BioVendor Group CLIA

SIRS, sepsis, viral infections

CRP wide-range
IL-6
MxA
Procalcitonin

Diagnostic panel

Určeno pro platformu Kleeya®

Introduction

Sepsis and septic shock are among the leading causes of death worldwide. According to WHO data, in 2020, there were 48.9 million reported cases of sepsis globally, resulting in 11 million deaths. This represents 20% of all global fatalities, highlighting the critical impact of sepsis on global health.

SIRS and **sepsis** can appear diagnostically similar, but they differ significantly in their consequences.

SIRS

SIRS (Systemic Inflammatory Response Syndrome) is a systemic inflammatory response of the body that can be triggered by non-infectious factors such as burns, pancreatitis, ischemia, and other traumas. SIRS affects temperature, heart rate, and breathing, but it does not always progress to sepsis.

SEPSIS

Sepsis is a life-threatening condition that leads to organ dysfunction, affecting systems such as the brain, kidneys, lungs, and liver. It is most commonly caused by bacterial infections, but viral, parasitic, and fungal infections can also be triggers. The condition can worsen with pre-existing diseases like Diabetes mellitus, potentially resulting in septic shock and death. Distinguishing sepsis from other non-infectious conditions in critically ill patients presents significant challenges, highlighting the need for prompt and precise diagnosis to ensure effective treatment.

Sepsis development

Accurately distinguishing between viral and bacterial infections is crucial for reducing the overuse of antibiotics

Sepsis diagnosis is challenging because its symptoms often overlap with those of viral infections. Accurately distinguishing between viral and bacterial infections enables targeted antibiotic therapy, which can significantly improve patient prognosis.

Antimicrobial resistance complicates the treatment of sepsis and septic shock because some bacteria have become resistant to even the most powerful antibiotics due to overuse. Proper identification of infections is crucial for preventing further resistance. The MxA marker can help reduce unnecessary antibiotic use in viral infections, thereby lowering the risk of resistance development and improving treatment effectiveness.

Biomarkers used in the diagnosis of sepsis and viral infections

Procalcitonin - PCT

- PCT is a highly specific marker for bacterial infections, playing a crucial role in guiding antibiotic therapy decisions
- PCT is produced by neuroendocrine cells in response to bacterial infections
- PCT levels increase within 2–4 hours after the onset of infection, peaking at 12–24 hours
- Persistently elevated PCT levels suggest a severe systemic infection that may require intensive care, while a decrease in PCT levels is a positive indicator of clinical improvement

C-reactive protein – CRP

- CRP is a sensitive but less specific marker of acute-phase response to local or systemic inflammation, bacterial infection, and sepsis
- CRP is synthesized in the liver, induced by interleukins
- Its levels start to rise within 6–8 hours, peaking typically after 35–50 hours
- CRP is useful for monitoring inflammatory responses, detecting postoperative complications, and assessing the effectiveness of antibiotic therapy

