The sensitivity and specificity of Abbott Panbio™ COVID 19 Ag Rapid test in the context of four SARS-CoV-2 variants

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A R T I C L E   I N F O

A B S T R A C T

Rapid antigen tests for the detection of SARS-CoV-2 are commonly used for the diagnosis of Covid-19. Previously published data showed a wide range of sensitivity and specificity of RATs, but these studies were performed on relatively small numbers of samples and using only limited numbers of virus variants. The aim of the study was to evaluate the main parameters of a commonly used RAT for 4 different virus variants in comparison with PCR.

Material and methods: A set of 2874 samples obtained from Covid-19 patients were examined both by PCR and RAT. Two commercial PCR kits (Generi Biotech, Diana Biotechnologies) and one RAT – Abbott Panbio™ COVID 19 Ag Rapid – were compared for their sensitivity and specificity in samples positive for one of the four different SARS-CoV-2 variants – B.1.258 (n = 496), Alpha (n = 645), Delta/Delta+ (n = 687), and Omicron (n = 1046).

Results: The sensitivity of Panbio™ COVID19 Ag Rapid test varied from 80.0 % in Omicron to 88.92 % in Alpha variants. The specificities of the RAT for all variants reached above 93 %. Statistically significant differences were found between the results from RAT assay in select virus variants. In addition, significantly higher sensitivity (p < 0.05) was detected in samples with higher viral loads than in those with lower.

Conclusion: Despite the different sensitivity and specificity of Panbio™ COVID19 Ag Rapid test (Abbott ®) for different SARS-CoV-2 variants, this test sensitivity was proven to be always above the 80 % suggested by WHO, which makes it suitable for common use, regardless of the virus variability.

1. Introduction

With emergence of the COVID-19 pandemic with its worrisome death and hospitalization rates, subsequent fluctuating incidence rates, and the repeated discovery of new variants, there has been an urgent need for rapid diagnostic tools to reduce disease transmission. Two detection methods have predominated, the gold standard being polymerase chain reaction (PCR), which requires a high number of skilled lab technicians working in specialised diagnostic laboratories to detect viral nucleic acids. Subsequently, to simplify the diagnosis and reduce the time required to obtain results, rapid antigenic tests (RATs) have been developed which can be used in

point of care settings (POCs).

Although the advantages of PCR include its high specificity and sensitivity, the issue with this approach includes both the time required for detection and specific device needs. Thus, RATs were welcome as a promising faster alternative with a simpler application providing results in approximately 30 min. These features made RATs a main diagnostics tool for mass screening during COVID pandemic waves all over the world. Despite the obvious advantages of antigenic tests, which include low cost, shorter diagnostic time and simplicity of administration, discussion is ongoing about the correlation of their sensitivity and specificity compared to the gold standard – PCR. According to some studies, the sensitivity of RATs in clinical settings was significantly lower than published in the manufacturer's data. The meta-analysis study by Dinnes et al. showed a fair variability in the sensitivity of RATs compared to the PCR, ranging from 58.1 % in asymptomatic patients to 78.9 % in symptomatic patients [1].

The main target virus structures used for SARS-CoV-2 diagnosis include the S antigen (spike protein) containing two subunits, S1 with its receptor binding domain (RBD) and S2, as well as the N antigen (nucleocapsid protein). The spike glycoprotein facilitates entry of the virus into the host cell enabling the fusion of its membrane with that of the cell. At the same time, this antigen structure is highly variable, leading to the emergence of different virus variants. The N protein is necessary for binding to RNA to yield a ribonucleo-protein (RNP) complex, and this antigen is more genetically conserved [2,3]. The WHO advised that RATs show the best performance in patients with high viral loads in upper respiratory tract samples, and in those populations where the prevalence of SARS-CoV-2 infection is $\geq$ 5 %. The WHO authorities also recommended for practical use only those RAT assays with sensitivity of $\geq$80 % and specificity of $\geq$97 % [4].

