

Resource Summary Report

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SensingSelf S1 Rapid Antigen Test (Saliva/Sputum/Stool)

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Type: Protocol

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Protocol Information

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Group: Coronavirus Method Development Community, SensingSelfMission, XPRIZE
Rapid Covid Testing

Summary: Summary:The S1 COVID-19 Rapid Antigen test kit developed by Sensing Self Pte. Ltd. can quickly and qualitatively detect the spike glycoprotein of novel coronavirus (SARS-COV-2) in human saliva/sputum/stool samples. It can be used as an aid for COVID-19 diagnosis.Objective:According to the clinical trial plan, the S1 COVID-19 Rapid Antigen test kit or “test reagent”, is to test saliva/sputum/stool samples from healthy subjects and confirmed COVID-19 patients. Test results are compared with another commercial SARS-COV-2 nucleic acid detection kit with CFDA approval, which is defined as the “gold standard”. The sensitivity, specificity, and total agreement rate are used to evaluate the feasibility of the test reagent in clinical applications.Method:A collection of clinical samples were examined by the S1 COVID-19 Rapid Antigen test kit and the gold standard SARS-COV-2 nucleic acid detection kit in parallel, to calculate the clinical sensitivity, clinical specificity and total agreement rate of the test reagent.Results:Compared to the gold standard, the clinical sensitivity of test reagent reached 90.0%, the clinical specificity reached 100.0%, and the total coincidence rate reached 95.0%.Conclusions:The performance of test reagent has a high agreement rate with the gold standard, proving its good feasibility in diagnosing suspected COVID-19 cases.

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