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Accuracy of Rapid Antigen Screening Tests for SARS-CoV-2 Infection at Correctional Facilities in Korea: March - May 2022

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ABSTRACT

Background: The number of confirmed cases of individuals with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection increased rapidly due to the Omicron variant. Correctional facilities are vulnerable to infectious diseases, and they introduced rapid antigen tests (RATs) to allow for early detection and rapid response. We aimed to evaluate the diagnostic performance and usefulness of SARS-CoV-2 RATs in newly incarcerated people.
Materials and Methods: We conducted a cross-sectional study at correctional facilities in Korea from 9 March to 22 May 2022. The study population was newly incarcerated people who were divided into two groups. In one group, 799 paired SARS-CoV-2 RATs and real-time polymerase chain reaction (RT-PCR) were conducted simultaneously in 522 individuals in March 2022. In the other group, 4,034 paired RATs and RT-PCR consecutively in 4,034 participants; only individuals with negative RATs results underwent RT-PCR from April to May 2022. We analyzed data using descriptive statistics and a logistic regression model.
Results: Among the 799 specimens in March, RT-PCR was positive in 72 (9.0%), and among the 4,034 specimens in April - May 2022, RT-PCR was positive in 40 (1.0%). Overall, the RATs had a sensitivity of 58.3%, specificity of 100.0%, positive predictive value (PPV) of 100.0%, and negative predictive value (NPV) of 96.0%. Asymptomatic individuals constituted 98.2% of the study group, and symptomatic individuals 1.8%. In asymptomatic cases, the sensitivity of RATs was 52.5%, specificity was 100.0%, PPV was 100.0%, and NPV was 96.3%. In symptomatic cases, the sensitivity of RATs was 84.6%, specificity was 100.0%, PPV was 100.0%, and NPV was 33.3%. Sensitivity (P = 0.034) and NPV (P = 0.004) differed significantly according to the presence and absence of symptoms, and the F1 score was the highest at 0.9 in symptomatic individuals in March. There was a positive linear trend in the proportion of false-negative RATs in newly incarcerated people following the weekly incidence of SARS-CoV-2 (P = 0.033). The best-associated predictors of RATs for SARS-CoV-2 infection involved symptoms, timing of sample collection, and repeat testing.

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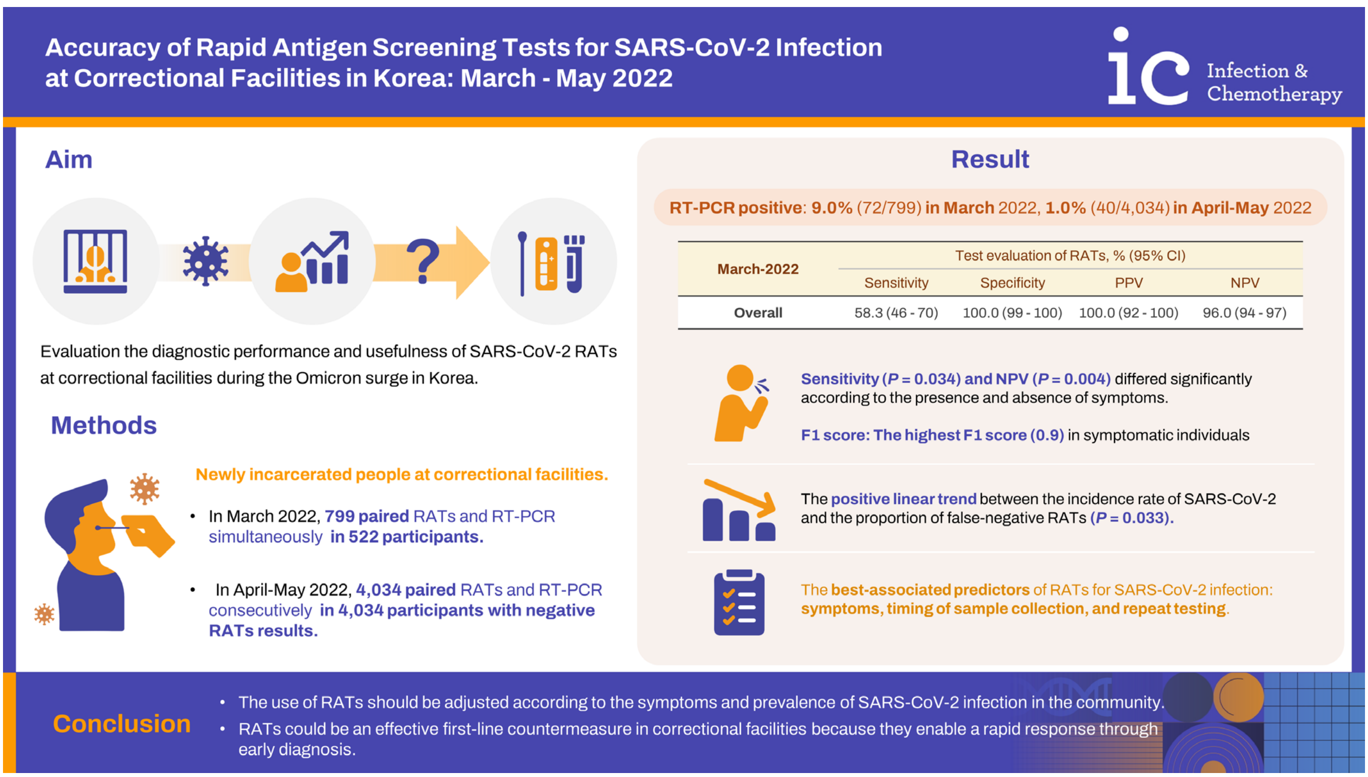
Conclusion: Sensitivity and NPV significantly depend on whether symptoms are present, and the percentage of false negatives is correlated with the incidence. Thus, using RATs should be adjusted according to the presence or absence of symptoms and the incidence of SARS-CoV-2 infection in the community. RATs could be a useful screening tool as an effective first-line countermeasure because they can rapidly identify infectious patients and minimize SARS-CoV-2 transmission in correctional facilities.

