

COVID-19 rapid diagnostic test for instrumentation-free virus detection in saliva

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I. INTRODUCTION

Widespread home point of care (POC) testing for detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV2) is pivotal to control the coronavirus disease 2019 (COVID-19) [1]. Modeling suggests that accessibility to the test, frequency of testing and sample-to-answer time are of priority over test sensitivity for COVID-19 surveillance [2]. Hence the reverse transcription polymerase chain reaction, as the current gold-standard tool for diagnosis of COVID-19, even with excellent sensitivity and specificity is not well-suited for home POC diagnostics as it is expensive, hard to administer and limited to a peripheral instrument. Here, we aim to develop a user-friendly, instrument-free microfluidic kit for rapid and quantitative diagnosis of COVID-19.

II. RESULTS

We developed a fully-autonomous capillary microfluidic chip, called domino capillary circuits (DCCs) [3,4], to perform on-chip enzyme-linked immunosorbent assay (Fig. 1 b). The developed CC enabled fluidic operations such as sample metering, aliquoting, reagent incubation and washing. The reagents and washing buffer are loaded into the chip and upon adding saliva, the DCC sequentially delivers the sample, reagents and washing buffer with precise flow rate to the reaction site.

We used commercially-available antibodies and materials for the detection of SARS-CoV-2 nucleocapsid protein in saliva sample (Fig. 1a). We also developed a cell phone readout platform, enabling the time-insensitive colorimetric signal generated on the nitrocellulose membrane to be quantified.

Fig.1c shows the off-chip standard curve of the spiked saliva sample. The colorimetric signals were analyzed and a four-parameter logistic curve was fitted to the points which yielded in the limit of detection of 0.28 ng/mL.

Taken together, we developed a capillary chip for rapid and quantitative detection of SARS-CoV-2 in saliva. The

chip is fully-automated and user-friendly, and has the potential to be employed for home POC diagnostics.

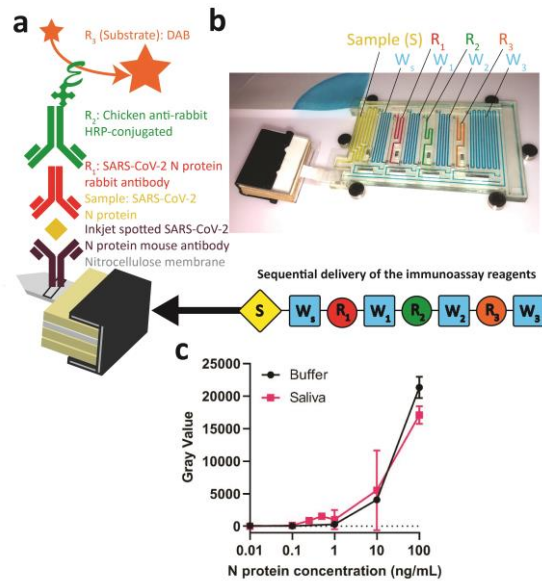


Fig. 1 (a) Schematic illustration of the immunoassay workflow. (b) The DCC loaded with food dyes. (c) The dose response curve of the saliva spiked with different concentration of the nucleocapsid protein (N protein).

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