DOI: 10.24938/kutfd.1702068 Kırıkkale Üniversitesi Tıp Fakültesi Dergisi 2025;27(2):197-202
Original Article *Özgün Araştırma*

EVALUATION OF THE DIAGNOSTIC PERFORMANCE OF COVID-19 RAPID ANTIGEN TEST IN COMPARISON TO SARS-COV-2 REVERSE TRANSCRIPTASE POLYMERASE CHAIN REACTION

COVID-19 Hızlı Antijen Testinin Sars-Cov-2 Reverz Transkriptaz Polimeraz Zincir Reaksiyonu İle Karşılaştırmalı Tanısal Performansının Değerlendirilmesi

Ezgi GÜLTEN[1] Duygu ÖCAL[2] Elif Mukime SARICAOĞLU[1] İrem AKDEMİR[1] Güle ÇINAR[1] Zeynep Ceren KARAHAN[2] Ebru EVREN[2] Ebru US[2] Alpay AZAP[1] Atilla Halil ELHAN[3]

[1]*Department of Infectious Diseases and Clinical Microbiology, Faculty of Medicine, Ankara University, ANKARA, TÜRKİYE*

[2]*Department of Medical Microbiology, Faculty of Medicine, Ankara University, ANKARA, TÜRKIYE*

[3] *Department of Department of Biostatistics, Faculty of Medicine, Ankara University, ANKARA, TÜRKİYE*

ABSTRACT

Objective: The World Health Organization recommends reverse transcriptase polymerase chain reaction (RT-PCR) as the reference method for COVID-19 diagnosis. However, it is time-consuming, costly, and requires specialized equipment and trained personnel. Therefore, rapid antigen tests (RATs), which provide results within 15–30 minutes, have emerged as a potential alternative. The aim of the current study was to assess the diagnostic performance of the SARS-CoV-2 Rapid Antigen Test (Ref No: 9901-NCOV-01G, Roche Diagnostics) compared to RT-PCR in adult patients with COVID-19-related symptoms.

Material and Methods: In this prospective observational study, 492 symptomatic adult patients, aged ≥ 18 years, were tested using simultaneous oro-nasopharyngeal swabs for RAT and RT-PCR. Diagnostic metrics were calculated, and the impact of cycle threshold (Ct) values and symptom duration on RAT performance was analyzed.

Results: In total, 167 (33.9%) of 492 patients' oro-nasopharyngeal swab samples tested by RT-PCR result were positive. Compared to RT-PCR, the sensitivity, specificity, positive and negative predictive value of RAT were 90.4% [95% confidence interval (CI): 85%-94%], 98.8% (95% CI: 96.9%-99.5%), 97.4% (95% CI: 93.6%-99%) and 95.3% (95% CI: 92.4%-97.1%), respectively. The Ct values of samples with false-negative RAT results were higher than the samples that tested positive by RAT and RT-PCR [23.93±4.40) vs. 18.42±4.56), p<0.001]. Based on the Ct values, RAT sensitivity was 96.5%, 80.5%, and 30.8% for the <22, 22-26, and >26 groups, respectively. Furthermore, as Ct values increased, RAT was less likely to detect SARS-CoV-2 infection (p<0.001).

Conclusion: The SARS-CoV-2 RAT exhibited high diagnostic performance in symptomatic patients and exceeded the minimum sensitivity and specificity thresholds recommended by the World Health Organization. Although its sensitivity decreases with higher Ct values, which may reflect lower viral loads, RAT remains a valuable point-of-care tool for early detection and isolation of COVID-19 cases. Confirmatory RT-PCR testing should be considered in symptomatic patients with negative RAT results.

Keywords: *COVID-19, diagnostic accuracy, rapid antigen test, SARS-CoV-2*

ÖZ

Amaç: Dünya Sağlık Örgütü, COVID-19 tanısında referans yöntem olarak reverz transkriptaz polimeraz zincir reaksiyonunu (RT-PZR) önermektedir. Ancak bu yöntem; zaman alıcı ve maliyetli olup özel donanım ve eğitimli personel gerektirmektedir. Bu nedenle, hızlı antijen testleri (HAT) potansiyel bir alternatif olarak öne çıkmıştır. Bu çalışmanın amacı, COVID-19 ile ilişkili semptomları olan erişkin hastalarda SARS-CoV-2 Hızlı Antijen Testi'nin (Ref No: 9901-NCOV-01G, Roche Diagnostics) RT-PZR ile karşılaştırmalı tanısal performansını değerlendirmektir.