The objective of the presented study was to evaluate the sensitivity and specificity of the commonly used Abbott Panbio™ COVID 19 Ag Rapid antigenic test on a large cohort of samples from Covid-19 patients in the context of four different SARS-CoV-2 variants, and to find whether their characteristics were on a par with the WHO recommendation for RAT sensitivity and specificity.

2. Materials and methods

2.1. Samples

The study included 2874 samples of nasopharyngeal swabs obtained from 2874 patients during the period from 07-2020 to 03–2022, and thus covering infection cases with four main SARS CoV-2 virus variants (variant B.1.258, Alpha, Delta/Delta+, and Omicron). All samples were examined simultaneously using the rapid antigen tests and PCR analysis. The distribution of virus variants in the cohort was as follows: 496 samples covering the period of circulation of variant B.1.258, 645 with Alpha variant, 687 with Delta and Delta + variants, and 1046 with the variant Omicron. Determination of the SARS-CoV-2 variant was performed in two steps. First, the discriminatory PCR was performed, results of which were subsequently confirmed by sentinel whole genome sequencing (National Health Institute guidelines were followed for sequencing confirmation requirements and adjusted according to the developments in the epidemiological situation). The discriminatory PCR targeted specific base pair mismatches characteristic for each virus variant. The Alpha variant was identified using a Diana Biotechnologies kit (Diana Biotechnologies, Czech Republic), detecting the characteristic mismatch A570D. Identification of SARS-CoV-2 variants Beta, Gamma, Delta, Delta plus and Kappa was performed by real-time RT_PCR kit PowerChek, a SARS-CoV-2 S-gene Mutation Detection Kit (Kogene Biotech, South Korea), which targets mutations N501Y, K417N, E484K, P681R, E484Q and L452R. The identification of variants Delta and Omicron was performed using real-time RT-PCR kit DB-1219 (Diana Biotechnologies) detecting L452R and Y505H mutations. All patient related data were anonymized, and data processing strictly followed the Helsinki protocol. The study was approved by the Institutional Ethics Committee of Faculty Hospital in Hradec Kralove (reference number 202101I33P approved on December 21, 2020). Informed consent was obtained from all subjects and/or their legal guardians. The samples were obtained from 46.34 % of female and 53.66 % of male patients. Samples were collected by health care workers in COVID-19 sampling centres in the University Hospital in Hradec Kralove.

2.2. Test methods

Various RAT tests were utilized during the sampling period, but only data from the dominant Panbio™ COVID 19 Ag Rapid test (Abbott Rapid Diagnostics Jena GmbH, Jena, Germany) were included into the study. The results from the RAT were compared to PCR tests performed by the following assays: GB SARS-CoV-2 Multiplex (Generi Biotech, Hradec Králové, Czech Republic), or COVID-19 Multiplex RT-PCR kit (Diana Biotechnologies, Vestec, Czech Republic). The basic characteristics of all methods are shown in

Table 1
Main characteristics of the tests utilized in the study.

RAPID ANTIGEN TEST				
Test name	Manufacturer	Target antigen	Manufacturer listed sensitivity	Manufacturer listed specificity
Panbio™ COVID19 Ag Rapid Test	Abbott Rapid Diagnostics	N - antigen	93.30%–98.20 %	99.40 %
PCR KIT				
Test name	Manufacturer	Target gene	Manufacturer listed lower limit of detection	
GB SARS-CoV-2 test	Generi Biotech	E-gene, RDRP-gene	2-10 copies per reaction	
COVID-19 Multiplex RT-PCT Kit	Diana Biotechnologies	S-gene, EndoRNAse gene	10 copies per reaction	

Table 1. All methods were performed using the material from nasopharyngeal swabs and the procedures strictly followed the manufacturer's protocols. The antigenic tests were performed directly in the place of sampling, while all the PCR assays were conducted in the specialised laboratory.

