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Original article

Performance assessment of Standard ™ Q COVID-19 Ag Test in Ouagadougou, Burkina Faso

Abdou Azaque Zoure [*1], Henri Gautier Ouedraogo [1], Serge Théophile Soubeiga [1], Tegwinde Rebeca Compaoré [1], Sylvie Zida [1], Oumarou Ouedraogo [1], Dinanibè Kambiré [1], Dezemon Zingue [2], Charlemagne Dabiré [1], Alidou Kagambega [1], Charles Sawadogo [3], Zakariya Yabre [3], Tani Sagna [1], Lassana Sangare [4]

1- *Département Biomédical et Santé Publique, Institut de Recherche en Sciences de la Santé /National Centre for Scientific and Technologic Research (IRSS/CNRST), Ouagadougou, Burkina Faso.*
2- *Institut National de Santé Publique (INSP), Ministère de la santé et de l'Hygiène publique, Ouagadougou, Burkina Faso.*
3- *Direction des Laboratoires de Biologie Médicale (DLBM), Ministère de la santé et de l'Hygiène publique, Ouagadougou, Burkina Faso.*
4- *Unité de Formation et de Recherche en Sciences de la Santé (UFR-SDS), Université Joseph Ki-Zerbo, Ouagadougou, Burkina Faso*

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ABSTRACT

Background: Many rapid antigen kits for SARS-CoV-2 detection have been developed and the results interpreted usually within 30 minutes. Antigen tests are recommended to be used in areas where access to the PCR method is limited, as is the case in Burkina Faso. The aim of this study is to assess the performance of "Standard ™ Q COVID-19 Ag Test " in the detection of SARS-CoV-2 antigen. **Methods:** The evaluation was performed using swabs samples collected between January 26 and March 31, 2021, from 201 subjects previously diagnosed by RT-PCR. The performance of the rapid test "Standard ™ Q COVID-19 Ag Test was compared to the RT-PCR test "STANDARD M nCoV real-time detection kit". **Results:** Of these 201 samples, 16 were positive for the COVID-19 RT-PCR, and 185 were negative. The sensitivity of the "Standard ™ Q COVID-19 Ag Test" was 100% (IC95%: 34.24- 100) in symptomatic subjects with a symptom onset time of 1 to 5 days. This sensitivity decreased to 66.67% (IC95%: 20.77- 93.85) in symptomatic subjects with a symptom onset time of 1 to 7 days. The specificity, it was 95% (IC95%: 83.5-98.62) in all symptomatic subjects and 93.75% (IC95%: 79.85-98.2) in subjects whose symptoms appeared between 1 and 5 days. **Conclusion:** The " Standard ™ Q COVID-19 Ag Test " was better in subjects with delayed symptoms up to 5 days. However, this kit was not suitable for COVID-19 detection in asymptomatic subjects.

Introduction

The "Severe Acute Respiratory Syndrome corona-virus type 2" (SARS-CoV-2), belongs to the *Coronaviridae* family (subtype *Coronavirinae* and genus *βetacoronavirus*). It is the causative agent of the 2019 coronavirus disease (COVID-19), which quickly spread worldwide causing huge loss of human life [1,2], hence the name "enemy of humanity" given by the World Health Organization (WHO) [3]. This single-stranded, positive-sense, RNA-enveloped virus emerged in Wuhan, Hubei Province, China, in December 2019 and can be transmitted by aerosol droplets, direct and indirect contact [4,5].

Biological diagnosis has played a crucial role in the management of the COVID-19 pandemic.

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* *Corresponding author:* Abdou Azaque Zoure
E-mail address: zabdouazaque@yahoo.fr

Several diagnostic tests have been used for this purpose. Samples for the initial diagnosis of Covid-19 are nasopharyngeal and/or oropharyngeal and lower respiratory tract (sputum) in case of parenchymal involvement and blood [6, 7].