Keywords: Accuracy; Correctional facilities; Rapid Diagnostic Tests; SARS-CoV-2; Screening

GRAPHICAL ABSTRACT



INTRODUCTION

Real-time polymerase chain reaction (RT-PCR) testing is recognized worldwide as a standard method for diagnosing severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection. Although the accuracy of RT-PCR is high, it requires long turnaround times (1 day or more), expensive instrumentation, and a laboratory setting [1]. Conversely, the accuracy of rapid antigen tests (RATs) is relatively lower than that of RT-PCR; they can be used with "fast turnaround times (approximately 15 minutes)" and are cheaper [1]. Thus, the demand for RATs than RT-PCR increased as more sustainable and efficient testing methods were needed while the SARS-CoV-2 pandemic persisted, and the number of confirmed cases increased rapidly from January 2022 owing to the Omicron variant [2-4]. In this situation, the Korea Disease Control and Prevention Agency (KDCA) prioritized using RT-PCR tests for early diagnosis and treatment in high-risk groups [5]. From March 14, 2022, positive RATs results were considered confirmed cases [6].

Accuracy of RATs means the ability of a test to accurately determine the presence or absence of SARS-CoV-2 [7]. RATs clinical trials were conducted on confirmed patients or those with symptoms, mainly conducted in the hospital setting in Korea [8-11]. However, it is necessary to evaluate the accuracy of RATs in incarcerated people because the risk of SARS-CoV-2 transmission is higher in correctional facilities compared with the general population [12]. Since a large SARS-CoV-2 outbreak at the Dongbu Detention Center, in eastern Seoul, in November 2020 [13], the Ministry of Justice introduced RATs as a decision-support tool to screen SARS-CoV-2 infection for incarcerated people at the point of care [14]. Moreover, newly incarcerated people had to stay in a separate space for a period equivalent to the SARS-CoV-2 incubation period (14 - 7 days) and undergo RT-PCR to detect SARS-CoV-2 infection at the time of admission and before their release in quarantine [15]. The diagnostic test method in the correctional facility was adjusted around March 2022 due to a surge in the number of infections with the Omicron variant. Until March 2022, only RT-PCR tests were performed during admission and before release from quarantine [15]. In April 2022, the primary diagnostic tool for SARS-CoV-2 changed from RT-PCR as a confirmatory test to RAT as a screening test; therefore, when the result of RATs was positive, it was considered a confirmed case. If the RATs were negative at admission, RT-PCR was performed for confirmation.

Therefore, the primary objective of this study is to evaluate the diagnostic performance of RATs in screening for SARS-CoV-2 infection in newly incarcerated people in correctional facilities. The secondary objective was to evaluate the usefulness of RATs in screening for SARS-CoV-2 infection to allow for the quarantine of infected individuals and prevent outbreaks in correctional facilities.

MATERIALS AND METHODS

1. Data collection

We conducted a cross-sectional study to assess the accuracy of RATs for SARS-CoV-2 infection targeted newly incarcerated people at correctional facilities in Korea between March and May 2022. The data in March were collected only by those who agreed to this study before collecting specimens, and the data from April to May were analyzed using the data collected after testing for the purpose of quarantine management in correctional facilities. The information on participants and tests (RATs and RT-PCR) was provided by the Ministry of Justice's SARS-CoV-2 Correctional Facility Emergency Response Team. We identified the participant's SARS-CoV-2 vaccination history linked the SARS-CoV-2 vaccination management system of the KDCA (as of May 31, 2022). Data on the weekly incidence rate of SARS-CoV-2 per 100,000 people in Korea were obtained from the KDCA website.

2. Ethics statement

This study was reviewed and approved by the Korea Disease Control and Prevention Agency Institutional Review Board (2022-06-06-PE-A) and performed in accordance with the principles of the Declaration of Helsinki. Since incarcerated individuals are considered vulnerable research subjects, the IRB confirmed informed consent from all participants in March 2022. We ensured newly incarcerated individuals' voluntary participation and confidentiality during the testing process by the IRB guidelines. On the other hand, from April to May 2022, we conducted a secondary research study using the SARS-CoV-2 diagnostic test results performed as part of the correctional facility quarantine policy. Because the research presented a minimal risk to the study population, the IRB waived the requirement for consent. Overall, in order to protect personal information, we processed the data in a manner that rendered individual identification impossible and subsequently conducted the analysis.

3. Study setting and participants

There are 54 correctional facilities, including prisons and jails, in Korea. Among them, forty-eight correctional facilities; 36 prisons and 12 jails participated in this study. The criteria for selecting the study population were newly incarcerated people who were admitted to correctional facilities regardless symptoms.

We categorized the participants into two groups according to the sample collection period.

One group consisted of 565 individuals who underwent RATs and RT-PCR stimulations to evaluate the accuracy of RATs from March 9 to 29, 2022. Among them, we excluded 43 people who tested before the study period, those with inaccurate identification numbers, and those who did not undergo an RT-PCR test at the time of admission. Moreover, 277 individuals were tested twice when admitted to a correctional facility and released from quarantine. Therefore, we analyzed 799 RATs and RT-PCR pairs of 522 tested people. The second group consisted of 4,512 individuals from April 18 to May 22, 2022, and only individuals with negative RATs results subsequently underwent RT-PCR. Among them, 478 individuals who missed RATs or RT-PCR, those with incorrect identification numbers, those with positive RATs results, those with inconclusive RATs or RT-PCR results, and those who were enrolled twice or released from the facilities during the study period were excluded. Therefore, we analyzed the data of 4,034 individuals who underwent RATs and RT-

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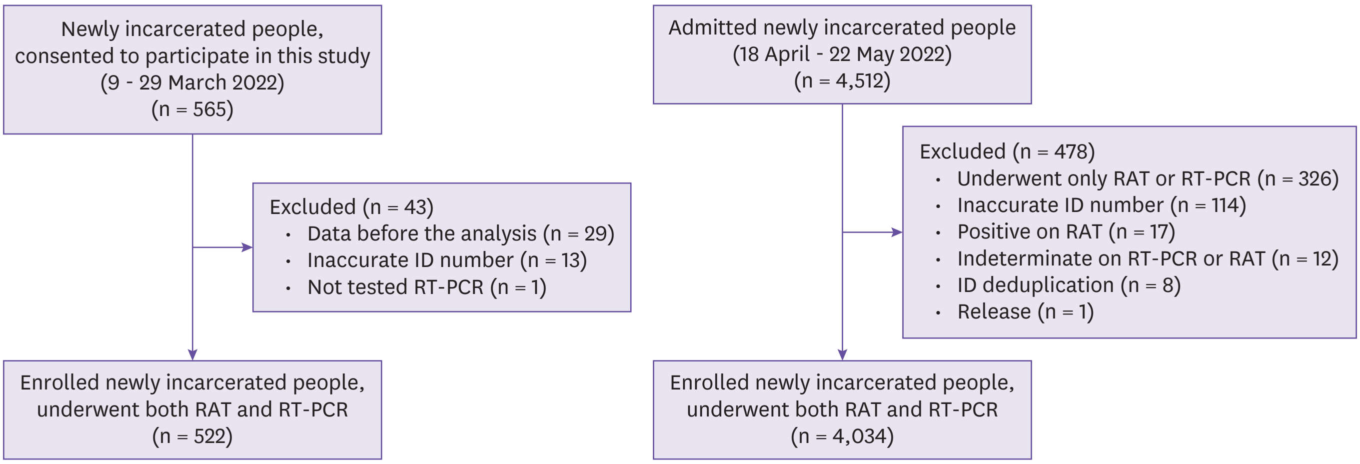

Figure 1. Study flowchart of newly incarcerated people at correctional facilities in Korea: March 9 - May 22, 2022.
RT-PCR, real-time polymerase chain reaction; RAT, rapid antigen tests.