Gereç ve Yöntemler: Bu prospektif gözlemsel çalışmada, 492 semptomatik erişkin hastadan eş zamanlı olarak alınan oro-nazofarengeal sürüntüler HAT ve RT-PZR yöntemleriyle test edilmiştir. Tanısal ölçütler hesaplanmış ve döngü eşiği (Ct) değerlerinin ve semptom süresinin HAT performansı üzerindeki etkisi analiz edilmiştir.

Bulgular: RT-PZR ile test edilen 492 hastanın 167'sinde (%33,9) oro-nazofarengeal sürüntü örnekleri pozitif bulunmuştur. RT-PZR ile karşılaştırıldığında, HAT'in duyarlılığı %90,4 [güven aralığı (GA) %95: %85–%94], özgüllüğü %98,8 (GA %95: %96,9–%99,5), pozitif prediktif değeri %97,4 (GA %95: %93,6–%99) ve negatif prediktif değeri %95,3 (GA %95: %92,4–%97,1) olarak hesaplanmıştır. Yanlış negatif HAT sonuçlarına sahip örneklerin Ct değerleri, her iki yöntemle de pozitif saptanan örneklere kıyasla daha yüksek bulunmuştur [23,93±4,40) vs. 18,42±4,56), p<0,001]. Ct değerlerine göre HAT'in duyarlılığı <22, 22–26 ve >26 grupları için sırasıyla %96,5, %80,5 ve %30,8 olarak saptanmıştır. Ayrıca, Ct değeri arttıkça HAT'in SARS-CoV-2 enfeksiyonunu saptama olasılığı anlamlı şekilde azalmıştır (p<0,001).

Sonuç: SARS-CoV-2 Hızlı Antijen Testi, semptomatik hastalarda yüksek tanısal performans göstermiş ve Dünya Sağlık Örgütü tarafından önerilen minimum duyarlılık ve özgüllük eşiklerinin üzerinde bulunmuştur. Ct değerinin artmasıyla, ki bu durum viral yükün azalmasını yansıtmaktadır, testin duyarlılığı düşse de HAT COVID-19 olgularının erken saptanması ve izolasyonu açısından değerli bir başvuru testi olarak ön plana çıkmaktadır. Semptomatik hastalarda negatif HAT sonucu alınması durumunda sonucun RT-PZR testi ile doğrulanması önerilmektedir.

Anahtar Kelimeler: *COVID-19, tanısal doğruluk, hızlı antijen testi, SARS-CoV-2*

Correspondence / Yazışma Adresi: **Dr. Ezgi GÜLTEN**
Department of Infectious Diseases and Clinical Microbiology, Faculty of Medicine, Ankara University, ANKARA, TÜRKİYE
Phone / Tel: +905309346320 **E-mail** / E-posta: ezgioztop@gmail.com
Received / Geliş Tarihi: 19.05.2025 **Accepted** / Kabul Tarihi: 03.06.2025

KÜ Tıp Fak Derg 2025;27(2):197-202
Doi: 10.24938/kutfd.1702068

INTRODUCTION

The Coronavirus disease-2019 (COVID-19) pandemic caused by severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) resulted in 777,310,393 infected people, with a death toll of 7,083,246 as of early 2025, according to World Health Organization (WHO) data.[1] Turkish Ministry of Health reported that, since the beginning of the pandemic, 17,232,066 people were infected with SARS-CoV-2 and 102,174 patients lost their lives.[2]

