

FIELD-DEPLOYABLE MICROFLUIDIC IMMUNOASSAY DEVICE FOR PROTEIN DETECTION

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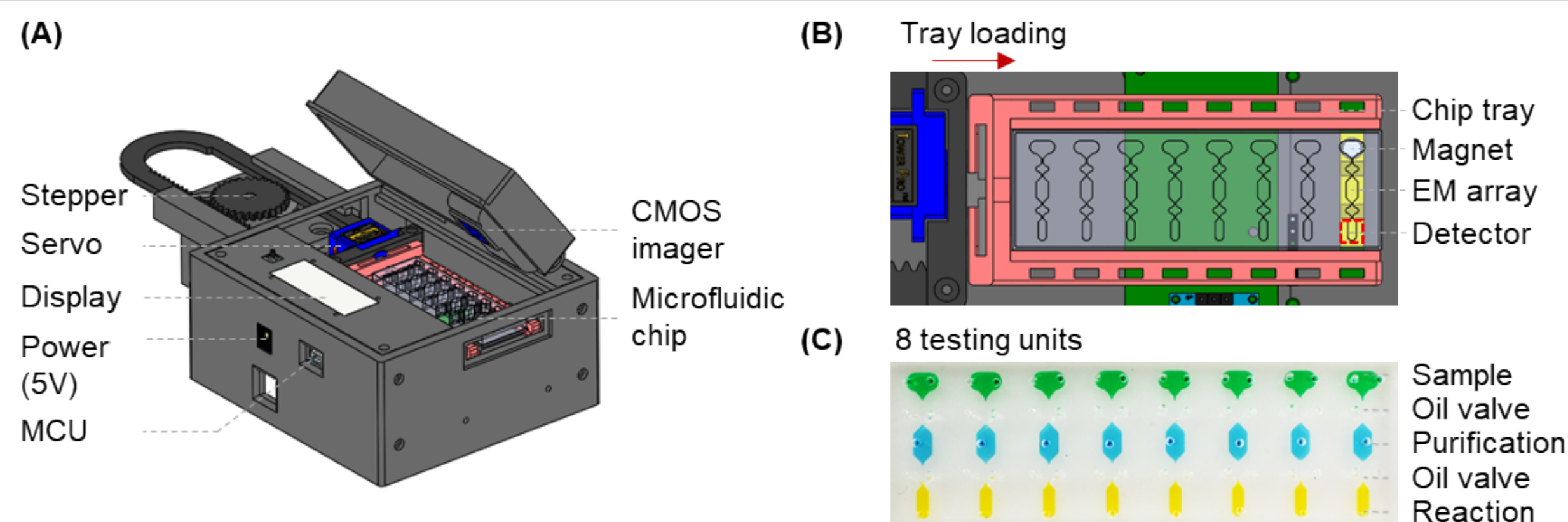
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Introduction

- Identifying specific protein biomarkers is a critical clinical procedure for timely and cost-effective diagnosis.
- Development of mobile and low-cost technology for sensitive protein detection is of interest in the clinical setting.
- Microfluidic approach is well suited for on-site clinical diagnosis because of portability, low sample/reagent volumes, and automated processing.
- Microparticles are frequently used because their high surface-to-volume ratio can significantly reduce assay time while improving sensitivity.
- Implementing bead-based immunoassays relies on the strategic actuation of beads and liquid droplets in a controllable manner.
- Integrating reliable, robust, and automated front-end immunoassay is still a common hurdle for most existing point-of-care microfluidic devices.

Instrumentation



- Platform footprint: 11×12×8 cm.
- Optical and electromechanical subsystems.
- A single microfluidic chip contains 8 testing units

Workflow

- Sample loading (1 min)**
8-channel pipette → PSA sealing → Inserting chip
Microfluidic chip
 - Automated sample process (36 min)**
Incubation (rolling, 25°C) → Purification
 - CL measurement / analysis (8 min)**
CL signal from each testing unit is measured one at a time; then analyzed.
- Step 1:** Load sample using 8-channel pipette, then seal microfluidic device with pressure sensitive adhesive.
 - Step 2:** Insert microfluidic chip to platform, then press start button. The platform processes samples in automated fashion (i.e., incubation and purification).
 - Step 3:** CL signal from each testing unit is measured one at a time; then analyzed.