PCR stimulations (**Fig. 1**).

4. Sample collection

SARS-CoV-2 tests for newly incarcerated people were conducted at clinics affiliated with the correctional facilities. The clinic's trained medical personnel had performed RATs and RT-PCR parallel testing.

A total of 12 RAT products which were used as index tests were licensed and registered by the Ministry of Food and Drug Safety (MFDS) in Korea (**Supplementary Table 1**). This method involves inserting a cotton swab of RATs into the nasopharyngeal mucosa of one nostril. For each RAT kit, two-three drops of the extracted sample were applied to the sample instillation site. The results were read in 10-20 minutes according to the manufacturer's manual without knowledge of RT-PCR results. A test was considered inconclusive if RAT control lines were faint at the test band.

In the case of RT-PCR as a reference standard, the specimen was collected from the same site; it was refrigerated immediately and transported to associated outside laboratory settings once or twice a day for RT-PCR (unaware of the RATs results). The RT-PCR test reagents differed in a total of 11 institution's laboratories; therefore, we labeled the results qualitatively as "positive, negative, and inconclusive" rather than quantitatively considering the cycle threshold (Ct) value.

5. Statistical analysis

First, we analyzed the demographic data of the study population based on RT-PCR results from March to May 2022. Categorical variables are expressed as numbers (percentages). Fisher's exact test was performed to compare categorical variables according to the results of RT-PCR. The normality test for continuous variables was performed using the Shapiro-Wilk test. Then, the Wilcoxon rank sum test was performed if the distribution was not normal (P <0.05). Second, we calculated the sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) using 2 × 2 tables of the RATs and RT-PCR results. We performed Chi-square or Fisher's exact tests to evaluate for significant differences according to characteristics. Furthermore, we calculated metrics (*i.g.*, accuracy, precision, recall, F1 score) for measuring the performance of RATs in imbalanced classification. F1 score ranges from 0 to 1, a higher score denotes a better quality classifier. Third, the Chi square-test for trend was performed to evaluate the associations between the results of RATs and the incidence rate of SARS-CoV-2 infection in the community in April and May 2022 [16-21]. Lastly, we investigated whether predictors of the RATs were related to the potential confounding variables using univariate and multivariate logistic regression analyses in March 2022. P <0.05 was considered statistically significant. It was presented with 95% confidence intervals (CI). All data were analyzed using R program 4.1.0 (R Studio Inc., Boston, MA, USA).

RESULTS

1. Characteristics of participants

We analyzed the characteristics of participants with positive and negative RT-PCR results. Among the 799 specimens in March, RT-PCR was positive in 72 (9.0%), and among the 4,034 specimens in April-May 2022, RT-PCR was positive in 40 (1.0%). Most individuals were male, and the median age was similar in both groups. Most participants were asymptomatic, 98.2% in March 2022 and 99.1% in April - May 2022. The third dose of SARS-CoV-2 vaccination was the highest, 39.9% in March 2022 and 48.8% in April - May 2022 (**Table 1**).

2. Diagnostic accuracy of RATs

The overall sensitivity of RATs was 58.3% (95% CI: 46.1 – 69.8%); the specificity was 100.0% (95% CI: 99.5 - 100.0%); the PPV was 100.0% (95% CI: 91.6 – 100.0%); and the NPV was 96.0% (95% CI: 94.4 – 97.3%) in March 2022. Among the 799 participants, 93.0% (n = 743) were male, and 7.0% (n = 56) were female. The sensitivity of RATs in male participants was higher at 61.8% (95% CI: 49.2 – 73.3%) than in female participants at 0.0% (95% CI: 0.0 – 60.2%), and the difference was significant (P = 0.027). The NPV of RATs in male participants was 96.3% (95% CI: 94.6 – 97.6%), and that in female participants was 92.9% (95% CI: 82.7 – 98.0%), and the difference was not significant (P = 0.695). The proportion of the 50-59 years old age group was the greatest at 24.2% (n = 193), the sensitivity was 68.8% (95% CI, 41.3 – 89.0%), and NPV was 97.3% (95% CI: 93.7 – 99.1%). There was no correlation between sensitivity and NPV and age.

The study sample mainly comprised asymptomatic participants (98.2%, n = 785). In asymptomatic people, the sensitivity was 52.5% (95% CI: 39.1 – 65.7%), specificity was 100.0% (95% CI: 99.5 – 100.0%), PPV was 100.0% (95% CI: 88.8– 100.0%), and NPV was 96.3% (95% CI: 94.7 – 97.5%), respectively. In symptomatic people, the sensitivity was 84.6% (95% CI: 54.6 – 98.1%), specificity was 100.0% (95% CI: 2.5 – 100.0%), PPV was 100.0% (95% CI: 71.5 – 100.0%), and NPV was 33.3% (95% CI: 0.8 – 90.6%) respectively. The sensitivity of RATs in symptomatic individuals was higher, and the NPV was lower than that in asymptomatic individuals. The sensitivity (P = 0.034) and NPV (P = 0.004) of RATs were significantly different according to the presence of symptoms at diagnosis. On the other hand, the sensitivity of RATs was 62.1% (95% CI: 42.3 – 79.3%) in people who had received two or more doses of vaccines and 47.4% (95% CI: 24.4 – 71.1%) in people who had received less than two doses of vaccines; the specificity was 100.0%, PPV was 100.0%, and NPV ranged from 95.1 to 97.0%. The sensitivity and NPV of RATs did not differ according to vaccination status (**Table 2**). The study has imbalanced distribution because it mainly counted male and asymptomatic individuals. Both precision and recall were high; the F1 score was the highest at 0.9 in symptomatic subjects (**Table 3**).