It is well-established that early and rapid diagnosis and isolation of symptomatic cases are the key measures to prevent the spread of COVID-19.[3] WHO recommends quantitative reverse transcriptase-polymerase chain reaction (RT-PCR) as the reference test for detection of SARS-CoV-2.[4] Nevertheless, there were complexities associated with the RT-PCR test. Advanced laboratory facilities with at least biosafety level-2 safety equipment and trained personnel are required to perform RT-PCR. Moreover, RT-PCR is a relatively time-consuming and expensive method.[5] Accordingly, lateral flow-based rapid antigen tests (RATs), which have been found recent use in the diagnosis of a number of infectious diseases, have been considered for the diagnosis of COVID-19. Compared to RT-PCR, RATs have advantages in that they can be performed outside the laboratory settings without trained personnel, provide results in a relatively shorter time manner, and are easy to use and cost-effective.[6,7] Therefore, it was suggested that RATs might be used as an alternative to RT-PCR in the diagnosis of COVID-19, especially in settings where laboratory facilities are limited and the test result time would delay diagnosis and preventive measures.[8] WHO reported that a RAT should meet minimum criteria of ≥80% sensitivity and ≥97% specificity to be used in the diagnosis of COVID-19.[7]

The present study aimed to evaluate the real-life clinical sensitivity and specificity of a RAT compared to RT-PCR with the variables affecting test results in the diagnosis of SARS-CoV-2 infection.

MATERIALS AND METHODS

This study was conducted between April 1st, 2022, and September 1st, 2022. Patients aged 18 years and over, who presented to the COVID-19 outpatient clinic of Ankara University Faculty of Medicine Hospital, with symptoms associated with COVID-19 infection were evaluated for study participation. Patients who volunteered to participate in the study and signed the informed consent form were included. Two simultaneous oro-nasopharyngeal swab (O-NFS) samples were collected from volunteers by the same personnel; one for SARS-CoV-2 RT-PCR and one for RAT. Personnel performing the swab collections were blinded to the prior test results to minimize potential bias. Data related to age, sex, date of presentation, COVID-19 vaccination status, time since the last COVID-19 vaccine dose, symptoms and symptom duration, RAT results, RT-PCR results, and cycle threshold (Ct) values for positive RT-PCR results were recorded.

RT-PCR Test

The O-NFS samples collected for RT-PCR were inserted in viral lysis buffer (vNAT, Bioeksen, Turkey) and sent to the microbiology laboratory within two hours in compliance with cold chain transportation rules. RT-PCR test was performed on the Rotorgene 5Plex HRM platform using DS Coronex COVID-19 Ver.2.0 kit (DS Bio and Nano Technology, Turkey) to detect SARS-CoV-2 RNA. All results were interpreted by a medical microbiologist and Ct values for samples, which were tested positive, were recorded.

Rapid Antigen Test

RAT was administered upon the manufacturer's recommendations, using the SARS-CoV-2 Rapid Antigen Test (Ref No: 9901-NCOV-01G, Roche Diagnostics) immediately after the collection of O-NFS samples. Test results within 15-30 minutes were recorded. For positive RAT results, the patients were isolated while RT-PCR results were awaited.

Statistical Analysis

The R software (R programming language version 4.2.3) was used to analyze the study data. While categorical variables were expressed in numbers and percentages, other variables were expressed in mean (±standard deviation) and median (minimum-maximum). The Chi-squared test was used for the intergroup comparison of categorical variables. Mann-Whitney U test and Kruskal-Wallis's analysis of variance were chosen to investigate the difference between two or more groups for continuous non-normally distributed variables. The coherence between the two alternative methods was measured using Cohen's kappa coefficient. Sensitivity, specificity, positive and negative predictive values for RAT were calculated using RT-PCR as the reference test. A p-value of <0.05 was considered statistically significant.

The study was approved by the Ankara University, Faculty of Medicine, Human Research Ethics Committee (Date: 14.10.2021 and Decision no: I9-591-21). The study procedures were performed in compliance with the WMA Declaration of Helsinki-Ethical Principles for Medical Research Involving Human Subjects.

RESULTS

Of the 492 volunteers included in the study, 326 (66.3%) were female. The mean age of the participants was 40.73±14.3. One hundred sixty-seven (33.9%) patients tested positive by RT-PCR method. The most common

KÜ Tıp Fak Derg 2025;27(2):197-202
Doi: 10.24938/kutfd.1702068

symptoms of patients, who were diagnosed with COVID-19 by the reference method were weakness-fatigue (83.2%), sore throat (82%), cough (70.7%), arthralgia-myalgia (61.1%), headache (46.1%), and fever (44.9%). The median symptom duration of RT-PCR-positive patients was 2 (1-7) days at presentation. 161 (96.4%) patients tested positive by RT-PCR method had been vaccinated against COVID-19 with two or more doses; the mean duration since the last dose of the COVID-19 vaccine was 216.1±108.4) days. The demographic and clinical characteristics of the study group are provided in Table 1.