Semiquantitative PCR analysis represented by cycle threshold (ct) was used as recommended in the literature (https://www.gov.uk/government/publications/cycle-threshold-ct-in-sars-cov-2-rt-pcr). Preliminary comparative analysis using calibration samples of the 2 PCR assays used – GB SARS-CoV-2 test (Generi Biotech) and COVID-19 Multiplex RT-PCR Kit (Diana Biotechnologies) – showed a maximum of 2-cycle variability between the assays (data not shown).

2.3. Statistical evaluation

The standard sensitivity (true positivity/true positivity + false negativity) and specificity (true negativity/true negativity + false positivity) values of the antigenic tests were calculated for each of the SARS-CoV-2 variants. The 95 % confidence intervals (CI) of sensitivity and specificity were calculated, and the inter-variant variability of sensitivity and specificity and the sensitivity level dependence on the viral load (represented by the ct value of the PCR test) were statistically evaluated by Chi-Square Test with significance level $p \leq 0.05$, using NCSS 2021 Statistical Software (NCSS, LLC. Kaysville, Utah, USA, ncss.com/software/ncss). For the comparison of the PCR ct-value with the rapid antigen test sensitivity, GraphPad Prism 9 software (version 9.20, GraphPad Software Inc., San Diego, CA USA) was used, both for graphical outputs and basic statistical evaluation. The normality evaluation was performed using the Anderson-Darling test and Shapiro-Wilk test. Normally-distributed data were analysed using one-way ANOVA with post hoc Sidak's multiple comparison test. Non-normally distributed data were analysed by Kruskal–Wallis test with post hoc Dunn's multiple comparisons test. The differences were considered significant for $p \leq 0.05$.

3. Results

Altogether, 2874 samples were tested using Panbio™ COVID19 Ag Rapid test (Table 2).sensitivity of antigenic test was calculated as true positivity against true positivity + false negativity; specificity of antigenic test was calculated as true negativity against true negativity + false positivity.

When the results were compared to the PCR values, the overall sensitivity was calculated as 85.09 % (95 % CI 82.84 to 87.15) and the overall specificity as 97.36 % (95 % CI 96.54 to 98.05). Sensitivity in the context of the individual SARS-CoV-2 variant varied from 88.92 % for the Alpha variant to 80.00 % for the Omicron variant. The specificity of the test varied from 98.73 % in Omicron variant positive samples to 93.61 % in those of the Alpha variant.

To further analyse the dependence of the RAT results on the viral load, the PCR positive samples from the analysed cohort were divided into two groups – patients with PCR ct value > 25 and patients with PCR ct value ≤ 25 (following the design published by Dinnes et al. [1]), and sensitivity results were recalculated in both groups. The overall sensitivity of the test independently of virus variant was calculated as 89.91 % (95 % CI 87.62 to 91.82) for samples with high viral load (HVL, ct value ≤ 25) and 67.39 % (95 % CI 60.32 to 73.75) in samples with low viral load (LVL, ct value over 25). The summary of this data is shown in Table 3.

Lower sensitivity in samples with LVL was observed for all SARS-CoV-2 variants. To summarize, in B.1.258 variant positive samples the sensitivity of RAT was calculated as 87.10 % for HVL samples and 69.57 % for LVL samples. Similarly, the sensitivity results for HVL and LVL samples for the Alpha variant were 92.03 % and 69.84 %, for the Delta/Delta + variant 90.97 % and 70.58 %, and for the Omicron variant 88.10 % and 62.50 %, respectively. Statistical analysis showed such differences in the RAT sensitivity to be significant overall (p < 0.0001) and also in all SARS-CoV-2 variants individually.

Further statistical evaluation was performed to uncover potential inter-variant sensitivity and specificity using Chi Square Test at the significance level p = 0.05 (Table 4).

Highly statistically significant differences in sensitivity were found between variants Omicron and Alpha (p = 0.0009). Significant differences in the test specificity were found comparing variants Alpha against B.1.258 (p = 0.0146) and Alpha against Omicron (p < 0.0001).