3. Incidence rate of SARS-CoV-2 infection and the accuracy of RATs

We calculated the number of false-negative RATs and estimated the association between the proportion and the

Table 1. Baseline characteristics of participants based on RT-PCR for SARS-CoV-2 infection in two groups at correctional facilities in March 2022 and April-May 2022

Characteristics	March-2022 Total	RT-PCR Positive	RT-PCR Negative	*P*-Value	April - May 2022 Total	RT-PCR Positive	RT-PCR Negative	*P*-Value
Total	799 (100.0)	72 (9.0)	727 (91.0)		4,034 (100.0)	40 (1.0)	3,994 (99.0)	
Sex				0.810				0.773
Male	743 (93.0)	68 (94.4)	675 (92.8)		3,689 (91.4)	36 (90.0)	3,653 (91.5)	
Female	56 (7.0)	4 (5.6)	52 (7.2)		345 (8.6)	4 (10.0)	341 (8.5)	
Age, median, [IQR]	43.0 (31.0 - 54.0)	41.5 (31.8 - 55.3)	43.0 (30.0 - 54.0)	<0.001	44.0 (31.0 - 55.0)	47.0 (31.5 - 58.0)	44.0 (31.0 - 55.0)	<0.001
Age, Distribution				0.491				0.690
≤19	16 (2.0)	1 (1.4)	15 (2.1)		105 (2.6)	1 (2.5)	104 (2.6)	
20 - 29	166 (20.8)	11 (15.3)	155 (21.3)		806 (20.0)	8 (20.0)	798 (20.0)	
30 - 39	143 (17.9)	19 (26.4)	124 (17.1)		731 (18.1)	5 (12.5)	726 (18.2)	
40 - 49	174 (21.8)	15 (20.8)	159 (21.9)		880 (21.8)	7 (17.5)	873 (21.9)	
50 - 59	193 (24.2)	16 (22.2)	177 (24.3)		925 (22.9)	10 (25.0)	915 (22.9)	
≥60	107 (13.4)	10 (13.9)	97 (13.3)		587 (14.6)	9 (22.5)	578 (14.5)	
Symptoms				<0.001				<0.001
Asymptomatic	785 (98.2)	59 (81.9)	726 (99.9)		3,996 (99.1)	25 (62.5)	3,971 (99.4)	
Symptomatic	14 (1.8)	13 (18.1)	1 (0.1)		38 (0.9)	15 (37.5)	23 (0.6)	
Vaccination status				0.363				0.764
≤1st	215 (26.9)	19 (26.4)	196 (27.0)		883 (21.9)	8 (20.0)	875 (21.9)	
2nd	265 (33.2)	29 (40.3)	236 (32.5)		1,181 (29.3)	10 (25.0)	1,171 (29.3)	
≥3rd	319 (39.9)	24 (33.3)	295 (40.6)		1,970 (48.8)	22 (55.0)	1,948 (48.8)	

SARS-CoV-2, severe acute respiratory syndrome coronavirus 2; RT-PCR, real-time polymerase chain reaction; IQR, interquartile range.

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Table 2. Diagnostic accuracy of RATs for SARS-CoV-2 infection: performance characteristics at correctional facilities from March 9 to 29, 2022

Characteristics	RATs					Sensitivity		Specificity	PPV	NPV	
	TP	FN	FP	TN	Total (%)	% (95% CI)	*P*-Value	% (95% CI)	% (95% CI)	% (95% CI)	*P*-Value
Total	42	30	0	727	799 (100.0)	58.3 (46.1 - 69.8)		100.0 (99.5 - 100.0)	100.0 (91.6 - 100.0)	96.0 (94.4 - 97.3)	
Gender							0.027				0.695
Male	42	26	0	675	743 (93.0)	61.8 (49.2 - 73.3)		100.0 (99.5 - 100.0)	100.0 (91.6 - 100.0)	96.3 (94.6 - 97.6)	
Female	0	4	0	52	56 (7.0)	0.0 (0.0 - 60.2)		100.0 (93.2 - 100.0)	-	92.9 (82.7 - 98.0)	
Age							0.773				0.829
≤19	0	1	0	15	16 (2.0)	0.0 (0.0 - 97.5)		100.0 (78.2 - 100.0)	-	93.8 (69.8 - 99.8)	
20 - 29	6	5	0	155	166 (20.8)	54.5 (23.4 - 83.3)		100.0 (97.6 - 100.0)	100.0 (54.1 - 100.0)	96.9 (92.9 - 99.0)	
30 - 39	12	7	0	124	143 (17.9)	63.2 (38.4 - 83.7)		100.0 (97.1 - 100.0)	100.0 (73.5 - 100.0)	94.7 (89.3 - 97.8)	
40 - 49	8	7	0	159	174 (21.8)	53.3 (26.6 - 78.7)		100.0 (97.7 - 100.0)	100.0 (63.1 - 100.0)	95.8 (91.5 - 98.3)	
50 - 59	11	5	0	177	193 (24.2)	68.8 (41.3 - 89.0)		100.0 (97.9 - 100.0)	100.0 (71.5 - 100.0)	97.3 (93.7 - 99.1)	
≥60	5	5	0	97	107 (13.4)	50.0 (18.7 - 81.3)		100.0 (96.3 - 100.0)	100.0 (47.8 - 100.0)	95.1 (88.9 - 98.4)	
Symptoms							0.034				0.004
Asymptomatic	31	28	0	726	785 (98.2)	52.5 (39.1 - 65.7)		100.0 (99.5 - 100.0)	100.0 (88.8 - 100.0)	96.3 (94.7 - 97.5)	
Symptomatic	11	2	0	1	14 (1.8)	84.6 (54.6 - 98.1)		100.0 (2.5 - 100.0)	100.0 (71.5 - 100.0)	33.3 (0.8 - 90.6)	
Vaccination status							0.528				0.499
≤1st	9	10	0	196	215 (26.9)	47.4 (24.4 - 71.1)		100.0 (98.1 - 100.0)	100.0 (66.4 - 100.0)	95.1 (91.3 - 97.6)	
2nd	18	11	0	236	265 (33.2)	62.1 (42.3 - 79.3)		100.0 (98.4 - 100.0)	100.0 (81.5 - 100.0)	95.5 (92.2 - 97.8)	
≥3rd	15	9	0	295	319 (39.9)	62.5 (40.6 - 81.2)		100.0 (98.8 - 100.0)	100.0 (78.2 - 100.0)	97.0 (94.5 - 98.6)	

RATs, rapid antigen tests; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2; PPV, positive predictive value; NPV, negative predictive value; TP, true positive; FN, false negative; FP, false positive; TN, true negative; CI, confidence interval.