Table 1: Demographic and clinical characteristics of the study group

	All patients	Patients tested positive by RT-PCR*
Number of patients, n	492	167
Mean age ±SD†	40.73±14.3	42.50±15.15
Sex, n (%)		
Female	326 (66.3)	103 (61.7)
Male	166 (33.7)	64 (38.3)
Symptom duration-day		
Mean (±SD)	2.60±1.4	2.67±1.4
Median (minimum-maximum)	2 (1-10)	2 (1-7)
Symptoms, n (%)		
Weakness/fatigue	385 (78.3)	139 (83.2)
Sore throat	387 (78.7)	137 (82)
Cough	310 (63)	118 (70.7)
Arthralgia/myalgia	256 (52)	102 (61.1)
Headache	206 (41.9)	77 (46.1)
Fever	150 (30.5)	75 (44.9)
Loss of taste/smell	49 (10)	30 (18)
Shortness of breath	57 (11.6)	22 (13.2)
Nausea/vomiting	63 (12.8)	16 (9.6)
Diarrhea	51 (10.4)	15 (9)
Runny nose	33 (6.7)	12 (7.2)
Other symptoms‡	30 (6)	12 (7.2)
Number of patients with a history of ≥2 doses of COVID-19 vaccine (%)	470 (95.5)	161 (96.4)
Days since the last dose of vaccine in patients tested positive by RT-PCR with a history of ≥2 doses of COVID-19 vaccine§	-	216,11±108.4
Mean (±SD)		197 (6-517)
Median (minimum-maximum)		

*RT-PCR: Reverse transcriptase polymerase chain reaction,†SD: Standard deviation
‡Other symptoms: Hoarseness, perspiration, nasal discharge,§Evaluated only in the patient group tested positive by RT-PCR.

Comparison of RAT and RT-PCR results is shown in Table 2. While, the false positive RAT rate was 1.2%, the false negative rate of RAT was 9.6%. With RT-PCR as the reference method, the sensitivity, specificity, positive, and negative predictive values of RAT were 90.4% (95% confidence interval (CI): 85%-94%), 98.8% (95% CI: 96.9%-99.5%), 97.4% (95% CI: 93.6%-99%), and 95.3% (95% CI: 92.4%-97.1%), respectively.

Table 2: Comparison of RAT* and RT-PCR† results

	RT-PCR-positive results (n)	RT-PCR-negative results (n)	Total
RAT-positive results, n	151	4	155
RAT-negative results, n	16	321	337
Total, n	167	325	492

*RAT: Rapid antigen test,†RT-PCR: Reverse transcriptase polymerase chain reaction

The correlation between RAT results and Ct values was evaluated for patients who tested positive by RT-PCR. The mean Ct value was 18.8±5 in all patients who tested positive by RT-PCR, 23.9 (±4.4) in patients who tested negative by RAT and positive by RT-PCR, and 18.4 (±4.6) in patients who tested positive by both RAT and RT-PCR. There was a statistically significant intergroup difference ($p<0.001$). When RT-PCR test results were categorized into three groups based on Ct values of <22, 22-26, and >26, RAT gave negative results in 4/113 (3.5%), 8/41 (19.5%) and 4/13 (30.8%) samples, respectively (Table 3). Based on the Ct values, RAT sensitivity was 96.5%, 80.5%, and 30.8% for the <22, 22-26, and >26 groups, respectively. It was determined that the difference between the test results in the three groups mentioned above was significant and as Ct values increased, the probability of RAT to detect SARS-CoV-2 decreased ($p<0.001$).

