



Digital Protein Biomarker Array for Multiplex Immunoassays

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OVERVIEW

Pre-equilibrium digital enzyme-linked immunosorbent assay (PEdELISA)-based microarray test

- Detects multiple protein biomarkers in biofluids
- Fully automated, multiplexed, high-throughput, on-site virus screening

BACKGROUND

Predictive and prognostic biomarker testing for life-threatening acute illnesses, such as cytokine release syndrome (CRS) and acute respiratory distress (ARDS), could enable rapid clinical intervention. However, traditional ELISA-based assays have a 4-6 hour turnaround time. While testing and therapeutic plans for cancers and other chronic diseases are formulated over days to weeks, a life-saving treatment for critically ill patients must be delivered in minutes to hours, requiring fast diagnostic technologies near the patient that traditional ELISA cannot offer. The ideal testing assay should be sensitive, have a low turnover time, include easy to follow protocols, enable high throughput, be able to multiplex, and show cost-effectiveness. Currently available tests and testing platforms, whether PCR- or ELISA-based, contain limitations in at least one or more of these areas.

INNOVATION

Researchers at the University of Michigan have developed a PEdELISA-based microarray that is a viable solution for rapid biomarker testing in critical care. This platform can test for multiple protein biomarkers in the same biofluid with a short (15-30 min) turnaround. The multiplexed analysis will provide a comprehensive picture of the immune status of the host under acute inflammation. The system is fully automated, incorporating microfluidic, disposable chips with embedded specific antibody conjugates, automated pipetting system for sample loading, and

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automated fluorescent imaging combined with a proprietary algorithm for data analysis. The image processing algorithm incorporates machine learning-based convolution neural network and parallel computing for fast, high-throughput image analysis showing high accuracy without human supervision. Together, this technology enables detection of various biomarkers (e.g., proteins, enzymes, DNA, and RNA) in blood, saliva, urine, and other samples at high speed, accuracy, sensitivity, and specificity. As such, the device serves as a general platform for immunoassays in bedside settings or intensive care units (ICUs).

References

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