Today, three methods are most used for COVID-19 diagnosis: nucleic acid amplification tests (NAATs), Enzyme linked immunosorbent assay (ELISA) and rapid detection tests (RDT) [8, 9]. However, many other nucleic acid-based techniques, such as loop-mediated isothermal amplification (LAMP) is well implanted and used in routine practice and CRISPR (clustered regularly interspaced short palindromic repeats), is promising option [9,10]. The reference test for biological diagnosis remai.ns the reverse transcriptase polymerase chain reaction (RT-PCR), specific for the detection of the SARS-CoV-2 genome [7]. RT-PCR assays generally target one or more of the following genes: open reading frame1a/b (ORF1a/b), ORF1b-nuclear shuttle protein14 (ORF1b-nsp14) RNA-dependent RNA polymerase (RdRp), envelope (E), spike (S), or nucleocapsid (N) [11]. However, RT-PCR tests are costly, longer (4-8 hours) and require specific equipment, and qualified staff. This delay is also inappropriate in the health care setting where patients with characteristic symptoms must be rapidly diagnosed and treated according to their pathology [12]. Thus, many rapid antigen kits for SARS-CoV-2 detection have been developed and are available on the market. Most of them are lateral flow immunochromatographic tests and the results can be obtained without specialized instruments and interpreted usually within 30 minutes [13]. However, most of these tests have poor performance [14-16]. Nevertheless, antigen tests are recommended to be used in areas where access to the PCR method is limited, as is the case in Burkina Faso [8]. For all deseases and in this context of the COVID-19 pandemic, tests with good sensitivity and specificity are best suited for effective diagnosis. Indeed,WHO recommended the use of some antigen test after their evaluation [13]. Therefore, evaluation of antigenic tests is recommended [17]. To respond to this need, this study aims to contribute to the assessment the performance of the rapid antigen test "Standard™ Q Covid-19 Ag Rapid Test" (SD Biosensor, Gyeonggi-do, South Korea) in SARS-CoV-2 diagnosis.

Material and Methods

Type, period of study

This study was an evaluation of the "Standard ™ Q COVID-19 Ag Test" performed between January 26 and March 31, 2021. The study took place at the Kossodo Medical Center with Surgical Branch (CMA) in Ouagadougou.

Study population

The study population consisted of males or females of any age who were clinically suspected (symptomatic) or not of COVID-19 and who freely consented to participate in the study. A subject suspected for COVID-19 was defined as presenting an acute onset of fever AND cough OR an acute onset of THREE OR MORE of the following symptoms: fever, cough, general weakness/fatigue, headache, muscle pain, sore throat, runny nose, difficulty breathing, lack of appetite/nausea/vomiting, loss of smell, diarrhea, mental disturbance; AND/OR severe acute respiratory infection (SARI): with a history of fever (T°≥ 38°C) and cough; occurring within the last 7 days; and requiring hospitalization [18].

Were excluded in this study (i) subjects with active nose bleeds, or with facial injuries/trauma or a condition that creates a mechanical barrier to safely obtaining samples; (ii) subject enrolled in a clinical trial; (iii) subjects with nasopharyngeal specimens collected within the last 24 hours of enrollment, and (iv) subjects with nasopharyngeal specimens collected more than 2 hours after enrollment.

Recruitment of attendees and sampling method

Participants were recruited by the providers (an investigator, a sampling agent and a laboratory technician) at the COVID-19 screening site at the CMA Kossodo. They actively searched for signs of COVID-19 in accordance with the national guidelines for the COVID-19 response in Burkina Faso [18]. Two nasopharyngeal swabs were collected on viral transport medium (VTM) tubes from each participant: one for the "Standard TM Q COVID-19 Ag Test" on site, an the other one for SARS-CoV2 RT-PCR in the laboratory. A total of 201 patients were enrolled in the study.

Realization of the tests

Test under evaluation: Standard ™ Q COVID-19 Ag Test. The “Standard ™ Q COVID-19 Ag Test” is an immunochromatographic test in the form of a cassette containing a lateral flow test strip, and can be stored at 2°C to 30°C. It is *in vitro* rapid

diagnostic test for the qualitative detection of SARS-CoV-2 antigen (Ag) in human nasopharyngeal swab specimens from individuals meeting the clinical and/or epidemiological criteria for COVID-19. and the result is obtained in 15-30 mn. The test is intended for use in patients with clinical symptoms of SARS-CoV-2 infection. The test has two pre-coated lines, the "C" line (control line) and the "T" line (test line) on the surface of the nitrocellulose membrane. Swab samples were tested immediately in the health facility after collection. External controls (positive and negative) were tested with a "Standard ™ Q COVID-19 Ag Test" when a new kit was opened, prior to starting the tests. Standard ™ Q COVID-19 Ag Test was used according to the manufacturer's instructions.

The results of the evaluation of the "Standard ™ Q COVID-19 Ag Test" were presented according to several situations: (i) the first one according to the use of the "Standard ™ Q COVID-19 Ag Test" at any time independently of the symptoms, (ii) the second one taking into account the symptoms and the time of their appearance within the framework of a diagnosis of the suspected COVID-19 cases, and (iii) the third one in asymptomatic subjects of COVID-19.

Reference test: RT-PCR of SARS-COV-2 in the laboratory

SARS-CoV2 RNA extraction was performed using the "QIAamp Viral RNA Mini kit (Qiagen)" and amplification was done with the "STANDARD M nCoV Real-Time Detection kit (SD BIOSENSOR, Inc.) in the thermal cycler "QuantStudioS5 (Applied Biosystems)" according to the manufacturer's instructions. This RT-PCR kit detects SARS-CoV2 RNA in human oropharyngeal/nasopharyngeal and throat swab samples. It targets the ORF1ab gene detected by the FAM fluorochrome, E gene by the JOE/VIC/HEX fluorochrome, and used an internal control (IC) detected by CY5 fluorochrome. The kit uses dUTP and UNG enzymes to avoid contamination of the amplification products.

