Smartphone EasyELISA - A point-of-care platform for cost-effective and easy-to-use in vitro diagnostics

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Summary

We have developed a Smartphone EasyELISA (SE-ELISA) point-of-care (POC) platform [1], which enables rapid, cost-effective and easy-to-use immunoassays (IA) at decentralized, remote and personalized settings. The performance of the SE-ELISA is demonstrated by a human C-reactive protein (CRP) sandwich immunoassay.

1 Material and Methods

The immunoassay is performed in 96-well microtiter plate (MTP) and the readout is performed by a smartphone. The procedure involves the displacements of SE-ELISA disposable lid having 24 (3×8) hollow projections into the adjacent 24-wells of the 96-well MTP. The MTP is divided into four sections, where the one-step kinetics-based immunoassay (IA) is performed in the first section [2], followed by two subsequent washings sections and finally, an enzyme-substrate reaction section (Fig. 1A). After the formation of colorimetric product, the enzymatic reaction is stopped by removing the SE-ELISA lid instead of sulfuric acid, which is used routinely in classical ELISA to stop the reaction.

The anti-human CRP antibody (Ab) is bound covalently to the projections of the lid by a leach-proof covalent binding procedure [3], which involves the incubation of KOH-pretreated lid with 1-Ethyl-3-[3-dimethyl-aminopropyl]carbodiimide hydrochloride (EDC)-activated Ab diluted in 3-aminopropyltriethoxysilane (APTES). All IA components, wash buffer and enzyme substrate are kept pre-stored in the respective wells of 96-well MTP. The user just has to move the E-ELISA lid into the adjacent 24 wells four times after dispensing the analyte sample to be analyzed into the first 24 wells.

The colorimetric readout is performed directly by smartphone imaging using our smartphone-based colorimetric reader (SBCR) [4] (Fig. 2B) and the captured image is then analyzed by a novel image processing algorithm to compute the analyte concentration based on pixel color (Fig. 2C).

2 Results

The performance of the SE-ELISA-based CRP IA (Fig. 3D) was similar to that of conventional ELISA procedure. However, the SE-ELISA format has several distinct features compared to a conventional format i.e. i) the washing procedure does not require inversion of MTP, ii) it bypasses a large number of procedural steps, and iii) obviates the use of bulky instruments, such as MTP readers, for colorimetric readout.

3 Conclusions and Outlook

SE-ELISA can be reliably employed for the development of POC in vitro diagnostics (IVD) as it can be easily used by a normal person with basic handling skills. Moreover, the SE-ELISA format is based on the already existing clinically-accredited ELISA and is superior to the recent diagnostic formats based on the use of lab-on-a-chip platforms, microfluidic technologies or nanomaterials-based IA. Being highly simplified, capable of mass production and compliant with the existing bioanalytical method guidelines in healthcare, industry and bioanalytical settings, SE-ELISA is a commercially-viable and appealing platform for IVD. The use of our proprietary SBCRs provides the unique opportunity of obviating the use of expensive MTP readers and enabling the assay results to be stored securely and transmitted to the centralized healthcare servers or Cloud. Therefore, the developed SE-ELISA provides smartphone-based mobile healthcare solution for colorimetric IA-based IVDs. Taking into account about 7 billion cell phone users worldwide with more than 70% in developing countries, SE-ELISA will be an ideal format for cost-effective and easy-to-use IVDs.

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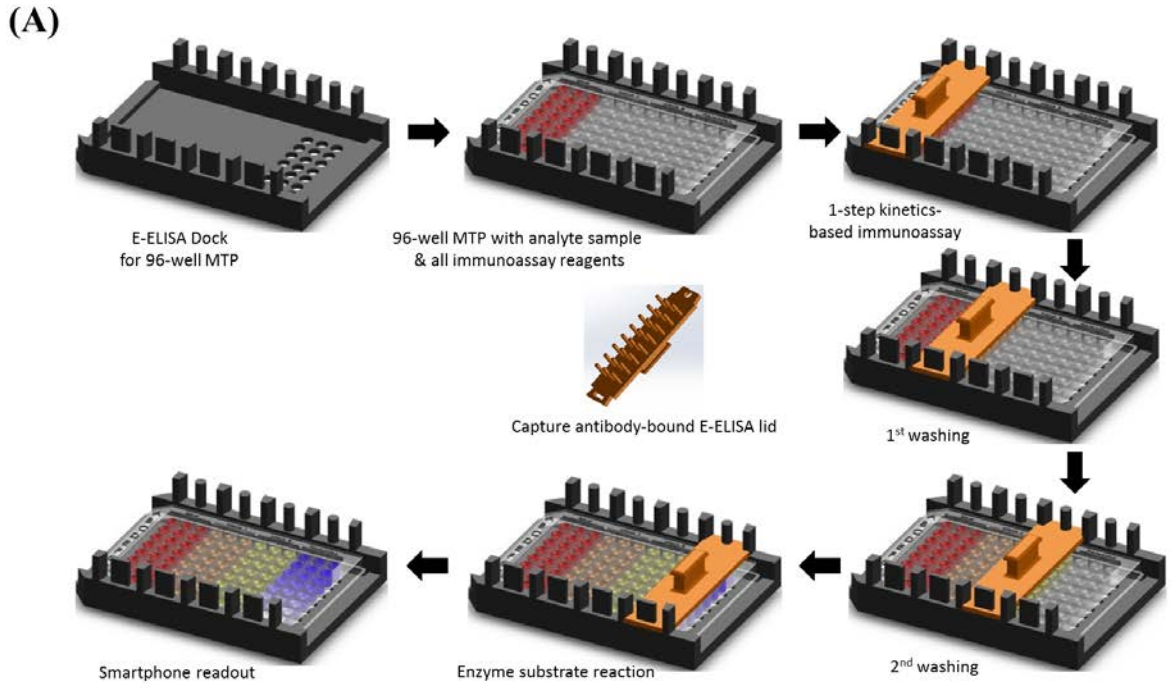

