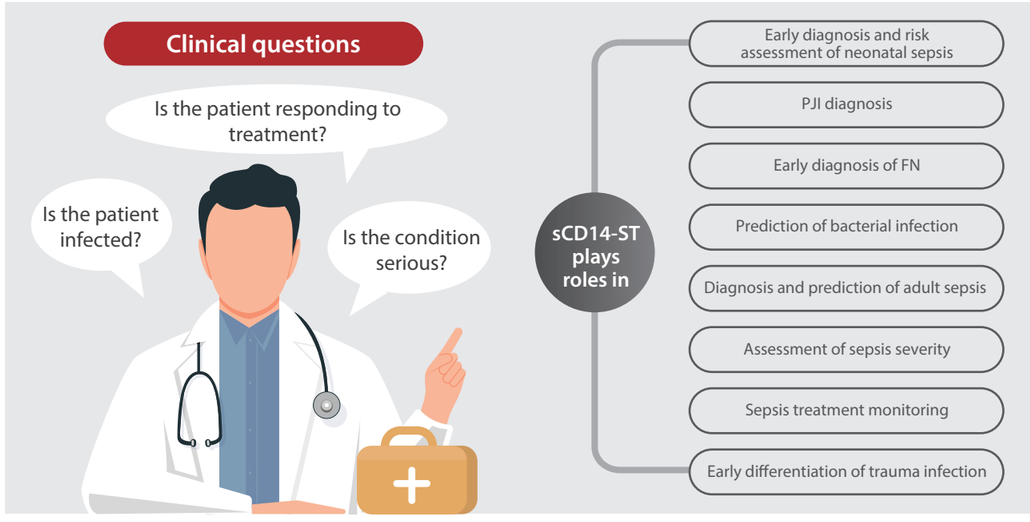


Fig. Comparison of sCD14-ST and PCT levels in the healthy, sterile, noninfected and infected groups. Trauma patients were divided into noninfected (n=89) and infected trauma groups (n=68); control groups were healthy adult volunteers (n= 60) and patients having had sterile surgery (n=60).

Clinical applications of sCD14-ST in infection

Infection is defined as "a pathologic process caused by the invasion of normally sterile tissue or fluid or body cavity by pathogenic or potentially pathogenic microorganisms". Infections are common in people of all ages and around the globe. However, the signs of infections are not always noticeable. If clinicians fail to pay adequate attention, they may administer inappropriate treatments, which would result in the development of organ dysfunction or even death[13-14].



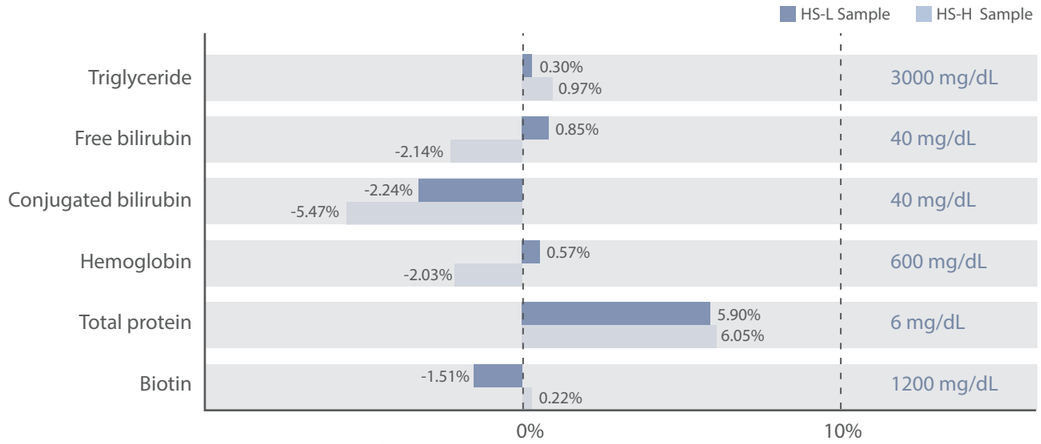
Performance

Performance of Mindray sCD14-ST

- Accuracy

Sample	Measured value (pg/mL)	Target value (pg/mL)	Relative deviation
Accuracy control (L)	130.10	122.29	6.38%
Accuracy control (H)	558.17	541.99	2.98%