Table 3. Performance metrics of RATs for SARS-CoV-2 infection: Performance characteristics at correctional facilities from March 9 to 29, 2022

Characteristics	RATs					Performance metrics			
	TP	FN	FP	TN	Total (%)	Accuracy	Precision	Recall	F1 score
Total	42	30	0	727	799 (100.0)	1.0	1.0	0.6	0.7
Sex									
Male	42	26	0	675	743 (93.0)	1.0	1.0	0.6	0.8
Female	0	4	0	52	56 (7.0)	0.9	-	0.0	-
Age									
≤19	0	1	0	15	16 (2.0)	0.9	-	0.0	-
20 - 29	6	5	0	155	166 (20.8)	1.0	1.0	0.6	0.7
30 - 39	12	7	0	124	143 (17.9)	1.0	1.0	0.6	0.8
40 - 49	8	7	0	159	174 (21.8)	1.0	1.0	0.5	0.7
50 - 59	11	5	0	177	193 (24.2)	1.0	1.0	0.7	0.8
≥60	5	5	0	97	107 (13.4)	1.0	1.0	0.5	0.7
Symptoms									
Asymptomatic	31	28	0	726	785 (98.2)	1.0	1.0	0.5	0.7
Symptomatic	11	2	0	1	14 (1.8)	0.9	1.0	0.9	0.9
Vaccination status									
≤1st	9	10	0	196	215 (26.9)	1.0	1.0	0.5	0.6
2nd	18	11	0	236	265 (33.2)	1.0	1.0	0.6	0.8
≥3rd	15	9	0	295	319 (39.9)	1.0	1.0	0.6	0.8

RATs, rapid antigen tests; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2; PPV, positive predictive value; NPV, negative predictive value; TP, true positive; FN, false negative; FP, false positive; TN, true negative; CI, confidence interval.

weekly incidence rate of SARS-CoV-2 infection from April to May 2022. The weekly incidence rate of SARS-CoV-2 infection was highest (163.1/100,000) in the third week of April 2022 and dropped to 33.9/100,000 people by the fourth week of May 2022 [16, 21]. Despite the marked changes, the NPV remained at 98.6% and higher without a specific trend. However, the number of false-negative RATs decreased as the incidence of SARS-CoV-2 infection in the community declined. There was a significant positive linear trend between the proportions of false-negative RATs and the weekly incidence rate of SARS-CoV-2 infection in the community (P = 0.033) (**Table 4**).

4. Predictors of RATs associated with SARS-CoV-2 infection

A total of 799 participants in March were included in the analysis. There were 58.3% (n = 42) subjects reactive by RATs, with 9.0% (n = 72) positive by RT-PCR. Of the

Table 4. Negative predictive value of RATs for SARS-CoV-2 infection concerning disease incidence rate in Korea from April 18 to May 22, 2022

Test		National incidence rate[a]	Total	FN		TN		NPV	
Month	week			n (%)	*P* for trend	n (%)	*P* for trend	% (95% CI)	*P* for trend
April	3rd [16]	163.1	831	12 (1.4)	0.033	819 (98.6)	0.224	98.6 (97.5 - 99.3)	-
	4th [17]	105.2	852	11 (1.3)		841 (98.7)		98.7 (97.7 - 99.4)	
May	1st [18]	74.3	559	5 (0.9)		554 (99.1)		99.1 (97.9 - 99.7)	
	2nd [19]	65.7	880	7 (0.8)		873 (99.2)		99.2 (98.4 - 99.7)	
	3rd [20]	48.6	905	5 (0.6)		900 (99.4)		99.4 (98.7 - 99.8)	
	4th [21]	33.9	7	0 (0.0)		7 (100.0)		100.0 (59.0 - 100.0)	

[a]Weekly incidence rate per 100,000 population.
RATs, rapid antigen tests; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2; FN, false negative; TN, true negative; NPV, negative predictive value; CI, confidence interval.

distribution of the symptoms, only 26.2% (n = 11) of all the subjects had SARS-CoV-2 symptoms. In univariate analysis, we observed increased odds ratios (ORs) for symptomatic individuals. To establish independent sensitivity predictors, we calculated ORs for those having a positive RAT according to subgroups in multivariate analysis. The best set of associated predictors with SARS-CoV-2 infection included having symptoms, the timing of sample collection, and repeat testing after adjustment for age, symptoms, vaccination status, and repeat testing. Compared to asymptomatic individuals, the sensitivities of RATs in symptomatic individuals were 22.91 higher (CI: 3.39 - 154.75, *P* = 0.001), and the sensitivities of specimen collected on the day of symptom onset was 16.97 higher (CI: 2.45 – 117.82, *P* = 0.004). Additionally, repeated tests were carried out on 277 participants in this study, and the sensitivity of RATs was 7.58 higher in repeated testing than in initial testing (CI: 2.14 – 26.81, *P* = 0.002) (**Table 5**).

DISCUSSION

We aimed to investigate the diagnostic performance and usefulness of RATs as a screening tool in correctional facilities during the Omicron wave from March to May 2022. The present finding shows that the characteristics associated with RATs were having symptoms, collecting on the symptom onset date, and testing repeatedly. RATs were helpful in rapidly identifying and preventing SARS-CoV-2 outbreaks and reducing incidence in correctional facilities.

In our study, the overall sensitivity of RATs (58.3%) was lower than that in a previous study focusing on the Omicron variant (65.2%) because the percentage of asymptomatic individuals was high [22].

Similar to other studies on the performance of antigen tests, we found that the sensitivity of RATs in symptomatic individuals was higher than that in asymptomatic individuals (84.6% *vs.* 52.5%), and the NPV in symptomatic individuals was lower than that in asymptomatic individuals (33.3% *vs.* 96.3%) [23-26]. The F1 score in symptomatic subjects was the highest at 0.9 in imbalance datasets. As a result, the sensitivity and NPV of the RATs were significant, and RATs can better screen people with symptoms even with imbalanced data. These symptomatic individuals were likely to be confirmed as SARS-CoV-2 infection in real-life applications [27]. On the other hand, asymptomatic individuals at the screening point would likely be pre-symptomatic or infected without developing symptoms [28]. Therefore, it is thus necessary to confirm SARS-CoV-2 status by performing tests periodically with asymptomatic people in correctional facilities [29].

