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Highly sensitive and specific diagnosis of COVID-19 by reverse transcription multiple cross-displacement amplification-labelled nanoparticles biosensor

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We devised a novel method (COVID-19 RT-MCDA-BS) to diagnose COVID-19. Its rapidity, low cost and ease of use make the method an ideal tool for use in field, primary and clinical laboratories, especially for resource-poor settings. <https://bit.ly/3j08CU2>

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ABSTRACT

Background: The ongoing outbreak of the novel human coronavirus severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (also known as 2019-nCoV) has become a global health concern. Rapid and easy-to-use diagnostic techniques are urgently needed to diagnose SARS-CoV-2 infection.

Methods: We devised a reverse transcription multiple cross-displacement amplification (RT-MCDA) coupled with a nanoparticle-based biosensor assay (RT-MCDA-BS) for rapid, sensitive and specific diagnosis of coronavirus disease 2019 (COVID-19). Two primer sets were designed to target the open reading frame 1a/b and nucleoprotein gene of SARS-CoV-2. A total of 183 clinical samples, including 65 patients with COVID-19 infection and 118 patients with other pathogen infections were used to testify the assay's feasibility. Diagnosis results were reported visually using the biosensor.

Findings: The assay designed was performed using a simple instrument which could maintain the reaction in a constant temperature at 64°C for only 35 min. The total COVID-19 RT-MCDA-BS test procedure could be finished within 1 h. The COVID-19 RT-MCDA-BS could detect down to five copies of target sequences. Among 65 clinical samples from the COVID-19 patients, 22 (33.8%) positive results were obtained from faeces, nasal, pharyngeal and anal swabs *via* COVID-19 RT-MCDA-BS assay, while real-time reverse transcription-PCR assay only detected 20 (30.7%) positive results in these samples. No positive results were obtained from clinical samples with non-COVID-19 infections.

Interpretation: COVID-19 RT-MCDA-BS was a rapid, reliable, low-cost and easy-to-use assay, which

could provide an attractive laboratory tool to diagnose COVID-19 in multiple clinical specimens, especially for field, clinic laboratories and primary care facilities in resource-poor settings.