Automated Sample Process

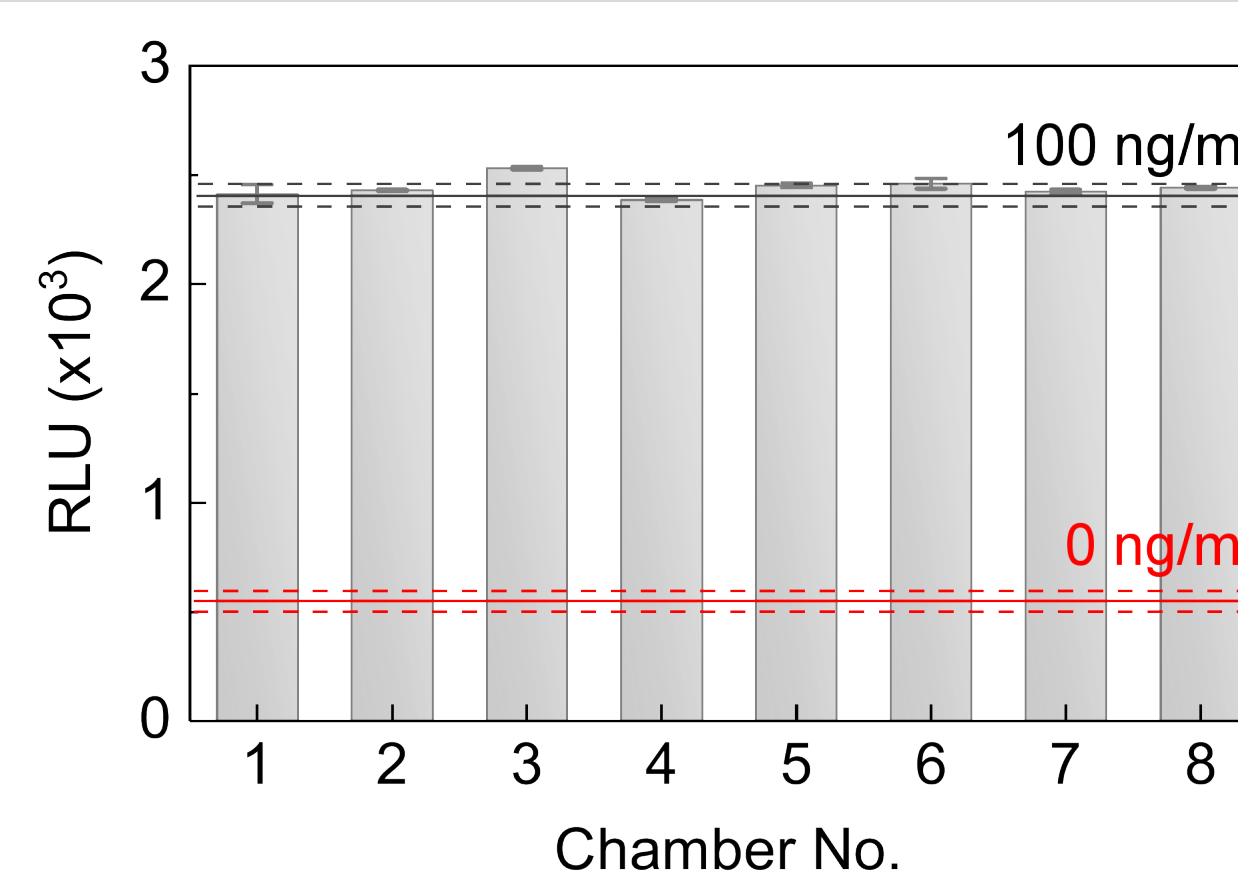
Incubation

Purification

CL reaction

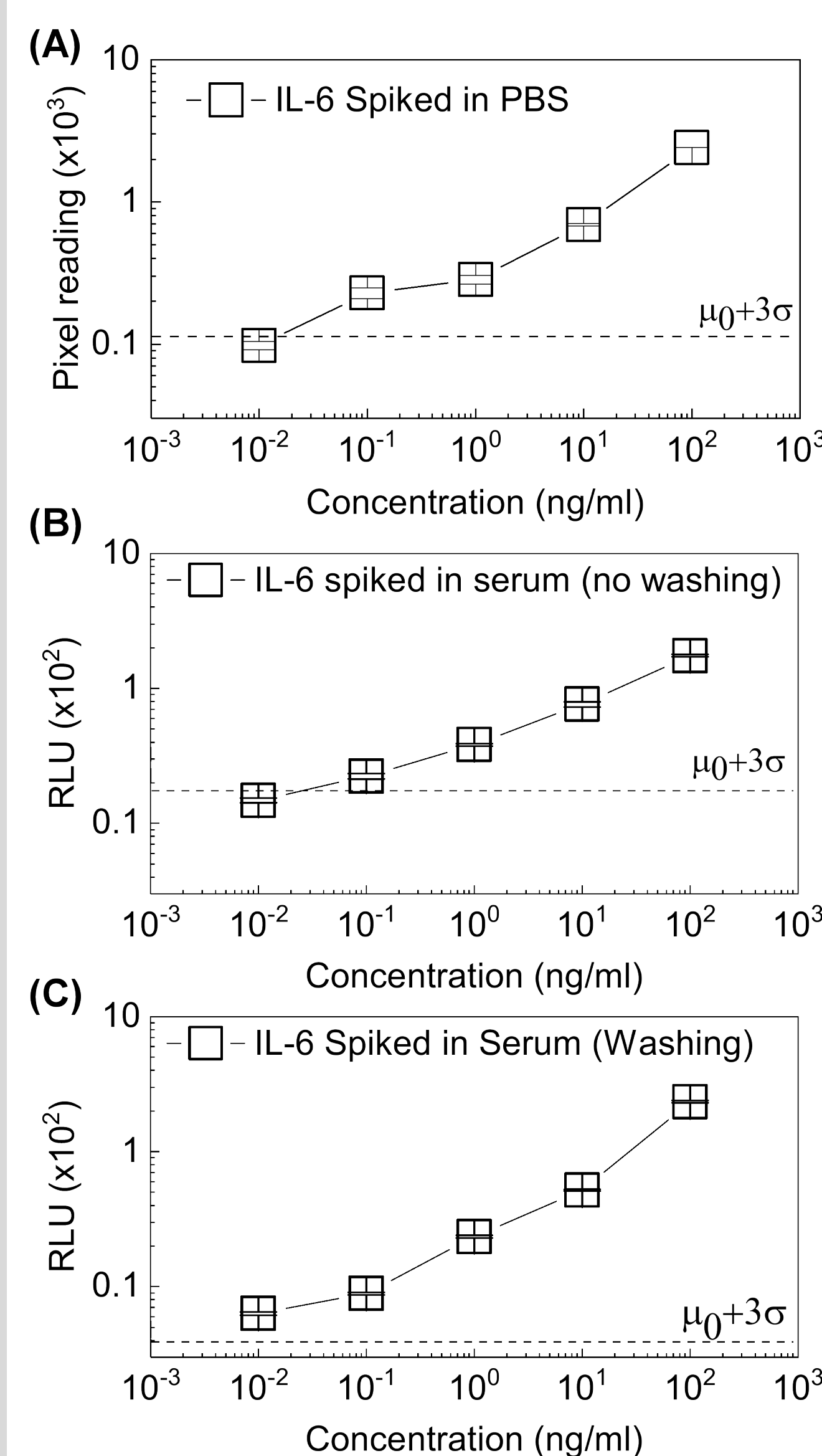
- Bead-based immunoassay is performed in microfluidic chip without user intervention.
- Magnetic beads are actuated by controlled magnet motion on electromagnet micro-actuators.
- Purification:** Beads are agitated to remove the reagent carryovers from the sample chamber.
- Reaction:** Washed beads are transferred to the reaction chamber for CL measurement.

Uniformity



- The quantitative results among 8 testing units showed excellent uniformity (100 ng/ml: 2410 ± 50 , 0 ng/ml: 548 ± 20).
- Robust reagent mixing & washing during the sample prep. and consistent bead transfer.

Sensitivity



- The device facilitated the sandwich immunoassay on the microfluidic chip in automated manner.
- The linear standard curve showed the quantitative ability of system.
- Without purification, sample matrix effect was observed with serum spiked samples.
- This is mainly due to the unbound HRP-labeled detector antibodies carryovers to CL reaction chamber.
- With purification, the detection limit of 10 pg/ml was achieved with the presence of sample matrix.
- Sample purification mitigates sample matrix hindrance and enables sensitive detection.

	in PBS (no wash)	in serum (no wash)	in serum (wash)
S:B	4.2	2.8	5.2
LOD (pg/ml)	480	480	10

- Result from serum spiked sample also indicates that the assay is specific to the IL-6.

Conclusion

- A mobile platform operates eight microfluidic immunoassay tests for sensitive protein detection in 45 minutes.
- Integrated planar electromagnetic actuator enables robust and automated front-end immunoassay without user intervention.
- Achieved detection limit of 10 pg/ml with IL-6 spiked in human serum.
- Enables immunoassay for accurate & timely diagnosis at point-of-need.

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