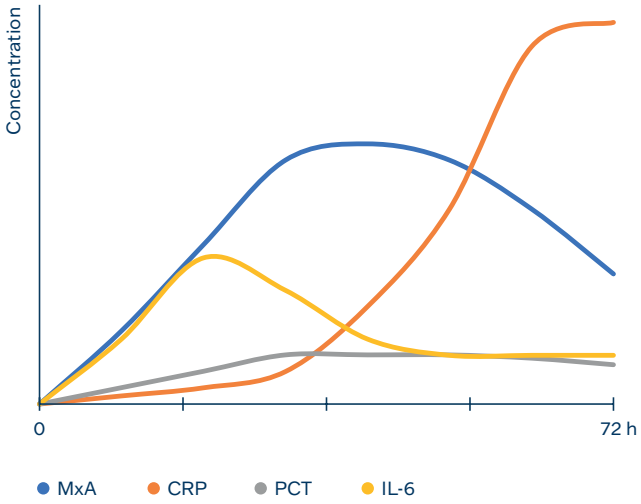
Interleukin 6 - IL-6

- IL-6 is a pro-inflammatory cytokine that plays a key role in both innate and adaptive immunity
- Its expression is induced by infectious agents and cytokines like IL-1β and TNF-α, leading IL-6 to act on hepatocytes to initiate the production of acute-phase reactants such as CRP, SAA, and fibrinogen
- In healthy individuals, IL-6 levels are typically low, but they rise rapidly in patients with sepsis, usually within 2 hours of infection onset
- Higher IL-6 levels are associated with the severity of organ dysfunction and can predict the risk of developing septic shock

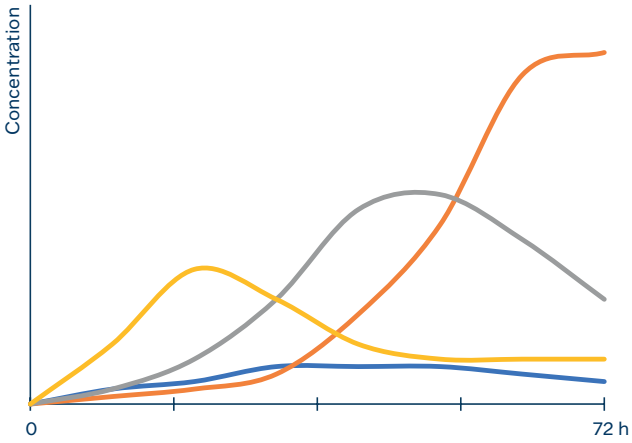
MxA

- MxA is a marker for viral infections that inhibits the replication of RNA viruses in the cytoplasm and the cell nucleus.
- It is primarily expressed in lymphocytes and monocytes
- MxA protein levels increase rapidly within 1–2 hours following a viral infection, with a half-life of approximately 60 hours
- MxA reaches its peak concentration within 16 hours of infection and remains elevated as long as interferon levels are high
- In the case of a bacterial infection, MxA concentrations remain low, distinguishing it from viral infections

Viral infection



Bacterial infection



Clinical application

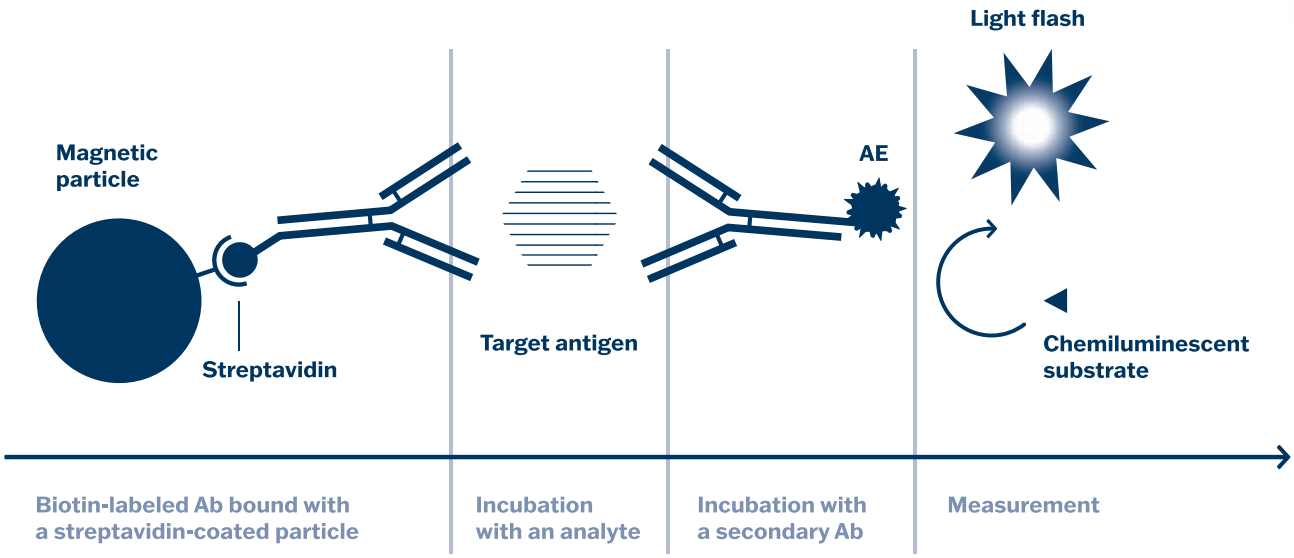
- **PCT** - Diagnosis and monitoring of septic conditions by measuring Procalcitonin levels in human serum in the general population.
- **CRP** - Diagnosis of inflammatory diseases by measuring CRP levels in human serum in the general population.
- **IL-6** - Diagnosis and monitoring of pathological inflammatory conditions by measuring Interleukin-6 levels in human serum in the general population.
- **MxA** - Monitoring and screening of viral infections by measuring MxA levels in whole blood lysate in the general population.

