Clin. Lab. 2022;68:XXX-XXX

SHORT COMMUNICATION

Comparison Between GenBody COVID-19 Rapid Antigen Kit and SARS-CoV-2 RT-PCR

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SUMMARY

Background: **SARS-CoV-2 rapid antigen test can supplement the nucleic acid amplification method.**
Methods: **We calculated the sensitivity and specificity of the GenBody COVID-19 antigen assay using 155 nasopharyngeal specimens.**
Results: **The sensitivity in samples with their respective cycle thresholds varied from 33.3% to 100%; the sensitivity of the antigen assay was inferior to that of the gold standard polymerase chain reaction test.**
Conclusions: **Considering the relatively fast speed of the antigen test and high sensitivity at a low cycle threshold value indicating a high viral load, the GenBody COVID-19 antigen test can be an easy and quick measure for detecting SARS-CoV-2 in individuals with high viral loads.**
(Clin. Lab. 2022;68:xx-xx. DOI: 10.7754/Clin.Lab.2021.210717)

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Short Communication accepted September 17, 2021

KEY WORDS

COVID-19, lateral flow assay, antigen, SARS-CoV-2, rapid antigen test

INTRODUCTION

SARS-CoV-2, a novel virus that emerged in 2019, is currently spreading around the world [1]. Due to its high infectivity [2], the rapid detection of the virus in contagious individuals is very important. Presently, the gold standard to confirm SARS-CoV-2 infection is a nucleic acid amplification method using a real-time polymerase chain reaction (RT-PCR) [3]. The standard PCR method has high sensitivity and specificity; however, it involves complex techniques to confirm the result and uses expensive equipment requiring professionally trained personnel.

To compensate for these shortcomings, the SARS-CoV-2 rapid antigen test, which can supplement the nucleic acid amplification method, has recently become available [4-7]. We compared the SARS-CoV-2 rapid antigen test (GenBody COVID-19 Ag (GenBody, Cheonan, Korea)) confected as lateral flow assay with the real-time RT-PCR kit (Allplex 2019-nCoV Assay (Seegene,

Table 1. Number of SARS-CoV-2 antigen-positive and -negative samples among 55 SARS-CoV-2-positive and 100 SARS-CoV-2-negative specimens.

	SARS-CoV-2 RNA-positive	SARS-CoV-2 RNA-negative	Total
SARS-CoV-2 antigen-positive	50	1	51
SARS-CoV-2 antigen-negative	5	99	104
Total	55	100	155

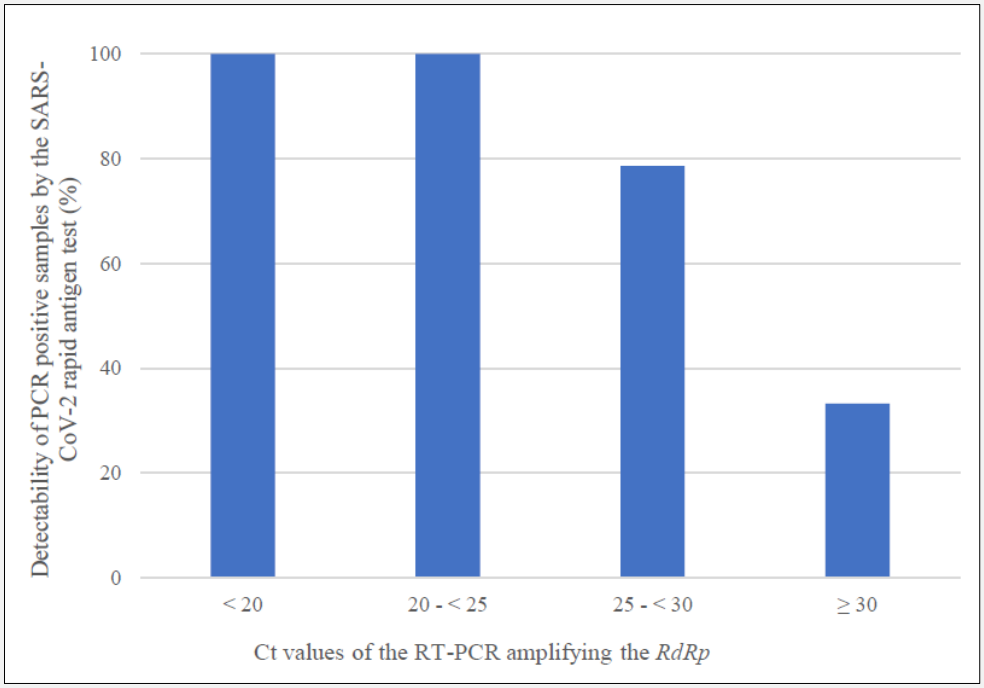

Figure 1. Sensitivity of the SARS-CoV-2 rapid antigen test with respect to the viral load of clinical specimens.