Interpretation of RT-PCR results positive or negative was done according to the manufacturer's instructions. The presence of SARS-CoV-2 RNA reflects an ongoing COVID-19 infection. ORF1ab gene (FAM): Ct≤36 "SARS-CoV-2 ORF1ab (RdRp) gene positive"; E gene (JOE/VIC/HEX): Ct≤36 "SARS-CoV-2 E gene positive" and IC (CY5): Ct≤26 "Internal control positive".

Origin of the tests

The "Standard ™ Q COVID-19 Ag Test" kit under evaluation, as well as the reference RT-PCR test used in this study were provided by the Ministry of Health of Burkina Faso.

Data processing and analysis

Data were entered into Excel and analyzed using OpenEpi software ((http://www.openepi.com). The results obtained with the "Standard ™ Q COVID-19 Ag Test" were compared with those of the RT-PCR test, and the main performance characteristics of the "Standard ™ Q COVID-19 Ag Test" were determined. For this purpose, the results were classified into 2 categories (positive or negative results). Compared to the known results of the RT-PCR method, the results of the Standard ™ Q COVID-19 Ag Test were classified as true positive (TP), false positive (FP) and false negative (FN) on a double entry contingency table. The sensitivity of the test was calculated according to the formula (VP)/(VP+FN) and the diagnostic specificity according to the formula (VN)/(VN+FP). In addition to the two main characteristics (Sensitivity and Specificity) of the diagnostic performance of the test, other test-specific parameters such as positive predictive value (PPV) and negative predictive value (NPV): PPV = VP/VP+FP and NPV=VN/VN+FN); the positive (RV+) and negative (RV-) likelihood ratios; and the Kappa Coefficient of agreement between the "Standard ™ Q COVID-19 Ag Test" and the RT-PCR test. These characteristics were calculated with their 95% confidence intervals. The results of these calculations were expressed as a percentage. The Kappa coefficient of agreement was interpreted according to the criteria of Landis and Koch (1977) [19] as follows: Kappa <0, no agreement; 0 < kappa≤ 0.2 = slight agreement; 0.2< kappa < 0.4 = moderate agreement; 0.4 <kappa≤ 0.6; moderate agreement; 0.6<kappa≤0.8 = substantial agreement; 0.8<kappa≤1, near perfect agreement.

Results

Socio-demographic characteristics of attendees

The majority of attendes were male (54.72%). The mean age of the participants was 34.5 ±10 years with extremes from 9 to 81 years. According to clinical status, asymptomatic participants were the most represented (75.11%)., compared to 24.39% who had symptoms. Of the 49 participants with symptoms, those with a symptom onset time of 1 to 7 days were in the majority (60.61%) followed by

those with a symptom onset time of 1 to 5 days (40.82%). In addition, only 16.33% of the symptomatic participants had a symptom onset time of more than 7 days, compared to 12.24% symptomatic participants whose symptom onset time was unknown. Of the 201 individuals (symptomatic or not) tested by both RT-PCR and the Standard ™ Q COVID-19 Ag Test, 16 were positive for COVID-19 RT-PCR and 185 were negative **(Table 1).**

Performance of the Standard ™ Q COVID-19 Ag Test

Compared to the reference test, the "Standard™ Q COVID-19 Ag Test" recorded TP=6 and FN=10 in all of 201 participants (symptomatic or asymptomatic). Thus, according to several scenarios, the results of the performance of "Standard ™ Q COVID-19 Ag Test" in comparison with RT-PCR, showed that its sensitivity was 100% (IC95% : 34.24- 100) in symptomatic subjects with a delay in the onset of symptoms from 1 to 5 days. This sensitivity decreased to 66.67% (CI95%: 20.77- 93.85) in symptomatic subjects with a symptom onset time of 1 to 7 days to 0.0% (CI95%: 0.0- 29.92) in asymptomatic COVID-19 subjects **(Table 2 , 4).**

Based on Ct (cycle threshold) values, and in general, in all participants (symptomatic and asymptomatic) the sensitivity was 66.67% (95% CI: 35.42- 87.94) for Ct values ≤ 33, compared with 0.0% (95% CI: 0.0- 35.43) when the Ct value was greater than 33 **(Table 3 , 5).**

Of 9 asymptomatic participants tested positive by RT-PCR, eight (8) returned negative to the "Standard™ Q COVID-19 Ag Test" (100%). Of the 16 of the participants with symptoms tested positive to the Standard™ Q COVID-19 Ag Test, 6 had a Ct value ≤ 33 and none had a Ct > 33, which is considered low contagious according to the literature [20,21].

