



Technology Commercialization Opportunity

Sepsis diagnosis via PAL (Peptidoglycan Associated Lipoprotein) detection in urine

Inventor(s):

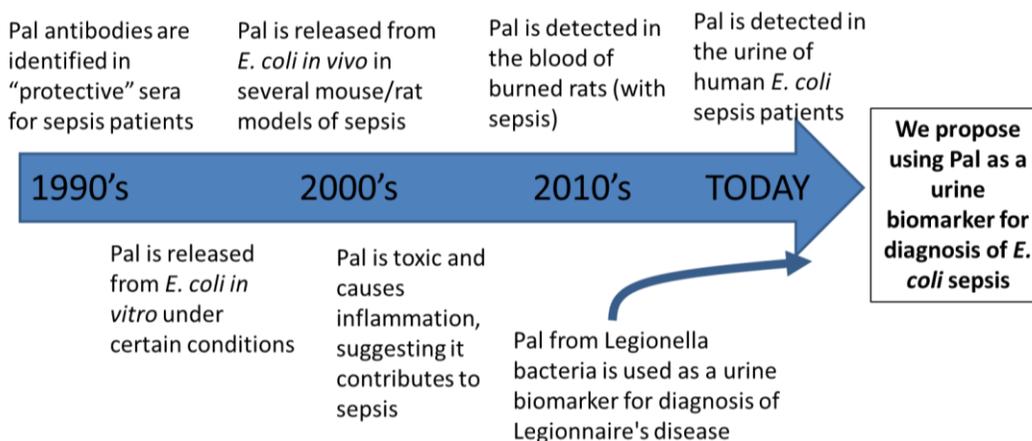
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Background and Technology Description:

According to a recent retrospective study, sepsis is among the **most expensive** conditions treated in US hospitals and **is a leading cause of mortality in hospitals**. During an initial bacterial infection, bacterial components are released and stimulate a series of immunological responses, including the release of a wide array of proinflammatory cytokines. Sepsis occurs when proinflammatory immune responses become abnormally elevated. For most sepsis patients, **early diagnosis of sepsis is a critical step** toward achieving a positive clinical outcome.

Gram-negative sepsis accounts for about 40% of all sepsis cases, and of those cases, most are caused by the pathogenic bacterium, *Escherichia coli* (*E. coli*). For several decades, scientists have focused on implicating **peptidoglycan associated lipoprotein (Pal)** in Gram-negative sepsis. Pal was shown A) to be released from *E. coli* in human sera (in a test tube); B) to be released from *E. coli* in several animal models of sepsis; C) to be toxic in animals; and D) to contribute to inflammation. The results of these studies pointed to Pal being implicated in the pathogenesis of sepsis. We proposed that if Pal was released by *E. coli* in the blood of human sepsis patients, Pal might also be filtered into urine. In a recent unpublished study, we detected *E. coli* Pal in the urine of several human sepsis patients. Pal has never been detected in the urine of healthy patients or patients with severe inflammation, but no *E. coli* infection.

This invention conceptualizes and advances the notion that Pal can be a **biomarker** for *E. coli* sepsis in the urine of human patients. We envision a point-of-care (POC) assay, similar to a pregnancy test, which detects the presence of Pal in patient urine. The assay would require a Pal antibody or small molecule specific for Pal coated/bound to a strip. If Pal is present in the urine, it would bind to the strip, resulting in a color change in the strip and notifying the clinician of the presence of Pal in the patient's urine.



Keywords: *E. coli*, sepsis, urine biomarker, Pal, diagnostic, medical test.

Technology Readiness:

This diagnostic method is currently in the concept stage. Results from small pilot study on *E. coli* sepsis patients suggest that Pal is detectable in patient urine using anti-Pal antibodies. No purification step was required, supporting the feasibility of a point-of-care diagnostic test.

Idea	Concept	Prototype	Alpha Version	Beta Version	Released
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Intellectual Property (IP):

The technology is currently the subject of a pending US patent application.

How it is different from current technologies:

Currently, there is no single test to fully and effectively diagnose sepsis. Doctors typically employ several tests and observational methods to diagnose sepsis, which include measuring procalcitonin levels, lactate levels, white blood cells, blood pressure, and blood bacterial levels. Such tests can take overnight. These tests are not always definitive and sepsis severity “scoring” can vary between doctors, depending on levels of expertise and experience. In summary, conventional sepsis diagnosis is very difficult, and the methods are highly variable between hospitals.

While many of the current diagnostic tests for sepsis focus on patient symptoms (ex. high blood pressure) that could overlap with other ailments, our proposed Pal diagnostic test detects a bacterial component that would otherwise not be found in patient urine and is specific to sepsis.

In addition, because we envision a point-of-care urine test to detect Pal, results would be rapid, allowing for early diagnosis of sepsis. The test could also be helpful in tracking a patient’s recovery, since we predict Pal levels would increase with increased bacterial load and then decrease as the patient recovers. And finally, since Pal is a lipoprotein found only in Gram-negative bacteria, a positive Pal biomarker diagnostic test would allow for a more specific and targeted antibiotic regimen for that patient.

Target Customers:

Hospitals, medical offices, and clinics who receive patients with sepsis

Opportunity:

RIT researchers are interested in working with parties who are interested in A) supporting or performing large scale longitudinal studies with sepsis patient urine to corroborate the effectiveness of using the Pal biomarker to diagnose sepsis; B) designing or creating a prototype for a point-of-care diagnostic tool to detect Pal in urine; and C) the commercialization of this medical technology. Arrangement types include funding research opportunities, licensing the technology to existing or new organizations, or forming strategic partnerships with those who have expertise in the field.

Contact:

Those interested in learning more about this opportunity should contact:

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Please refer to RIT ID 2019-004.