When RT-PCR testing was in high demand due to the Omicron surge, subsequent RT-PCR testing was performed only in those who were RATs negative in correctional facilities. There was a linear trend between the proportion of false-negative RATs and the weekly incidence rate of SAS-CoV-2 infection (*P* = 0.033). RT-PCR can be detected even after replication because it amplifies and tests RNA [27]. However, if this is not the case, false-negative RATs may potentially transmit SARS-CoV-2 in high prevalence, as appropriate control and protection measures may not be implemented [30]. Therefore, it is necessary to strategically determine the best testing method, such as RATs serial testing and RT-PCR parallel testing for screening when using RATs to improve the usefulness in high prevalence [31, 32].

WHO recommends using RATs to monitor closed-group outbreaks, such as in prisons [33, 34]. The rate of SARS-CoV-2 infection is estimated to be 5.5 times higher among incarcerated people in correctional facilities than in the general public [35]. Overcrowding is the greatest factor contributing to SARS-CoV-2 transmission in correctional facilities [36]. In addition, people in correctional facilities may be more vulnerable to SARS-CoV-2 owing to underlying

Table 5. Predictors of positive RATs amongst SARS-CoV-2 RT-PCR positive samples in univariate and multivariate logistic regression models at correctional facilities from May 9 to 29, 2022 (N = 72)

Characteristics	Positive on RATs	Positive on RT-PCR			
		Univariate		Multivariate[a]	
	n (%)	OR (95% CI)	*P*-Value	OR (95% CI)	*P*-Value
Total	42 (58.3)				
Gender					
Male	42 (100.0)	1.00			
Female	0 (0.0)	-			
Age (yrs)					
<43	21 (50.0)	1.00		1.00	
≥43	21 (50.0)	1.31 (0.51 - 3.35)	0.577	1.08 (0.35 - 3.36)	0.891
Symptoms					
Asymptomatic	31 (73.8)	1.00		1.00	
Symptomatic	11 (26.2)	4.97 (1.01 - 24.38)	0.048	22.91 (3.39 - 154.75)	0.001
<1 day[b]	8 (19.0)	3.61 (0.71 - 18.47)	0.123	16.97 (2.45 - 117.82)	0.004
1 - 5 days[b]	2 (4.8)				
≥6 days[b]	1 (2.4)				
Sore throat					
No	35 (83.3)	1.00			
Yes	7 (16.7)	5.80 (0.67 - 49.91)	0.109		
Cough					
No	39 (92.9)	1.00			
Yes	3 (7.1)	2.23 (0.22 - 22.56)	0.497		
Sputum					
No	40 (95.2)	1.00			
Yes	2 (4.8)	1.45 (0.13 - 16.76)	0.766		
Runny nose					
No	41 (97.6)	1.00			
Yes	1 (2.4)	-			
Myalgia					
No	40 (95.2)	1.00			
Yes	2 (4.8)	-			
Fever					
No	41 (97.6)	1.00			
Yes	1 (2.4)	0.71 (0.04 - 11.78)	0.809		
Other[c]					
No	40 (95.2)	1.00			
Yes	2 (4.8)	-			
Vaccination status					
≤1st	9 (21.4)	1.00		1.00	
2nd	18 (42.9)	1.82 (0.56 - 5.87)	0.317	3.26 (0.79 - 13.47)	0.102
≥3rd	15 (35.7)	1.85 (0.55 - 6.29)	0.323	1.57 (0.39 - 6.38)	0.527
Repeat testing					
Initial	17 (40.5)	1.00		1.00	
Repeated	25 (59.5)	2.54 (0.97 - 6.67)	0.058	7.58 (2.14 - 26.81)	0.002

[a]Independent variables: age, symptoms, vaccination status, repeat testing.
[b]Days between reported symptom onset and specimen collection.
[c]Flu-like symptoms.
RATs, rapid antigen tests; SARS-CoV-2, severe acute respiratory syndrome coronavirus; RT-PCR, real-time polymerase chain reaction; OR, odds ratio; CI, confidence interval.

risk factors such as male, older age, and a high prevalence of chronic underlying health conditions [12, 37-39].

In Korea, when introducing RATs as a screening tool in correctional facilities, there was a concern about the occurrence of outbreaks within the crowded group residence facilities due to the low sensitivity of RATs. It was essential for correctional health to determine whether to identify people infected with SARS-CoV-2 accurately or to undergo a screening process to response rapidly. RATs can be reduced the workload and administrative burden under a lack of available workforce due to confirmed cases among employees. Rapid RATs results made it somewhat easier to manage incarcerated people because there was limited space for long-term isolation until the RT-PCR results were released. Moreover, early detection and quarantine management prevent a large-scale outbreak, it is able to prevent SARS-CoV-2 infection not only incarcerated people but also correctional staff [40].

This study had some limitations. First, most of the participants were male and reported being asymptomatic at the time of testing. Data imbalances might lead to selection bias. Because there was insufficient data to calculate the NPV of the symptomatic, the NPV results cannot be generalized. Second, the usefulness of RATs as a screening tool cannot be normally generalized because they proved effective in correctional facilities during the high prevalence period. Third, the accuracy of each RATs product cannot be considered due to the use of various commercial RAT kits.

Analytical and clinical validity are important prerequisites for assessing the clinical usefulness of RATs. However, we conducted only diagnostic accuracy (clinical validity) of RATs with SARS-CoV-2 infection. Therefore to establish the RATs diagnostic system as a screening tool, we propose a further study to quantitatively analyze the difference of Ct values according to clinical and epidemiological information such as symptoms and vaccination status and the distribution of Ct values by collecting more data related to symptoms.

In conclusion, sensitivity and NPV significantly depend on whether symptoms are present, and the percentage of false negatives is correlated with the incidence. Therefore, using RATs need a strategic approach according to symptoms in a high-prevalence environment. RATs could be an effective first-line countermeasure to prevent transmission and spread in correctional facilities through early detection of confirmed patients. This is the first large-scale study to evaluate the diagnostic accuracy of SARS-CoV-2 RATs in Korea. We hope this study will be used as primary data for preventing and managing emerging respiratory infectious diseases in correctional facilities.

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Conflict of Interest
No conflicts of interest.

Author Contributions
Conceptualization: HYL, YJP, SEL. Data curation: HYL, YJP. Formal analysis: HYL, YJP. Investigation: HSP, JYK, JYM. Methodology: HYL, YJP, SEL. Software: HYL. Visualization: HYL, YJP. Writing – original draft: HYL, YJP. Writing – review & editing: SEL, YJP, HYL, MY, HP, JJL, JC, HSP, JYK, JYM.

SUPPLEMENTARY MATERIAL

Supplementary Table 1

List of SARS-CoV-2 Rapid Antigen Diagnostic Tests, used by correctional facilities in South Korea (As of March 11, 2022).

