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BIDMC 1363: Diagnostic Test to Distinguish Sepsis from a Non-infective Systemic Inflammatory Response (SIRS)

➤ Rapid, PCR-based assay of circulating bacterial and mitochondrial DNA

Background: SIRS, the clinical manifestation of globally activated innate immunity, is the major cause of organ failure and ICU morbidity. SIRS can be caused by either a non-infectious event such as direct trauma, ischemia or toxins or it can result from an invasive microbial infection, in which case the condition is termed sepsis. It is often difficult to distinguish between these two conditions and the treatment of each is vastly different. Sepsis requires antibiotic therapy whereas anti-microbials are not helpful in non-infective SIRS. In fact, despite the enormous effort and costs devoted to antibiotic therapy, they often lead to the emergence of resistant infections and worse outcomes. Conversely, anti-inflammatory therapies often fail to improve and can increase mortality in early sepsis whereas they might improve outcomes if patients with non-infective SIRS could be reliably identified.

In the current invention, sepsis is distinguished from non-infective SIRS using a PCR-based assay that directly discriminates between the two. The assay measures the relative amounts of circulating mitochondrial and bacterial DNA where elevated levels of mitochondrial DNA specific for tissue injury are an indicator of non-infective SIRS and elevated levels of bacterial DNA indicate sepsis.

Stage of Development:

- In-vitro testing completed
- Clinical validation underway
- Currently optimizing speed & ease of use

Related Publication:

Nature Letters (464) March 4 2010: 104

Competitive Advantage:

Sensitive – femtomole levels of DNA detected from all major clinically important bacteria and from human mitochondria

Specific – non-infective SIRS measured using mitochondrial DNA sequences not found in bacteria; sepsis measured using DNA broadly expressed in bacteria and not found in mitochondria.

Reliable – built-in positive control for sample quality

Fast – Expect results in < 3 hours

Patent/Licensing Status:

- Provisional patent filed
- Flexible licensing options available

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