

Smart ELISA for Real-World Applications: From Clinical Diagnostics to Food Safety

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Enzyme-linked immunosorbent assay (ELISA) has long been regarded as the gold standard for quantitative protein analysis because of its high sensitivity and specificity. However, conventional ELISA requires multiple washing and incubation steps, expensive analytical instruments, and skilled operators, limiting its applicability to rapid on-site testing in clinical settings, food production, and other point-of-need environments.

To address these limitations, numerous microfluidic immunoassay platforms have been developed. Nevertheless, many of these systems rely on external pumps or other active fluid-driving mechanisms, resulting in complex and costly instrumentation. In contrast, paper-based microfluidic devices offer operational simplicity but often suffer from limited control of fluid flow, leading to insufficient quantitative accuracy and analytical sensitivity.

To overcome these challenges, we have developed Smart ELISA, a novel microfluidic immunoassay platform that enables highly accurate ELISA simply by dispensing the sample and reagents onto a disposable microfluidic chip¹⁻². Smart ELISA integrates a disposable microfluidic cartridge, an autonomous fluid-control mechanism, and smartphone-based image analysis to perform quantitative immunoassays without external pumps or complicated fluid-handling procedures. The system requires only a small sample volume and provides accurate quantitative results within approximately 15 minutes.

Smart ELISA has broad applicability in clinical diagnostics, food safety, healthcare, and environmental monitoring. We have successfully demonstrated its performance in a wide range of applications, including antigen and antibody testing for COVID-19, detection of inflammation- and disease-related biomarkers, food allergen analysis, skin biomarker assessment using the stratum corneum, pesticide detection, salivary stress biomarker measurement, and fertility-related hormone testing. In addition to a dedicated reader, a smartphone-based analysis system is being commercialized, including the release of an iOS application, while mass production of the disposable microfluidic cartridges is also underway.

In this presentation, we will introduce the design concept and core technologies underlying Smart ELISA, including the microfluidic cartridge architecture, autonomous reagent control, smartphone-based quantitative image analysis, and multiplex immunoassay capability. We will also present a compact fully automated Smart ELISA analyzer and discuss recent application examples spanning clinical diagnostics to food safety, highlighting the platform's potential for real-world implementation and future development.

Keywords: Smart ELISA; Microfluidics; Immunoassay; Point-of-Care Diagnostics

References

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