KÜ Tıp Fak Derg 2025;27(2):197-202
Doi: 10.24938/kutfd.1702068

Table 3: Correlation between RAT* results and RT-PCR† test Ct‡ values

	Ct <22	Ct: 22-26	Ct >26
RAT negative results, n (%)	4 (3.5)	8 (19.5)	4 (30.8)
RAT positive results, n (%)	109 (96.5)	33 (80.5)	9 (69.2)
Total, n (%)	113 (100)	41 (100)	13 (100)

*RAT: Rapid antigen test,†RT-PCR: Reverse transcriptase polymerase chain reaction,‡Ct: Cycle threshold

The correlation between the test results and symptom duration was evaluated. The results indicated no difference in the duration of symptoms in RT-PCR positive/negative and RAT positive/negative patients (p=0.43). The mean and median symptom duration of patients with false negative RAT results were 2.4±1 and 2 (1-4) days, respectively.

The correlation between the RAT and RT-PCR results and the vaccination status of the patients was not taken into consideration due to the heterogeneity of the COVID-19 vaccination status (number and type of vaccines) of the patients included in the study group.

DISCUSSION

The diagnostic value of RATs in patients with COVID-19 was demonstrated in previous studies. In our study, RAT results were compared with the reference method, RT-PCR, and indicated 90.4% sensitivity and 98.8% specificity in the study population. The results exceeded the minimum requirements recommended by WHO. The United States Food and Drug Administration approved more than 200 RATs for emergency use in the diagnosis of COVID-19.[9] Real-life data should also be evaluated in addition to manufacturers' studies which were designed to provide regulatory permission for emergency use of these tests. Seitz et al. evaluated the diagnostic performance of five different RATs, including the RAT kit used in the present study, and reported that the sensitivity of CLINITEST and Roche tests was >85% in samples with a Ct value of 30 and below.[10] The performance of RAT kits made available for the diagnosis of COVID-19 was compared to RT-PCR in several previous studies. In a pooled meta-analysis of these reports, the sensitivity and specificity of RAT were 69% (95% CI: 68-70) and 99% (95% CI: 99-99), respectively, with positive and negative predictive values of 72 (95% CI: 44-119) and 0.30 (95% CI: 0.26-0.36).[11] Consistently, a Cochrane review by Dinnes et al. reported the mean sensitivity and specificity of RAT as 56.2% and 99.5%.[12]

In the present study, the mean Ct values of RT-PCR positive/RAT negative samples were higher compared to the mean Ct values of samples tested positive by both RAT and RT-PCR. Furthermore, the sensitivity of the RAT kit in this study for samples with a Ct value of >26 (69.2%) was below the recommended limit of WHO (80%). In another study, which investigated the diagnostic value of the Roche RAT in SARS-CoV-2 infection, Heydecke et al. similarly reported that sensitivity decreased as Ct values increased (as viral load decreased), with sensitivity decreased from 91.8% (95% CI: 82.2%-96.4%) in samples with a Ct level of <25 to 71% (95% CI: 61.1%-79.2%), when samples with Ct values up to 30 were included.[13] Consistently, another study by Pérez-García et al. reported the sensitivity for Panbio and SD Biosensor COVID-19 RAT kits as 93% to 95%, respectively, for samples with RT-PCR Ct values ranged between 20-25, 41% to 52% for Ct values between 25-30, and finally 5% to 17% for samples with Ct values of >30.[14] In another study, where RAT sensitivity and specificity were reported as 33.3% and 99.3%, respectively, it was observed that the positivity rate of RAT was 51.7% in patients with Ct values <25, whereas it decreased to 3.4% in patients with higher Ct values.[15] A meta-analysis of 166,943 patient samples from 135 studies reported the sensitivity as 100% (95% CI: 70%-100%) for samples with Ct values of <20 and 24% (95% CI: 16%-33%) for samples with Ct values of >30.[16] Although it was demonstrated that RAT sensitivity decreased as Ct values increased, it is not clear whether this constitutes a clinical disadvantage. Kahn et al. reported that viral load was low in samples with high Ct values.[17] The lack of an amplification step included in the RAT working principle, unlike RT-PCR, may account for the inconsistent results between RAT and RT-PCR in samples with high Ct values.[18] Robert Koch Institute reported that patients with samples with Ct values of above 30 were at lower risk of transmitting SARS-CoV-2 infection.[19] Therefore, even though the results of the present study supported that the sensitivity of RAT decreased in samples with high Ct value, RAT is still considered useful because of the ability to rapidly diagnose and isolate COVID-19 cases with low Ct values to reduce the further spread of infection in the community. Nevertheless, RT-PCR testing is recommended in symptomatic patients who tested negative by RAT to exclude the likelihood of COVID-19 infection. A concise comparison of the practical characteristics of RAT and RT-PCR is presented in Table 4 to further highlight their respective advantages and limitations in clinical settings.