For better understanding of potential reasons for the false negativity of the RAT test we defined the average and median ct value of

Table 2
Summary of the sensitivity and specificity results of Panbio™ COVID19 Ag Rapid test (Abbott ®) antigenic test compared to the PCR result.

Panbio™ COVID19- Ag Rapid Test (Abbott ®)				
SARS CoV-2 variant		No	%	CI (95 %)
B.1.258 (n = 496)	sensitivity	162/190	85.26 %	(79.53, 89.60)
	specificity	299/306	97.71 %	(93.35, 98.89)
Alpha (n = 645)	sensitivity	337/379	88.92 %	(85.36, 91.70)
	specificity	249/266	93.61 %	(90.00, 95.97)
Delta/Delta+ (n = 687)	sensitivity	163/189	86.24 %	(80.61, 90.44)
	specificity	484/498	97.19 %	(95.34, 98.32)
Omicron (n = 1046)	sensitivity	268/335	80.00 %	(75.39, 83.93)
	specificity	702/711	98.73 %	(97.61, 99.33)
OVERALL (n = 2874)	sensitivity	930/1093	85.09 %	(82.84, 87.15)
	specificity	1734/1781	97.36 %	(96.51, 98.05)

Table 3

Panbio™ COVID19 Ag Rapid test sensitivity results according to PCR results in high viral load (PCR ct value ≤ 25) and low viral load samples (PCR ct > 25).

	PCR ct ≤ 25			PCR ct > 25			
	No	sensitivity	CI (95 %)	No	sensitivity	CI (95 %)	p value
SARS CoV-2 B.1.258	81/93	87.10 %	(78.79, 92.46)	16/23	69.57 %	(49.13, 84.40)	0.0419
SARS CoV-2 Alpha	254/276	92.03 %	(88.23, 94.68)	44/65	69.84 %	(57.64, 79.76)	<0.0001
SARS CoV-2 Delta/Delta+	141/155	90.97 %	(85.41, 94.54)	24/34	70.59 %	(53.83, 83.17)	0,0012
SRAS CoV-2 Omicron	237/269	88.10 %	(83.69, 91.45)	40/64	62.50 %	(50.25, 73.33)	<0.0001
OVERALL	713/793	89.91 %	(87.62, 91.82)	124/184	67.39 %	(60.32, 73.75)	<0.0001

Significance level p < 0.05.

Table 4

The specificity and sensitivity evaluation for the individual SARS-CoV-2 variants.
*indicates statistically significant (p < 0.05) differences.

Panbio™ COVID19 Ag Rapid test (Abbott ®), sensitivity					Panbio™ COVID19 Ag Rapid test (Abbott ®), specificity				
SARS-CoV-2	B.1.258	Alpha	Delta/Delta+	Omicron	SARS-CoV-2	B.1.258	Alpha	Delta/Delta+	Omicron
B.1.258		0.216	0.785	0.132	B.1.258		0.0146*	0.651	0.230
Alpha	0.216		0.355	0.0009*	Alpha	0.0146*		0.169	<0.0001*
Delta/Delta+	0.785	0.355		0.0725	Delta/Delta+	0.651	0.169		0.0529
Omicron	0.132	0.0009*	0.0725		Omicron	0.230	<0.0001*	0.0529	

PCR positivity in all RAT-PCR concordant samples, and then in the samples with false negativity of RAT test only (Fig. 1).

The data show significant (p < 0.05) differences in ct values in these two groups for all four SARS-CoV-2 variants included. The ct value medians of all samples ranged from 19.90 in the Delta/Delta + variant to 21.05 in B.1.258. In the case of samples with falsely negative Ag test results, the ct values ranged from 23.33 in the Delta/Delta + variant to 25.25 in the Omicron variant.

