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Brief Communication

Performance of STANDARD™ M10 SARS-CoV-2 Assay for the Diagnosis of COVID-19 from a Nasopharyngeal Swab

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ABSTRACT

The STANDARD™ M10 severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) assay (M10 assay) (SD Biosensor Inc., Suwon, Korea) is a rapid, fully-automated, cartridge-type molecular diagnostic assay that detects SARS-CoV-2 RNA using primers and probes for each target gene (ORF1ab gene, E gene). This study evaluated its performance by assessing its concordance with the approved SARS-CoV-2 real-time PCR assay. Tests were performed on 80 nasopharyngeal samples. The sensitivity and specificity of the M10 assay were 100%. The M10 assay effectively diagnosed SARS-CoV-2 infection, and it was comparable to the approved SARS-CoV-2 real-time PCR assay. It is a viable point-of-care test due to its short turnaround time.

Keywords: COVID-19; SARS-CoV-2 RT-PCR testing; COVID-19 nucleic acid testing

The current diagnostic modalities for coronavirus disease 2019 (COVID-19) include the reverse transcription-polymerase chain reaction (RT-PCR) assay, virus culture, antigen test, and antibody test. A real-time RT-PCR test, using upper respiratory tract specimens, is recommended as a confirmatory test [1]. However, the real-time RT-PCR assay is limited due to its long turnaround time. Moreover, it requires skilled personnel and specialized equipment. Meanwhile, the COVID-19 antigen test is inexpensive with a short turnaround time. However, the antigen test is also limited due to its low sensitivity, which varies depending on the viral load of the specimen [2-4]. Thus, a simple, rapid, and sensitive clinical test to detect COVID-19 should be developed.

The STANDARD™ M10 severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) assay (M10 assay) (SD Biosensor Inc., Suwon, Korea) automates and integrates sample preparation, nucleic acid extraction, and amplification, and detects target sequences using molecular diagnostic assays. The M10 assay utilizes a cartridge, containing primers and probes for each target gene (ORF1ab gene, E gene) to detect SARS-CoV-2 RNA. Since all processes are fully automated and performed in one cartridge, cross-contamination is minimized, and the test is less affected by test proficiency. In addition, the test results can be obtained within 1 hour. Thus, it can be used as a point-of-care test. In the United States, the cartridge-type Gene Xpert Xpress SARS-CoV-2 commercial kit (Cepheid, Sunnyvale, CA, USA) has been approved

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Ethics Statement
This clinical trial was approved by the IRB of Seoul National University Bundang Hospital (IRB number: B-2004/607-105). The IRB approved a request to waive the informed consent.

Conflict of Interest
KUP is associate editor and HBK is editorial board of Infect Chemother; however, they did not involve in the peer reviewer selection, evaluation, and decision process of this article. Otherwise, no potential conflicts of interest relevant to this article was reported.

Author Contributions
Conceptualization: JSP, KHS. Data curation: SYH, JSP, KUP. Formal analysis: SYH, KHS, ESK, KUP, HBK. Investigation: SYH, HJ, JJ. Methodology: JSP, KHS. Supervision: JSP, KHS. Writing - Original draft: SYH, JSP, KHS. Writing - review & editing: JSP, KHS, ESK, KUP, HBK.

for diagnostic use [5, 6]. This study aimed to evaluate the performance and clinical viability of the M10 assay in comparison to the approved STANDARD™ M nCoV Real-Time Detection kit (SD Biosensor Inc.) [7].

Nasopharyngeal swabs for evaluation were obtained from Seoul National University Bundang Hospital (SNUBH) from February 1, 2020, to May 14, 2020. To calculate the sample size, we used Buderer's formula [8]. The sample size calculated with a prevalence of 50% (n/2 positive samples + n/2 negative samples), $\alpha = 0.05$ and marginal error = 0.1 was 70. Taking into consideration the possibility of inappropriate samples for tests, a total of 80 nasopharyngeal swabs were collected. Forty positive samples were collected from patients hospitalized for COVID-19 infection, and all patients were symptomatic. Samples were collected at 14.725 ± 8.45 (mean ± SD) days from the onset of symptoms. Each patient was confirmed to be COVID-19-positive by SARS-CoV-2 RT-PCR performed on the day of sample acquisition. Forty negative samples were obtained from patients who visited the emergency room in SNUBH due to suspicion of COVID-19 infection, but were confirmed as negative by SARS-CoV-2 RT-PCR. The collected samples were given unique identification codes and were randomly assigned to be deidentified.

The STANDARD™ M nCoV Real-Time Detection kit (M nCoV assay, SD Biosensor Inc.) and M10 assay were performed on 80 collected samples. Both tests were performed according to the manufacturer's instructions. All collected samples were stored at -70 °C prior to testing. Testing was conducted from December 9, 2020 to December 10, 2020.

The sensitivity and specificity of M10 assay were evaluated to assess its diagnostic effectiveness. For the binomial confidence interval, the Clopper-Pearson method was used [9].

Both assays were performed on 80 samples, and the sensitivity and specificity of M10 assay were 100%, respectively (**Table 1**). The overall test results are presented in **Supplementary Table 1**. In one sample (case number 59), only the E gene was detected in both tests. A nasopharyngeal swab collected on the same day from the same patient showed a positive result when tested by The PowerChek™ 2019-nCoV Real-time PCR Kit (Kogene Biotech, Seoul, Korea); hence, this test result was considered as a positive result.

In this study, the M10 assay exhibited a 100% overall agreement with the approved STANDARD™ M nCoV Real-Time assay for detecting SARS-CoV-2. In addition, the M10 assay has an advantage in that it has a short turnaround time of less than 1 hour. Although molecular diagnostic assays on similar platforms are commercially available [6, 10], the M10 assay is superior in that it amplifies two target genes at once, the manual hands-on time is short, and it does not require additional equipment installation. However, its limitations

Table 1. Sensitivity and specificity of STANDARD™ M10 SARS-CoV-2 assay compared with STANDARD™ M nCoV real-time detection kit

	STANDARD™ M nCoV real-time detection kit		
	Positive	Negative	Total
STANDARD™ M10 SARS-CoV-2			
Positive	40	0	40
Negative	0	40	40
Total	40	40	80
Sensitivity (95% CI)	40/40, 100% (91.19 – 100.00%)		
Specificity (95% CI)	40/40, 100% (91.19 – 100.00%)		

SARS-CoV-2, severe acute respiratory syndrome coronavirus-2; CI, confidence interval.

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include a low sample throughput and high cost. Thus, the M10 assay can be used in places where skilled personnel or real-time PCR equipment is limited. Moreover, it is a viable point-of-care test for emergency cases, requiring rapid screening.

The M10 assay noted an excellent specificity (100%) and sensitivity (100%). However, this study has a few limitations. First, the number of samples included was small. Second, in one of 40 positive samples, only the E gene was amplified in the test. Clinically, it corresponds to "indeterminate" result and requires retesting, but a retest was not performed due to insufficient sample volume.

In summary, the M10 assay effectively diagnosed SARS-CoV-2 infection, and its performance was comparable to the approved SARS-CoV-2 real-time PCR assay. It is a viable point-of-care test due to its short turnaround time.

SUPPLEMENTARY MATERIAL

Supplementary Table 1

Test results of STANDARD™ M nCoV Real-Time Detection kit and STANDARD™ M10 SARS-CoV-2 assay

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