Problem description

Sepsis is a condition characterized by the body's inflammatory response to an infection. Sepsis is diagnosed where there is evidence of systemic inflammation, in addition to a documented or presumed bloodstream infection. The rapid identification of the blood infection is key because if sepsis is not treated with antibiotics it can progress to severe sepsis or septic shock and can lead to multiple organ failure and death. In the world, sepsis is estimated to be responsible for 27 million of hospital admissions and 8 million deaths per year. During the first 3 hours of inpatient, less than 40% of the sepsis patients have started the antibiotic therapy, increasing 10% of the mortality rate each hours without treatment.

Blood culture is considered the gold standard for the identification of bloodstream bacteria and fungi infection. However, it has been estimated that after 15 hours of blood culture only 30–60% of blood cultures taken from patients with sepsis are positive. This may indicate poor sensitivity, which may be attributed to commencement of antimicrobial therapy prior to sample collection, low pathogen levels in blood and inadequate blood sampling. The clinical need addressed is a way to identify blood infection faster than 3 hours in sepsis suspected patients in order to reduce their mortality (starting early the therapy).

Solution concept

The immune system responds specifically to an invading pathogen. Determining infection status in suspected sepsis patients has traditionally focused on finding and characterizing the invading pathogen. However, detecting the specific immune response can determine infection earlier and more accurately, and characterize the type of pathogen to which the host response is developing – viruses, bacteria, yeast and fungi. Small differences in the pathogen, host, or circumstances of the infection result in differences in the immune response. Finding and characterizing the invading pathogen can take days. In many cases, the causative pathogen is never identified. To be found, the causative pathogen must be in the sample in the first place, and this occurs in only 30% of suspected sepsis cases. In contrast, the specific host response can be detected in hours, and provide actionable clinical information in 100% of suspected sepsis cases.

Product description

Sepsis Loop dx is a diagnostic device that analyze the biological activity of blood immune cells identifying a previous contact with a bacterial stimulus. Prototype features are shown in the figure. The device is able to quantify directly from whole blood specific markers from the patient's own immune system – the "host response".