4. Discussion

The meta-analysis performed by Dinnes et al. on 24 418 samples from 77 studies showed a correlation of RAT analysis sensitivity to clinical outcome and disease stage. This analysis showed that the overall sensitivity of RATs varies from 58.1 % in asymptomatic patients to 78.3 % in patients examined during the first 7 days from the onset of COVID symptoms. The authors also showed differences of sensitivity of various RATs ranging from 28.6 % in Coris Bioconcept-Covid-19 Ag Respi Strip in asymptomatic patients to 88.1 % in SD Biosensor-STANDARD Q COVID-19 Ag in symptomatic patients [1]. Another study evaluated the Panbio™ COVID-19 Ag rapid test (Abbott®) in 634 patients, and the overall sensitivity of the test was calculated as 48.1 % with specificity of 100 % [5]. Other published results showed relatively sufficient sensitivities of 73.3 % in 255 samples [6] and 71.4 % in 1369 of participants [7], or, conversely, very low sensitivity of 45.5 % in a pediatric population of 1620 [8]. Another review study evaluated 4 RATs targeting the N antigen (Nadal COVID-19 RAT, Panbio™ COVID-19 RAT, Standard Q COVID-19 RAT, Wondfo 2019-nCoV RAT) and 1 RAT targeting the envelope antigen (CerTest SARS-CoV-2) [9]. The data showed that the Panbio™ RAT exhibited relatively low sensitivity in asymptomatic patients (48.1 %) while the overall sensitivity ranged from 61.8 % to 95 %. As a result, the authors recommended use of the RAT preferably in patients with high viral load (ct value ≤ 25 or >10^6 genomic virus copies/ml. In our study, which analysed 2874 samples, the most extensive number to date, the overall sensitivity of the Panbio™ COVID-19 Ag Test was calculated as 85.09 %, which fulfilled WHO limits for its suitability in COVID diagnosis.