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REFERENCES

1. Fernandez-Montero A, Argemi J, Rodríguez JA, Ariño AH, Moreno-Galarraga L. Validation of a rapid antigen test as a screening tool for SARS-CoV-2 infection in asymptomatic populations. Sensitivity, specificity and predictive values. EClinicalMedicine 2021;37:100954.
PUBMED | CROSSREF

2. European Centre for Disease Prevention and Control (ECDC). Options for the use of rapid antigen tests for COVID-19 in the EU/EEA and the UK. 2020. Availableat: https://www.ecdc.europa.eu/sites/default/files/documents/Options-use-of-rapid-antigen-

tests-for-COVID-19_0.pdf. Accessed 15 September 2022.

3. Centers for Disease Control and Prevention (CDC). Overview of testing for SARS-CoV-2, the virus that cause COVID-19. 2022. Available at: https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html. Accessed 15 September 2022.
4. Vashist SK. *In vitro* diagnostic assays for COVID-19: recent advances and emerging trends. Diagnostics (Basel) 2020;10:202.
PUBMED | CROSSREF
5. Korea Disease Control and Prevention Agency (KDCA). Coronavirus infectious disease-19 outbreak in Korea (January 31, 2022, press release). 2022. Available at: https://kdca.go.kr/board/board.es?mid=a20501020000&bid=0015&list_no=718514&cg_code=C01&act=view&nPage=51. Accessed 15 September 2022.
6. Korea Disease Control and Prevention Agency (KDCA). Coronavirus infectious disease-19 outbreak in Korea (March 14, 2022, press release). 2022. Available at: https://kdca.go.kr/board/board.es?mid=a20501020000&bid=0015&list_no=718989&cg_code=C01&act=view&nPage=1. Accessed 15 September 2022.
7. Korean Society for Preventive Medicine. Chapter 5. Validity and reliability. Preventive Medicine and Public Health. 4th ed. Seoul: Gyechuk Culture Publishing; 2021;151.
8. Verde P, Marcantonio C, Costantino A, Martina A, Simeoni M, Taffon S, Tritarelli E, Campanella C, Cresta R, Bruni R, Ciccaglione AR, Pisani G, Nisini R, Spada E. Diagnostic accuracy of a SARS-CoV-2 rapid antigen test among military and civilian personnel of an Air Force airport in central Italy. PLoS One 2022;17:e0277904.
PUBMED | CROSSREF
9. Kweon OJ, Lee JH, Choi YS, Kim BS, Lim YK, Lee MK, Park JH, Park JY, Kim SH. Positivity of rapid antigen testing for SARS-CoV-2 with serial followed-up nasopharyngeal swabs in hospitalized patients due to COVID-19. J Korean Med Sci 2022;37:e168.
PUBMED | CROSSREF
10. Kweon OJ, Kim HR, Lee MK, Lim YK. Real-world accuracy of a SARS-CoV-2 rapid diagnostic tests in the Republic of Korea. J Korean Med Sci 2022;37:e310.
PUBMED | CROSSREF
11. Lee H, Kang H, Cho Y, Oh J, Lim TH, Ko BS, Lee J. Diagnostic performance of the rapid antigen test as a screening tool for SARS-CoV-2 infection in the emergency department. J Pers Med 2022;12:1172.
PUBMED | CROSSREF
12. Centers for Disease Prevention and Control (CDC). Guidance on management of COVID-19 in homeless service sites and in correctional and detention facilities. 2023. Available at: https://www.cdc.gov/coronavirus/2019-ncov/community/homeless-correctional-settings.html. Accessed 11 May 2023.
13. Korean Institute of Criminology and Justice (KICJ). Changes in the criminal justice system in the post-corona era (II) - changes in corrections and probation during the pandemic and adaptation to new trend. 2022. Available at: https://www.kicj.re.kr/boardDownload.es?bid=0029&list_no=13402&seq=1. Accessed 11 May 2023.
14. Ministry of Justice (MOJ). Countermeasures to prevent the spread of infectious diseases in correctional facilities (January 20, 2021, press release). 2021. Available at: https://www.moj.go.kr/bbs/moj/437/541962/artclView.do. Accessed 11 May 2023.
15. Government Policy Coordination and Prime Minister's Secretariat (OPC/PMS). Correctional facility COVID-19 outbreak and quarantine management status (August 3, 2021, press release). 2021. Available at: https://www.opm.go.kr/flexer/view.do?ftype=pdf&attachNo=123795. Accessed 11 May 2023.
16. Korea Disease Control and Prevention Agency (KDCA). Coronavirus infectious disease-19 outbreak in Korea (April 24, 2022, press release). 2022. Available at: https://www.kdca.go.kr/board/board.es?mid=a20501020000&bid=0015&list_no=719374&cg_code=C01&act=view&nPage=61. Accessed 15 September 2022.
17. Korea Disease Control and Prevention Agency (KDCA). Coronavirus infectious disease-19 outbreak in Korea (May 1, 2022, press release). 2022. Available at: https://www.kdca.go.kr/board/board.es?mid=a20501020000&bid=0015&list_no=719441&cg_code=C01&act=view&nPage=42. Accessed 15 September 2022.
18. Korea Disease Control and Prevention Agency (KDCA). Coronavirus infectious disease-19 outbreak in Korea (May 8, 2022, press release). 2022. Available at: https://www.kdca.go.kr/board/board.es?mid=a20501020000&bid=0015&list_no=719506&cg_code=C01&act=view&nPage=41. Accessed 15 September 2022.
19. Korea Disease Control and Prevention Agency (KDCA). Coronavirus infectious disease-19 outbreak in Korea (May 15, 2022, press release). 2022. Available at: https://www.kdca.go.kr/board/board.es?mid=a20501020000&bid=0015&list_no=719552&cg_code=C01&act=view&nPage=39. Accessed 15 September 2022.
20. Korea Disease Control and Prevention Agency (KDCA). Coronavirus infectious disease-19 outbreak in Korea (May 22, 2022, press release). 2022. Available at: https://www.kdca.go.kr/board/board.es?mid=a20501020000&bid=0015&list_no=719609&cg_code=C01&act=view&nPage=57. Accessed 15 September 2022.
21. Korea Disease Control and Prevention Agency (KDCA). Coronavirus infectious disease-19 outbreak in Korea (May 29, 2022, press release). 2022. Available at: https://www.kdca.go.kr/board/board.es?mid=a20501020000&bid=0015&list_no=719677&cg_code=C01&act=view&nPage=36. Accessed 15 September 2022.
22. Schrom J, Marquez C, Pilarowski G, Wang CY, Mitchell A, Puccinelli R, Black D, Rojas S, Ribeiro S, Tulier-Laiwa V, Martinez J, Payan J, Rojas S, Jones D, Martinez D, Nakamura R, Chamie G, Jain V, Petersen M, DeRisi J, Havlir D. Comparison of SARS-CoV-2 reverse transcriptase polymerase chain reaction and BinaxNOW rapid antigen tests at a community site during an Omicron surge: a cross-sectional study. Ann Intern Med 2022;175:682-90.
PUBMED | CROSSREF
23. Dinnes J, Sharma P, Berhane S, van Wyk SS, Nyaaba N, Domen J, Taylor M, Cunningham J, Davenport C, Dittrich S, Emperador D, Hooft L, Leeflang MM, McInnes MD, Spijker R, Verbakel JY, Takwoingi Y, Taylor-Phillips S, Van den Bruel A, Deeks JJ; Cochrane COVID-19 diagnostic test accuracy group. Rapid, point-of-care antigen tests for diagnosis of SARS-CoV-2 infection. Cochrane Database Syst Rev 2022;7:CD013705.
PUBMED
24. Farhana A, Zahoor D, Wani S, Khan RA, Nasir R, Kanth F. Diagnostic utility and performance of rapid antigen test in SARS CoV- 2 in symptomatic and asymptomatic patients during the second pandemic wave in Kashmir, North India. Indian J Med Microbiol 2022;40:572-6.
PUBMED | CROSSREF