The present study indicated that RAT/RT-PCR results were not affected by symptom duration. Several previous studies reported that RAT had a higher sensitivity in COVID-19 diagnosis within the first seven symptomatic days.[16,20] It is well-established that viral load reaches to highest levels during the first week after the onset of symptoms.[21] Although the median symptom duration was two days in patients with RAT-

KÜ Tıp Fak Derg 2025;27(2):197-202
Doi: 10.24938/kutfd.1702068

negative/RT-PCR-positive samples in our study, the mean Ct value of this group was significantly higher compared to the group of patients who tested positive by both RAT and RT-PCR. The prognosis of SARS-CoV-2 infection and viral kinetics vary between individuals. Low viral load (high Ct values) in patients with false-negative RAT results likely explain the lack of association between symptom duration and RAT performance in the present study.

Table 4: Practical Comparison of RAT* and RT-PCR† for SARS-CoV-2‡ Diagnosis

Feature	RAT	RT-PCR
Turnaround time	15–30 minutes	Several hours to 1–2 days
Test setting	Point-of-care, no need for specialized lab	Requires laboratory with advanced equipment
Personnel requirement	Minimal training required	Trained personnel required
Cost	Lower	Higher
Suitability in resource-limited Settings	Suitable	Limited suitability
Use for screening	Yes, especially for symptomatic individuals	Yes, but less practical for rapid screening
Confirmatory Use	Requires RT-PCR confirmation if negative	Gold standard

*RAT: Rapid antigen test,†RT-PCR: Reverse transcriptase polymerase chain reaction
‡SARS-CoV-2: Severe acute respiratory syndrome coronavirus-2,

The false positive rate of RAT was 1.2% in this study. Likewise studies mentioned above, RAT results were compared to the reference method, RT-PCR, in the current study. Earlier studies at the beginning of the COVID-19 pandemic suggested that RT-PCR testing had low clinical sensitivity in the diagnosis of SARS-CoV-2 infection.[22,23] In this context, the use of RT-PCR, which is not considered the gold standard diagnostic method, as a reference method might have affected the results. Nevertheless, since the patients included in the present study were not tested for other respiratory tract infections and RT-PCR results were not confirmed by viral cell culture, it is not possible to attribute the false positive results to the low sensitivity of RT-PCR. On the other hand, technical errors in sample collection, transport, and storage of the samples and analytical processes of RT-PCR might have also affected the results.

Asymptomatic cases were not included in our study. Several previous studies reported that RAT sensitivity was higher in symptomatic cases, probably due to higher viral load in symptomatic COVID-19 cases.[11,24] On the other hand, there are a few reports indicative of the fact that viral load and Ct values in asymptomatic cases were similar to those of symptomatic cases.[25,26] Previously, there was no clear consensus on the correlation between the occurrence of symptoms and RAT results, and it was suggested that viral load (Ct value) likely influenced test results to a greater extent than the occurrence of symptoms.[13,14,16] However, in a recent analysis, Wagenhäuser et al. evaluated 78,798 paired COVID-19 RAT/RT-PCR results from 2020 to 2023 and reported that high viral load and the presence of symptoms were factors positively correlated with a positive RAT result in individuals infected with SARS-CoV-2.[27] In a comparable study where 12,674 RT-PCR samples were matched with RAT results, with reported sensitivity and specificity of 53% and 98.8%, respectively, the presence of symptoms and high viral load (Ct ≤ 20) were associated with an increase in test sensitivity, consistent with the findings of our study.[28] Therefore, the exclusion of asymptomatic cases in the present study was not considered a limitation.