Abbreviations: Ct - cycle threshold, *RdRp* - RNA-dependent RNA polymerase gene.

Seoul, Korea)). The GenBody COVID-19 Ag test is based on nucleocapsid detection. The Allplex 2019-nCoV Assay was approved by the Korea Ministry of Food and Drug Safety and the United States Food and Drug Administration for emergency use. This study was approved by the Clinical Research Ethics Committee of Yeungam University Hospital in 2020 (Institutional Review Board, IRB; IRB File No. 2020-10-016-002).

In total, 155 nasopharyngeal swab specimens from patients admitted to Yeungnam University Hospital or patients who visited a drive-through COVID-19 screening site were used for GenBody COVID-19 Ag evaluation. Of these, 55 specimens were collected from individuals who were confirmed to be COVID-19 positive using the RT-PCR test and they showed different cycle threshold (Ct) values ($Ct < 20$: n = 13; $20 \leq Ct < 25$: n = 25; $25 \leq Ct < 30$: n = 14; $Ct \geq 30$: n = 3). The lowest Ct value was 14.03 and the highest Ct value was 32.58, amplifying the RNA-dependent RNA polymerase gene (*RdRp*). The cutoff of the *RdRp* Ct value was 40. Additionally, 100 specimens were collected from COVID-19-negative patients using RT-PCR. The collected nasopharyngeal swap specimens were mixed with 100 µL of extraction buffer provided by the manufacturer and were applied to the device. After incubation at room temperature for 15 - 20 minutes, the results were read. Specimens showing both the control line and the test line were considered SARS-CoV-2 antigen-positive,

and specimens showing only the control line were considered SARS-CoV-2 antigen-negative. Only one of 100 specimens negative with the SARS-CoV-2 RT-PCR test showed a positive result in the SARS-CoV-2 rapid antigen test (Table 1). Based on this result, the overall specificity was calculated as 99.0%. Conversely, of the 55 specimens that were positive based on the SARS-CoV-2 RT-PCR test, 50 showed positive results in the SARS-CoV-2 rapid antigen test. Based on this result, the overall sensitivity was calculated as 90.9%. Sensitivity was then recalculated in a Ct-dependent manner (Figure 1). Interestingly, in specimens with a high viral load ($Ct < 20$ and $20 \leq Ct < 25$), the sensitivity of the SARS-CoV-2 rapid antigen test was 100.0%. In the other specimens, the sensitivities were calculated as 78.6% and 33.3% for samples with medium ($25 \leq Ct < 30$) or low viral loads ($Ct \geq 30$), respectively.

In conclusion, the Ct-dependent sensitivity evaluation showed good sensitivity of the GenBody COVID-19 Ag test in patients with a high viral load ($Ct < 25$). However, in specimens from patients with a medium viral load ($25 \leq Ct < 30$), the sensitivity was not satisfactory. Moreover, the sensitivity of the assay with specimens containing only a limited viral load ($Ct \geq 30$) was very low. The overall sensitivity and specificity were similar to those of the recently announced SARS-CoV-2 rapid antigen test by SD Biosensor [8]. As described, the SARS-CoV-2 rapid antigen test showed limitations in detection adequacy, depending on the infection status of the patient. The SARS-CoV-2 rapid antigen test might not detect COVID-19 during early infection or in convalescent patients with low viral loads. Specimens with Ct values ≥ 30 usually do not allow successful viral culture, indicating their low infectivity. Although these patients are afflicted with COVID-19, such individuals are considered less contagious [9]. By using the SARS-CoV-2 rapid antigen test, we can isolate highly contagious individuals from those with low risk of transmission of SARS-CoV-2. This might help to prevent the rapid spread of SARS-CoV-2 in the hospital population. One of the most important points to be considered with this assay is that the SARS-CoV-2 rapid antigen test can be severely affected by the sampling method used. Depending on the sampling, the patient's viral load is not always accurately reflected by the viral load present in the patient's respiratory tract. Therefore, meaningful results can only be obtained with samples taken in an appropriate manner in accordance with the manufacturer's recommendations; otherwise, the viral load present in the patient could be underestimated. The small number of patients ($n = 3$) with a low viral load ($Ct \geq 30$) was significantly less than that for the other three groups, which is a limitation for the interpretation of the results. If a larger number of patients with either early infections or convalescence were included in the study population, the sensitivity of the SARS-CoV-2 rapid antigen test might have changed significantly for the low viral load-patient group. Taken together, we conclude that the sensitivity of the rapid antigen test is inferior to that of the RT-PCR, which remains the gold standard. However, antigen testing can be a quick and easy method for the detection of SARS-CoV-2 in individuals with high viral loads.

Declaration of Interest:
The authors declare that they have no conflict of interest related to the publication of this manuscript.

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