25. Peeling RW, Olliaro PL, Boeras DI, Fongwen N. Scaling up COVID-19 rapid antigen tests: promises and challenges. Lancet Infect Dis 2021;21:e290-5.
PUBMED | CROSSREF

26. Khalid MF, Selvam K, Jeffry AJN, Salmi MF, Najib MA, Norhayati MN, Aziah I. Performance of rapid antigen tests for COVID-19 diagnosis: a systematic review and meta-analysis. Diagnostics (Basel) 2022;12:110.
PUBMED | CROSSREF

27. Prestedge J, Williamson DA. The performance of rapid antigen tests against SARS-CoV-2 variants. Lancet Infect Dis 2023;23:883-4.
PUBMED | CROSSREF

28. Seymen AA, Gulten E, Ozgur E, Ortaç B, Akdemir I, Cinar G, Saricaoglu EM, Guney-Esken G, Akkus E, Can F, Karahan ZC, Azap A, Tuncay E. Clinical evaluation of DIAGNOVIR SARS-CoV-2 ultra-rapid antigen test performance compared to PCR-based testing. Sci Rep 2023;13:4438.
PUBMED | CROSSREF

29. Polechová J, Johnson KD, Payne P, Crozier A, Beiglböck M, Plevka P, Schernhammer E. SARS-CoV-2 rapid antigen tests provide benefits for epidemic control - observations from Austrian schools. J Clin Epidemiol 2022;145:14-9.
PUBMED | CROSSREF

30. Leiner J, Pellissier V, Nitsche A, König S, Hohenstein S, Nachtigall I, Hindricks G, Kutschker C, Rolinski B, Gebauer J, Prantz A, Schubert J, Patzschke J, Bollmann A, Wolz M. SARS-CoV-2 rapid antigen testing in the healthcare sector: a clinical prediction model for identifying false negative results. Int J Infect Dis 2021;112:117-23.
PUBMED | CROSSREF

31. Centers for Disease Control and Prevention (CDC). Considerations for SARS-CoV-2 antigen testing for healthcare providers testing individuals in the community. 2022. Available at: https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html. Accessed 15 September 2022.

32. European Centre for Disease Prevention and Control (ECDC). Options for the use of rapid antigen detection tests for COVID-19 in the EU/EEA and the UK – First update. 2021. Available at: https://www.ecdc.europa.eu/sites/default/files/documents/Options-for-the-use-of-rapid-antigen-tests-for-COVID-19-first-update.pdf. Accessed 15 September 2022.

33. World Health Organization (WHO). Antigen-detection in the diagnosis of SARS-CoV-2 infection using rapid immunoassays. 2022. Available at: https://www.who.int/publications/i/item/antigen-detection-in-the-diagnosis-of-sars-cov-2infection-using-rapid-immunoassays. Accessed 15 September 2022.

34. Alemany A, Baró B, Ouchi D, Rodó P, Ubals M, Corbacho-Monné M, Vergara-Alert J, Rodon J, Segalés J, Esteban C, Fernández G, Ruiz L, Bassat Q, Clotet B, Ara J, Vall-Mayans M, G-Beiras C, Blanco I, Mitjà O. Analytical and clinical performance of the panbio COVID-19 antigen-detecting rapid diagnostic test. J Infect 2021;82:186-230.
PUBMED | CROSSREF

35. Saloner B, Parish K, Ward JA, DiLaura G, Dolovich S. COVID-19 cases and deaths in federal and state prisons. JAMA 2020;324:602-3.
PUBMED | CROSSREF

36. Natoli LJ, Vu KL, Sukhija-Cohen AC, Engeran-Cordova W, Maldonado G, Galvin S, Arroyo W, Davis C. Incarceration and COVID-19: Recommendations to curb COVID-19 disease transmission in prison facilities and surrounding communities. Int J Environ Res Public Health 2021;18:9790.
PUBMED | CROSSREF

37. Beaudry G, Zhong S, Whiting D, Javid B, Frater J, Fazel S. Managing outbreaks of highly contagious diseases in prisons: a systematic review. BMJ Glob Health 2020;5:e003201.
PUBMED | CROSSREF

38. National Human Rights Commission of the Republic of Korea (NHRC). Survey on the right to health of detainees in detention facilities. 2016. Available at: https://www.humanrights.go.kr/base/board/read?boardManagementNo=17&boardNo=7600664&menuLevel=3&menuNo=115. Accessed 15 September 2022.

39. Choi S, Lee E, Bang JH. High prevalence of human immunodeficiency virus infection among inmates in Korean correctional facilities. J Korean Med Sci 2021;36:e92.
PUBMED | CROSSREF

40. Stufano A, Buonvino N, Cagnazzo F, Armenise N, Pontrelli D, Curzio G, De Benedictis L, Lovreglio P. Efficacy of the measures adopted to prevent COVID-19 outbreaks in an Italian correctional facility for inmates affected by chronic diseases. Front Public Health 2021;9:694795.
PUBMED | CROSSREF