In conclusion; the results of the current study supported the use of the RAT as a screening and diagnostic test with high sensitivity and specificity in the presence of symptoms that might be associated with COVID-19. Confirmation of negative RAT results by RT-PCR is recommended in symptomatic patients. Given their affordability and rapid turnaround time, RATs may offer significant public health benefits, particularly in resource-limited settings where access to molecular diagnostics is constrained.

Conflicts of Interest: The authors declare no conflicts of interest.

Author Contributions: Conceptualization, E.G., D.Ö., E.M.S., İ.A., Z.C.K. and A.A.; formal analysis, E.G., D.Ö., E.M.S., İ.A., G.Ç., A.A and A.H.E; data curation, E.G.; writing-original draft preparation, E.G., D.Ö., E.M.S., İ.A., G.Ç., Z.C.K, E.E., E.U., A.A. and A.H.E.; writing-review and editing, E.G., D.Ö., E.M.S., İ.A., G.Ç., Z.C.K, E.E., E.U., A.A. and A.H.E.; All authors have read and agreed to the published version of the manuscript.

Acknowledgments: We would like to thank our volunteers, who agreed to participate in our study, Laborant Meşure Taşkan for her contributions in collecting the RAT and SARS-CoV-2 RT-PCR O-NFS samples, all the staff of the COVID-19 outpatient clinic, and the Central Molecular Microbiology Laboratory of

KÜ Tıp Fak Derg 2025;27(2):197-202
Doi: 10.24938/kutfd.1702068

our hospital, and Roche company for their support in providing the RAT kits used in the study.

Ethics Committee Approval: The study protocol was approved by the Ankara University, Faculty of Medicine, Human Research Ethics Committee (Date: 14.10.2021 and Decision no: I9-591-21). Only individuals who confirmed their voluntary participation by reading and signing the informed consent form were included in the study.