Several studies showed a dependence of RAT sensitivity on viral loads (indicated by the PCR ct value). Thus, a low sensitivity ranging from 31.8 % to 50.3 % was reported in samples with ct values > 25, whereas high sensitivities of 91.0–96.7 % were observed in samples with ct ≤ 25 [1]. Similar results from Sweden using two different RATs, Panbio™ COVID-19 Ag Test (Abbott®) and Healgen Biotech Coronavirus Ag rapid test cassette (Zhejiang Orient Gene), indicated that the sensitivity varied from 13 % to 30.4 % in samples with ct level over 30, and from 93.6 % to 97.9 % in samples with ct value under 20 [10]. For the Panbio™ RAT, Perez-Garcia et al. demonstrated a sensitivity of 96.4 % in samples with ct ≤ 25 but only 24.4 % in samples with ct > 25, as well as a high sensitivity of 91.3 % in samples from patients within 5 days after the onset of symptom [11]. Similar results were published by Rodgers et al. who evaluated the Panbio™ RAT sensitivity *in silico* and *in vitro*, but in only a limited number of samples from patients. The overall Panbio™ RAT sensitivity was calculated as 96.6 % in samples with >4 log GE/test [12]. Lastly, another study conducted in nursing homes showed Panbio™ RAT to be reliable in detecting virus-positive asymptomatic geriatric individuals. Thus, the assay was shown to be effective in the detection of SARS-CoV-2 variants B.1.1.7, B.1.351 and P.1. with 90 % sensitivity and 100 % specificity in samples with PCR ct cut-off below 35 [13]. Such patients were also seen as less effective in further virus transmission due to lower viral loads [14].
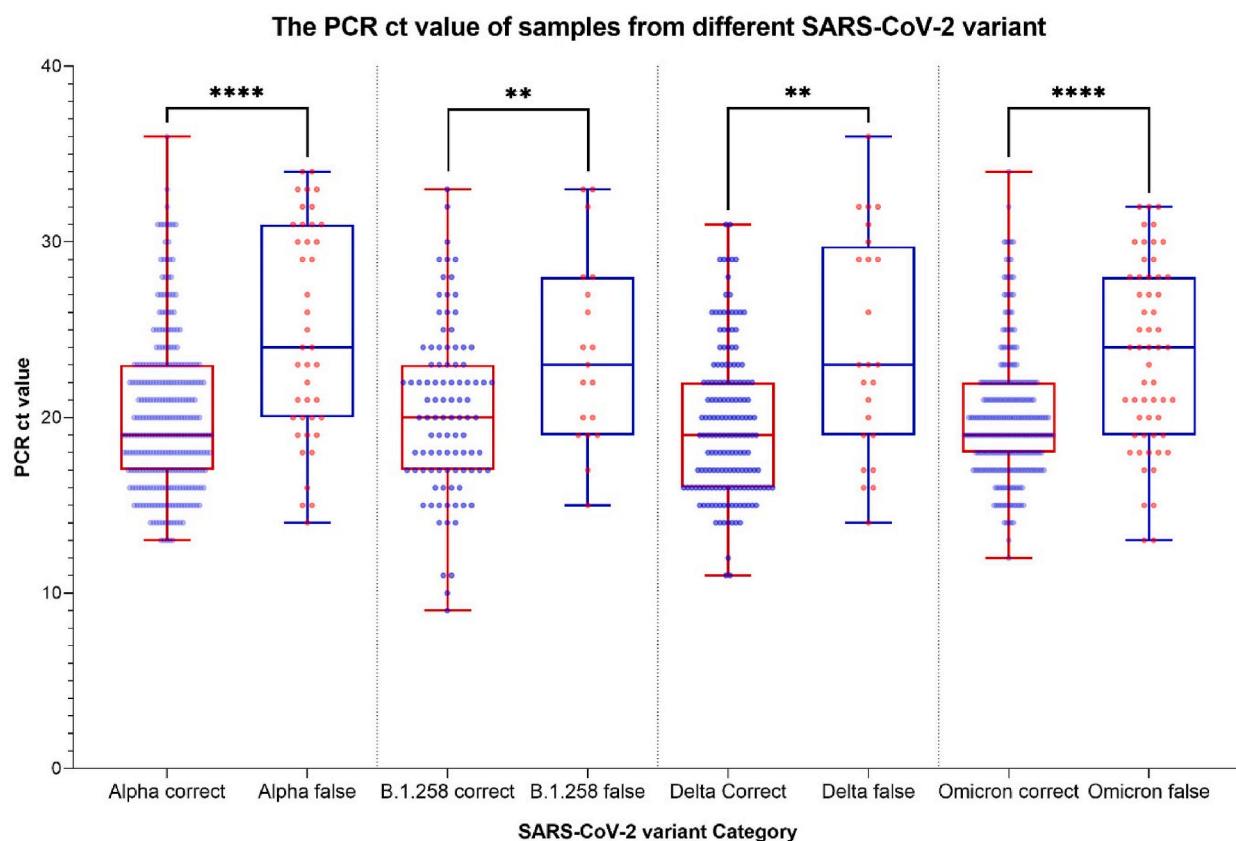
The PCR ct value of samples from different SARS-CoV-2 variant

Fig. 1. Comparison of PCR ct values between all samples and falsely negative samples. PCR ct values were compared in samples with concordance between PCR and RAT ("Variant correct") and falsely RAT negative samples ("Variant false") for each virus variant. The data showed high statistical significance in PCR ct value. Statistical significance: ****p < 0.001; **B.1.258 p = 0.0095; ** Delta p = 0.0015.

