Sepsis is a potentially life-threatening complication of an infection. Precise treatment strategies are focused on restoring the immune balance, not eliminating the natural process necessary for getting rid of infection. This requires clinicians to be able to rapidly measure therapeutic targets, such as serum cytokines (small inflammatory proteins), to guide therapy and determine its effectiveness. However, no FDA-approved devices exist to do that, so the measurements are not currently performed.

The Solution

A team at the University of Michigan, including Pediatric Intensivist Timothy Cornell, M.D., and engineers Katsuo Kurabayashi, Ph.D., Pengyu Chen, Ph.D., and Walker McHugh, M.S.E. ’17, has developed the MicroKine Assay Device, a platform that utilizes a microfluidic chip and Localized Surface Plasmon Resonance (LSPR) technology to rapidly and simultaneously measure serum cytokine concentrations in a small sample of blood and provide simultaneous analysis of multiple cytokines.

The next step is to design and develop an automated reader for the MicroKine Assay Device. The goal is to produce a reader that can rapidly detect serum cytokines in less than 30 minutes. Currently, all cytokines are determined by outside reference laboratories with 3-5 day turnaround times.
New device helps doctors more accurately diagnose sepsis and develop targeted therapies for high-risk pediatric patients.

Significant Need
Current guidelines focus on physiologic goals rather than on a precision therapeutic approach based on individual patient characteristics or cytokine profile.

Compelling Science
The innovative platform rapidly measures serum cytokine concentrations in a small sample of blood and provides simultaneous analysis of multiple cytokines. The next step is to develop a reader that can rapidly detect serum cytokines in less than 30 minutes.

Competitive Advantage
The new platform and reader device provide rapid, sensitive measurement of numerous cytokines from a small volume of blood, allowing for frequent serial measurements to monitor therapeutic effectiveness.

MTRAC Project Key Milestones

- Develop scalable automated reader
- Enroll patients for sample collection
- Initiate FDA approval process
- Engage Investors
  - On-going discussions with companies about license agreements

Overall Commercialization

Commercialization Strategy
Form a start-up producing the MicroKine assay and automated reader. Also examining licensing to therapeutic companies, particularly those developing cancer immunotherapies.

Regulatory Pathway
Undergone both external and internal regulatory classification review. Likely to be classified as Class II medical device.

Intellectual Property
Provisional patent application filed for the MicroKine Assay Device, additional patent application and copyright of the computer code for the automated reader to be filed.