REFERENCES

1. World Health Organization (WHO). WHO Coronavirus (COVID-19) Dashboard. Accessed date: 21 January 2025: https://data.who.int/dashboards/covid19/deaths?n=c
2. T.C. Sağlık Bakanlığı. T.C. Sağlık Bakanlığı COVID-19 Bilgilendirme Platformu. Accessed date: 21 January 2025: https://covid19.saglik.gov.tr
3. Albert E, Torres I, Bueno F, et al. Field evaluation of a rapid antigen test (Panbio™ COVID-19 Ag Rapid Test Device) for COVID-19 diagnosis in primary healthcare centres. *Clin Microbiol Infect.* 2021;27(3):472.e7-472.e10.
4. da Silva SJR, Silva CTAD, Guarines KM, et al. Clinical and laboratory diagnosis of SARS-CoV-2, the virus causing COVID-19. *ACS Infect Dis.* 2020;6(9):2319-2336.
5. Gupta A, Khurana S, Das R, et al. Rapid chromatographic immunoassay-based evaluation of COVID-19: A cross-sectional, diagnostic test accuracy study & its implications for COVID-19 management in India. *Indian J Med Res.* 2021;153(1&2):126-131.
6. Rai P, Kumar BK, Deekshit VK, Karunasagar I, Karunasagar I. Detection technologies and recent developments in the diagnosis of COVID-19 infection. *Appl Microbiol Biotechnol.* 2021;105(2):441-455.
7. World Health Organization (WHO). Antigen-detection in the diagnosis of SARS-CoV-2 infection – Interim guidance 2021. Accessed date: 21 January 2025: https://www.who.int/publications/i/item/antigen-detection-in-the-diagnosis-of-sars-cov-2infection-using-rapid-immunoassays
8. Elli S, Blasi F, Brignolo B, et al. Diagnostic accuracy of rapid antigen test for COVID-19 in an emergency department. *Diagn Microbiol Infect Dis.* 2022;102(4):115635.
9. US Food and Drug Administration. Coronavirus Disease 2019 (COVID-19) Emergency Use Authorizations for Medical Devices. Accessed date: 21 January 2025: https://www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices
10. Seitz T, Lickefett B, Traugott M, et al. Evaluation of five commercial SARS-CoV-2 antigen tests in a clinical setting. *J Gen Intern Med.* 2022;37(6):1494-1500.
11. Arshadi M, Fardsanei F, Deihim B, et al. Diagnostic accuracy of rapid antigen tests for COVID-19 detection: A systematic review with meta-analysis. *Front Med (Lausanne).* 2022;9:870738.
12. Dinnes J, Deeks JJ, Adriano A, et al; Cochrane COVID-19 Diagnostic Test Accuracy Group. Rapid, point-of-care antigen and molecular-based tests for diagnosis of SARS-CoV-2 infection. *Cochrane Database Syst Rev.* 2020;8(8):CD013705. Update in: Cochrane Database Syst Rev. 2021;3:CD013705.
13. Heydecke A, Gullsby K. Evaluation of the performance of a rapid antigen test (Roche) for COVID-19 diagnosis in an emergency setting in Sweden. *J Med Virol.* 2023;95(2):e28537.
14. Pérez-García F, Romanyk J, Moya Gutiérrez H, et al. Comparative evaluation of Panbio and SD Biosensor antigen rapid diagnostic tests for COVID-19 diagnosis. *J Med Virol.* 2021;93(9):5650-5654.
15. Gobena D, Gudina EK, Gebre G, Degfie TT, Mekonnen Z. Rapid antigen test as a screening tool for SARS-CoV-2 infection: Head-to-head comparison with qRT-PCR in Ethiopia. *Heliyon.* 2023;10(1):e23518.
16. Xie JW, He Y, Zheng YW, Wang M, Lin Y, Lin LR. Diagnostic accuracy of rapid antigen test for SARS-CoV-2: A systematic review and meta-analysis of 166,943 suspected COVID-19 patients. *Microbiol Res*. 2022;265:127185.
17. Kahn M, Schuierer L, Bartenschlager C, et al. Performance of antigen testing for diagnosis of COVID-19: A direct comparison of a lateral flow device to nucleic acid amplification based tests. *BMC Infect Dis*. 2021;21(1):798.
18. Torjesen I. Covid-19: How the UK is using lateral flow tests in the pandemic. *BMJ*. 2021;372:n287. Erratum in: BMJ. 2021;373:n1620.
19. Thommes L, Burkert FR, Öttl KW, et al. Comparative evaluation of four SARS-CoV-2 antigen tests in hospitalized patients. *Int J Infect Dis*. 2021;105:144-146.
20. Corman VM, Haage VC, Bleicker T, et al. Comparison of seven commercial SARS-CoV-2 rapid point-of-care antigen tests: A single-centre laboratory evaluation study. *Lancet Microbe*. 2021;2(7):e311-e319.
21. Wölfel R, Corman VM, Guggemos W, et al. Virological assessment of hospitalized patients with COVID-2019. *Nature*. 2020;581(7809):465-469. Erratum in: Nature. 2020;588(7839):E35.
22. Mandal DK, Bhattarai BR, Pokhrel S, et al. Diagnostic performance of SARS-CoV-2 rapid antigen test in relation to RT-PCR C_q value. *Adv Virol*. 2022;2022:9245248.
23. Dhakal S, Karki S. Early Epidemiological features of COVID-19 in Nepal and public health response. *Front Med (Lausanne)*. 2020;7:524.
24. Dinnes J, Sharma P, Berhane S, et al; 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(7):CD013705.
25. Zou L, Ruan F, Huang M, et al. SARS-CoV-2 Viral load in upper respiratory specimens of ınfected patients. *N Engl J Med*. 2020;382(12):1177-1179.
26. Singanayagam A, Patel M, Charlett A, et al. Duration of infectiousness and correlation with RT-PCR cycle threshold values in cases of COVID-19, England, January to May 2020. *Euro Surveill*. 2020;25(32):2001483. Erratum in: *Euro Surveill*. 2021;26(7).
27. Wagenhäuser I, Knies K, Pscheidl T, et al. SARS-CoV-2 antigen rapid detection tests: Test performance during the COVID-19 pandemic and the impact of COVID-19 vaccination. *EBioMedicine*. 2024;109:105394.
28. Kim AE, Bennett JC, Luiten K, et al. Comparative diagnostic utility of SARS-CoV-2 rapid antigen and molecular testing in a community setting. *J Infect Dis*. 2024;230(2):363-373.