Lim and coworkers showed the dependence of RAT specificity on viral load represented by ct value using four different RATs, including Panbio™ RAT. The study presented sensitivities ranging from 100 % in samples with ct < 20, to 89.6 % in samples with ct values 22–24, and to very low sensitivity of 13.9 % in samples with ct values over 26 [15]. Another study from Namibia presented the overall sensitivity of Panbio™ RAT at 86 % and specificity at 100 %. The authors also compared the dependence of sensitivity on the viral load, showing 97 % sensitivity in samples with Ct values ≤ 25 and 71 % in samples with Ct values ≥ 25 [16]. Our data showed the sensitivity in high viral load samples (ct ≤ 25) at 89.91 %, but only 67.39 % in those with low viral loads, which is in concordance with the previously published data. At the same time, it showed the same trend in PCR ct value dependence for all four tested SARS CoV-2 variants detecting the statistically lower test sensitivity (p < 0.05) in samples with PCR ct level over 25. This is also depicted in the analysis in Fig. 1, which shows significantly higher median and average PCR ct values in samples with false negative RAT results.

Recently published analysis compared the sensitivities of nine different RATs in a cohort of 281 samples positive for either Delta or Omicron variants of SARS-CoV-2. In the Delta variant positive samples, the obtained sensitivity ranged from 34.92 % to 58.46 % and in the Omicron variant samples from 22.22 % to 57.43 % [17]. This indicates a lower sensitivity of some RATs in the diagnosis of the Omicron variant, although only limited statistical analysis was performed to compare the results between the individual virus variants. The publication of Cocherie and coworkers showed an association of decreased sensitivity of the Panbio™ RAT test for the Omicron variant (55.8 %) compared to Delta variant (74.7 %) due to lower viral loads in the Omicron variant [18]. Another recent study evaluated the sensitivity of the Panbio™ RAT for different Omicron subvariants, with the results ranging from 50 % to 100 % [19]. In comparison to the studies mentioned above, our analysis included a significantly larger number of participants and used multiple statistical approaches. This allowed for detailed analysis of the selected parameters in the four SARS-CoV-2 variants and clearly showed a significant variability in both the sensitivity and specificity of the used antigenic tests. The lowest sensitivity of the Panbio™ RAT was shown for the Omicron variant, which was in concordance with findings by Osterman et al. [17]. The reason for these findings lies potentially in the multiple mutations of the spike antigen found in the Omicron variant compared to the previous variants, as well as mutations in the nucleocapsid antigen (which were not described in previous variants), which may affect its binding affinity to monoclonal antibodies used in the test. Other studies showed the dependence of the Panbio™ RAT sensitivity on other multiple variables. Wertenauer et al. calculated lower sensitivity in patients with comorbidities (34.4 % against 71 %) and in those without symptoms (23.3 % against 74.3 %) [20]. The sensitivity of the Panbio™ RAT was also shown to be dependent on the location of swabbing, with a high sensitivity of 89 % in nasopharyngeal swabs compared to the relatively poor sensitivity of 12.6 % in oral swabs

[21]. Another interesting study noticed a potential association of average and median ct values in patients with SARS-CoV-2 reinfection by a different virus variant, and its extrapolation to the RAT sensitivity [22].

5. Conclusion

The analysed rapid antigen test showed a clear dependence of sensitivity on the viral load in the tested samples, with statistically lower sensitivity in samples with PCR ct level over 25. The data showed only limited statistically significant differences in the used RAT in the context of different SARS-CoV-2 variants. The overall sensitivity of Panbio™ COVID 19 Ag Rapid test reached the minimum WHO recommended value in all tested SARS-CoV-2 variants. However, lower detection efficiency in samples with lower viral loads may pose a limitation, which may account for underestimations.

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Data availability statement

Data have not been submitted to any public repository and will be made available on request.

Additional information

No additional information is available for this paper.

CRediT authorship contribution statement

Miroslav Fajfr: Writing - original draft, Resources, Methodology, Investigation, Conceptualization. **Laith Rashad Hassan Muhammad Moolla:** Investigation. **Joudi Barout:** Investigation. **Saaz Sahani:** Investigation. **Rudolf Kukla:** Resources, Investigation. **Eva Cermakova:** Data curation. **Radek Sleha:** Visualization, Software, Investigation. **Pavel Bostik:** Writing - review & editing, Supervision, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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