Figure 1: (A) E-Elisa platform-based IVD

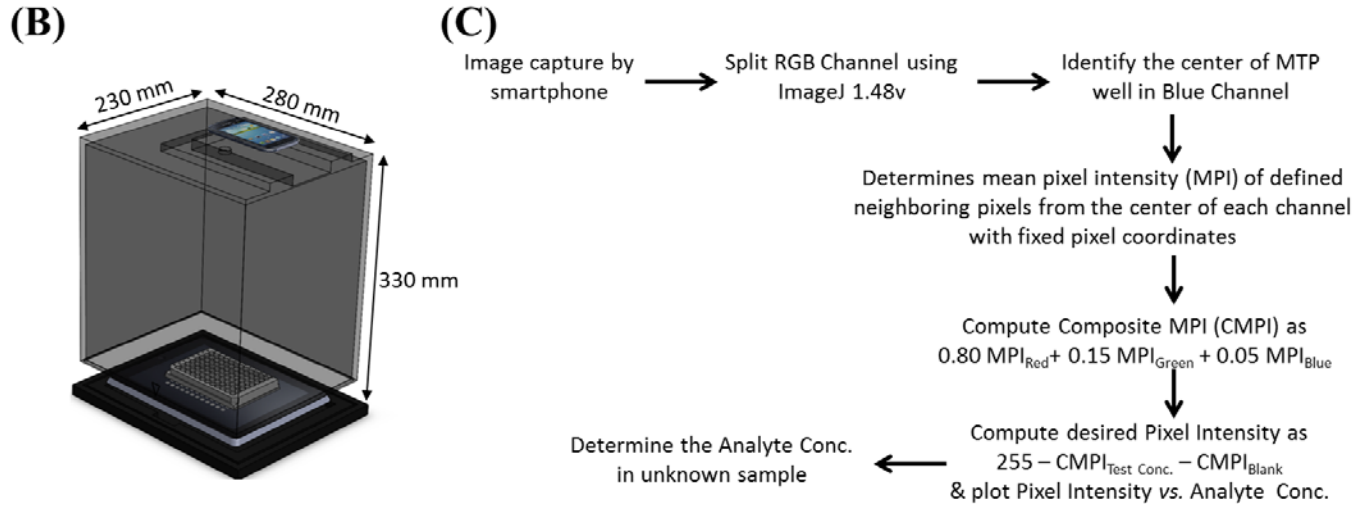

Figure 2: (B) Smartphone readout of E-Elisa by the developed SBCR. (C) Image analysis algorithm

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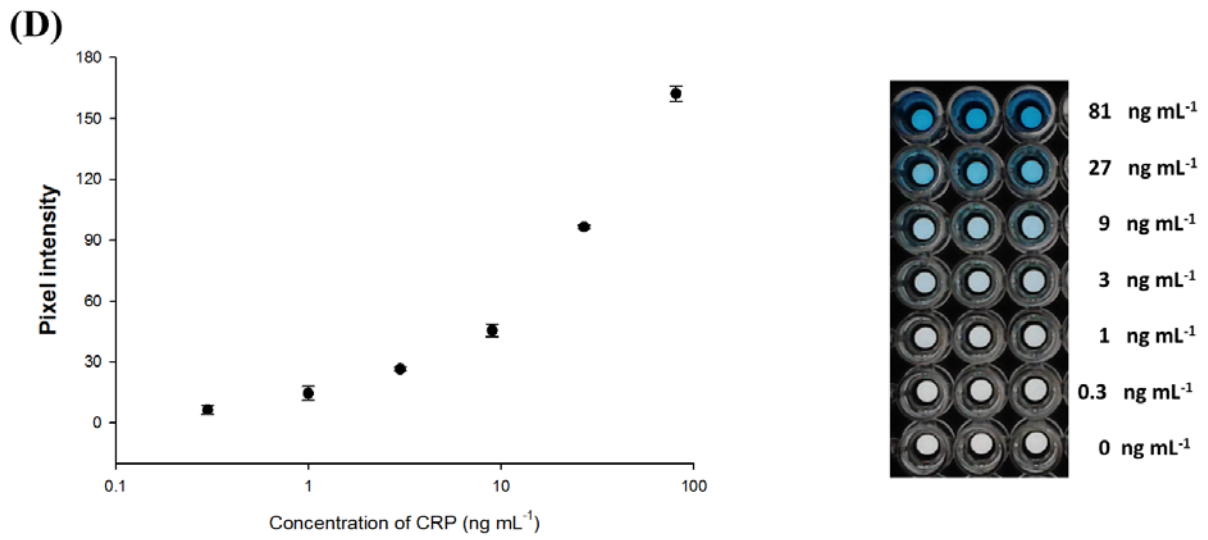

Figure 3 (D) Detection of CPR in PBS (10 mM, pH 7.4)

4 References

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