Pandemic screening with a low-cost COVID 19 diagnostic chip

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Abstract

Introduction: The fast-paced transmissibility of SARS-CoV-2 (also known as COVID 19) led to a substantial increase in the number of infected cases and deaths worldwide made it a public health emergency. The virus imposed unprecedented challenges on the healthcare system for the mass screening of the people to identify the positive carriers to prevent the spread. The vaccine administration process is ongoing; therefore, diagnostic can play an essential role in the containment of COVID-19, enabling the rapid implementation of control measures to limit the spread. The current gold standard diagnostic test for COVID 19 is RT-qPCR; however, it is insufficient to meet the global testing demand because of its high cost and complexity, time-consuming, and unavailability in remote areas. Alternate to RT-qPCR is RT-LAMP, which provides an easy, scalable, low-cost, and accurate detection of disease that can be implemented broadly at point-of-care (POC) settings. Herein, we aim to develop a portable, ease of using POC SARS-CoV-2 detection microfluidic chip that can be effectively deployed during this pandemic.

Materials and methods: We designed RT-LAMP primers specific to the SARS-CoV-2 virus. With the designed primers, RT-LAMP assays were performed off-chip and on-chip with saliva samples spiked with SARS-CoV-2 virus. The on-chip setup consists of a microfluidic chip made up of PMMA, a platform for magnetic actuation, and a heater and the sensor to control the target amplification temperature precisely. The magnetic platform controls the magnetic beads' movement that enables the isolation and purification of the target adhere to their surface for amplification and color change was visually observed for end point investigation.

Results and Discussion: To present a proof-of-concept of our designed assay, we processed saliva spiked (SARS-CoV-2 virus) sample with the clinical viremia range (10^4- 10^{11} virus copies/mL in saliva). The color change in the reactions (both off-chip and on-chip) due to the amplification from orange to green was observed only in the saliva sample spiked with SARS-CoV-2 virus within 40 minutes. The lowest limit of detection results was observed to be 10^3 virus copies/mL. This multistep target extraction process, unified on the platform, has proven to avoid contamination for the downstream amplification process.

Conclusion: We have developed an automated microfluidic chip-based RT-LAMP assay that combines the isolation, purification, and amplification steps on the same platform and enables the visual detection of the SARS-CoV-2 virus from the human saliva within 40 minutes. The entire SARS-CoV-2 virus detection is executed inside a uniquely designed inexpensive disposable microfluidic chip. All the components and reagents associated with the assay are optimized to provide highly specific and qualitative results without any human involvement after sample loading.