- Analytical specificity



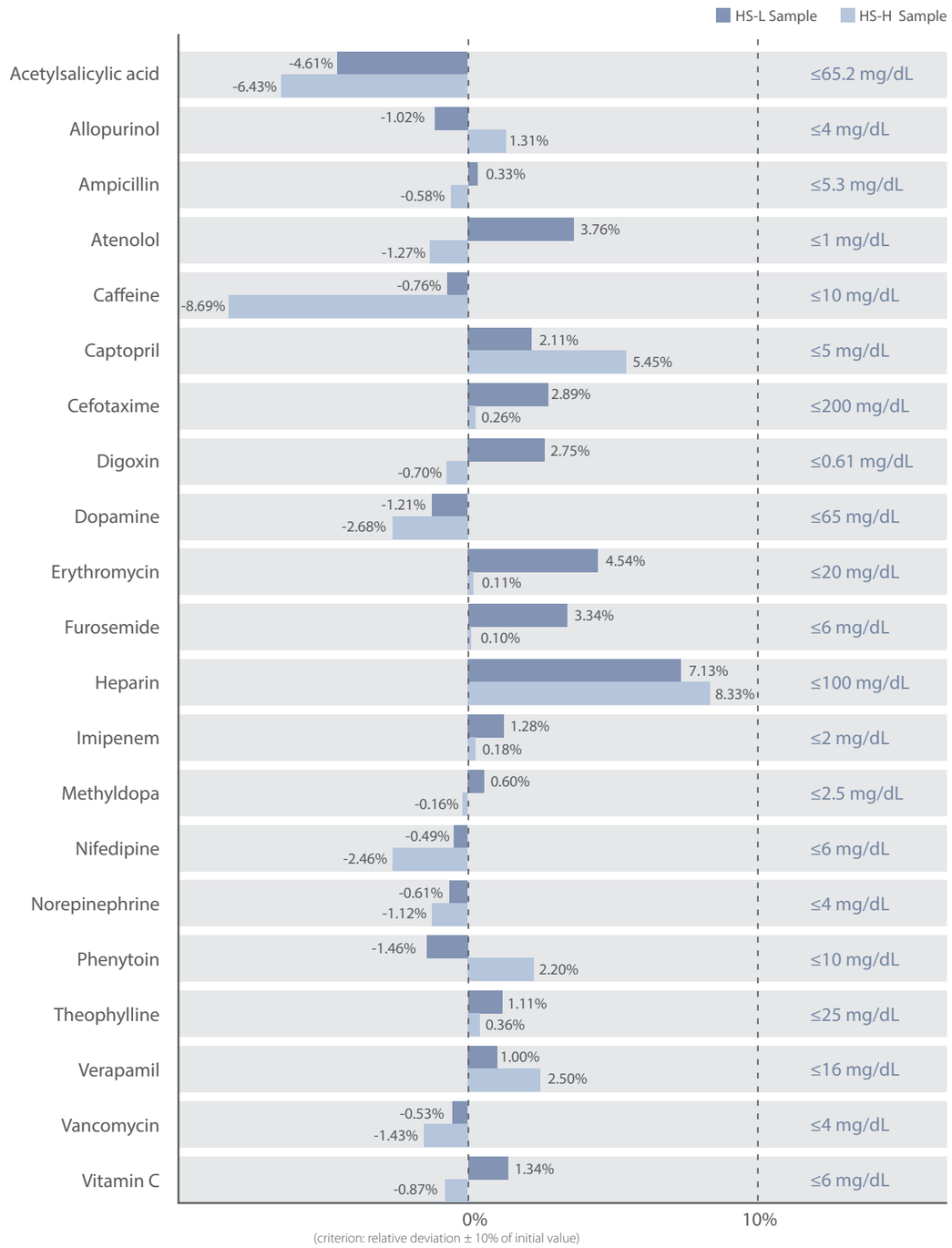
Criterion: Relative deviation within ± 10% of initial value

- Possible interferences

No significant cross reactivity was observed when Mindray sCD14-ST Calibrator C0 was spiked with sCD14 at 4.0 μg/mL, as indicated in the table below.

Substance	Cross-reactant concentration	Cross-reactivity rate
sCD14	4.0 μg/mL	≤0.02%

It is observed that the test results of Mindray sCD14-ST are not interfered with by the potential interfering drugs up to the following concentrations.

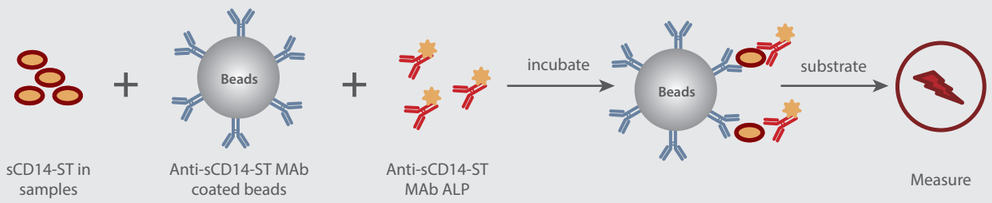


(criterion: relative deviation ± 10% of initial value)

Product Information

Detection principle of Mindray sCD14-ST

One-step sandwich assay (18 mins)



Threshold value and clinical significance

sCD14-ST (pg/mL)	Interpretation of results
＜200 pg/mL	Unlikely bacterial infection
200-500 pg/mL	Possible bacterial infection
≥ 500 pg/mL	High risk of bacterial infection

Ordering information

Product Name	Package	P/N	REF
sCD14-ST （CLIA）	2×50 tests/kit	105-023902-A0	105-023902-00
	2×100 tests/kit	105-023903-A0	105-023903-00
sCD14-ST Calibrator	C0:4×0.35 mL	105-023905-A0	105-023905-00
	C1:4×0.30 mL		
	C2:4×0.30 mL		
sCD14-ST Control	L:3×0.5 mL	105-023924-A0	105-023924-00
	H:3×0.5 mL	105-023925-A0	105-023925-00
	L:6×0.5 mL	105-023932-A0	105-023932-00
	H:6×0.5 mL	105-023933-A0	105-023933-00

Mindray inflammation solution

Mindray is dedicated to providing a total inflammation solution which consists of IL-6, PCT and sCD14-ST to meet different clinical demands from our end-users.

References

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