Test characteristics

	CRP wide-range C-reactive protein	**PCT** Procalcitonin	**IL-6** Interleukin 6	**MxA** Myxovirus resistance protein A
Sample	serum (12 µl)	serum (34 µl)	serum (34 µl)	whole blood (30 µl)
Measuring range	0.5–360 mg/l	62.5–4 000 ng/l	5–1 000 ng/l	31.25–2 000 ng/ml
Assay time	15 min	17 min	17 min	30 + 30 min

How does CLIA method work?

CLIA- Chemiluminescent Immunoassay is a highly advanced method known for its complete automation, rapidity, specificity, and sensitivity. It leverages magnetic particles to separate antigens in immunocomplexes and utilizes flash chemiluminescence for precise detection. The magnetic particle suspension enables automation, reduces reaction times significantly, and enhances specificity. Flash chemiluminescence using acridinium ester produces a strong light signal even at extremely low antigen concentrations, measured in relative light units (RLU). CLIA kits are specifically designed for seamless operation on the KleeYa® automated platform.



CLIA kits

CLIA diagnostic kits are used for the detection and monitoring of sepsis, inflammatory diseases, as well as for the screening and monitoring of viral infections in the general population. These quantitative, automated kits are designed for professional use in laboratories, specifically on the KleeYa® analyzer.

Control set CLIA

Control sets CLIA are designed to ensure the accuracy and reliability of results obtained from analyses using CLIA kits.

Ease of use

- Fully automated method
- Kits include all necessary reagents, incl. calibrators
- Control materials are available as independent sets

Advantages

- High diagnostic sensitivity and specificity
- Low sample (10 µl) and reagent consumption
- Short test time (30 min)
- Wide measuring range
- Full traceability of reagent consumption and number of tests available using RFID tags
- LIS connectivity available
- Superior customer service

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Ordering information

CLIA kits

CLIA diagnostic kits are used for the detection and monitoring of sepsis, inflammatory diseases, as well as for the screening and monitoring of viral infections in the general population on the KleeYa® analyzer.

Kit	Catalogue number	Number of tests
CLIA CRP wide-range	CL-CRP100	100
CLIA Procalcitonin	CL-PCT100	100
CLIA IL-6	CL-IL6100	100
CLIA MxA	CL-MxA050	50

Control sets

Control sets CLIA are designed to ensure the accuracy and reliability of results obtained from analyses using CLIA kits.

Control sets	Catalogue number	Number of tests
Control set CLIA CRP wide-range	CL-CRPCON	2× 20
Control set CLIA Procalcitonin	CL-PCTCON	2× 20
Control set CLIA IL-6	CL-IL6CON	2× 20
Control set CLIA MxA	CL-MxACON	2× 20

Supplementary products

Reagencies	Catalogue number	Quantity
Dilution cartridge 1 (pro CRP)	CL-DIC1	4× 100 ml
Lysis buffer (pro MxA)	CL-LYSBUF	25 ml

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