As for specificity, it was 95% (CI95%: 83.5- 98.62) in symptomatic subjects and 94.44% (CI95%: 74.24- 99.01) and 93.75% (CI95%: 79.85- 98.27) in patients with a delay in onset of symptoms of 1 to 5 days and in patients with a delay in onset of symptoms of 1 to 7 days, respectively.

This specificity reached a value of 100% (CI95%: 97.4- 100) in asymptomatic subjects **(Table 2 , 4)**

Table 1. Socio-demographic characteristics of participants.

Features	Number	Percentage (%)
Age (n=201)		
≤ 25 years	38	18.90
>25 years	154	76.62
Not specified	9	4.48
		100.00
Gender (n=201)		
Male	110	54.72
Female	75	37.32
Unknown	16	7 .96
		100.00
RT-PCR results (n=201)		
Negative	185	92.04
Positive	16	7.96
		100.00
Clinical status (n=201)		
Asymptomatic	151	75.11
Symptomatic	49	24.39
Unknown	1	0.50
Date of onset of symptoms (n=49)		
1-5 days	20	40.82
1-7 days	15	60.61
> 7 days	8	16.33
Unknown	6	12.24
Set		100.00

Table 2. Results of the Standard ™ Q COVID-19 Ag Test according to the symptomatic or asymptomatic profile of participants.

Results of Standard ™ Q COVID-19 Ag Test on all subjects tested				
		RT-PCR		
		Positive	Negative	Total
Standard ™ Q COVID-19 Ag Test	Positive	6	3	9
	Negative	10	182	192
Total		16	185	201
Results of Standard ™ Q COVID-19 Ag Test in symptomatic subjects tested				
		RT-PCR		
		Positive	Negative	Total
Standard ™ Q COVID-19 Ag Test	Positive	2	2	4
	Negative	1	38	39
Total		3	40	43
Results of Standard ™ Q COVID-19 Ag Test in symptomatic subjects tested with a symptom onset time of 1 to 5 days				
		RT-PCR		
		Positive	Negative	Total
Standard ™ Q COVID-19 Ag Test	Positive	2	1	3
	Negative	0	17	17
Total		2	18	20
Standard ™ Q COVID-19 Ag Test results in symptomatic subjects tested with a symptom onset time of 1-7 days				
		RT-PCR		
		Positive	Negative	Total
Standard ™ Q COVID-19 Ag Test	Positive	2	2	4
	Negative	1	30	31
Total		3	32	35
Results of Standard ™ Q COVID-19 Ag Test in asymptomatic test subjects				
		RT-PCR		
		Positive	Negative	Total
Standard ™ Q COVID-19 Ag Test	Positive	0	0	0
	Negative	9	144	153
Total		9	144	153

*2 patients out of 9 had a Ct value <=33 (2/9 for Orf1ab and 1/9 for the E gene)

Table 3. Results of the Standard ™ Q COVID-19 Ag Test by RT-PCR Ct value and presence of symptoms.

Standard ™ Q COVID-19 Ag Test results by viral load (Ct value) independent of symptoms			
		RT-PCR Positive	
		Ct ≤ 33	Ct > 33
Standard ™ Q COVID-19 Ag Test	Positive	6	0
	Negative	3	7
Total		9	7

Table 4. Performance of the Standard ™ Q COVID-19 Ag Test versus RT-PCR.

	Set		**Symptomatic subjects**		**Onset of symptoms within 1 to 5 days**		**Symptoms started 1-7 days ago**		**Asymptomatic**	
PARAMETER	%	95%CI	%	95%CI	%	95%CI	%	95%CI	%	95%CI
Sensitivity	37.5	18.48-61.36	66.67	20.77-93.85	100	34.24-100	66.67	20.77-93.85	0.0	0.0-29.92
Specificity	98.38	95.34-99.45	95	83.5-98.62	94.44	74.24-99.01	93.75	79.85-98.27	100	97.4-100
Positive predictive value	66.67	35.42-87.94	50	15- 85	66.67	20.77-93.85	50	15- 85	-	-
Negative predictive value	94.79	90.68-97.15	97.44	86.82-99.55	100	81.57-100	96.77	83.81-99.43	94.12	(89.2-96.87[1])
Accuracy of diagnosis	93.53	89.25-96.18	93.02	81.39-97.6	95	76.39-99.11	91.43	77.62-97.04	94.12	(89.2-96.87[1])
Likelihood ratio of positive test	23.13	6.981 - 76.61	13.33	3.066 - 57.99	18	2.535 - 127.8	10.67	2.453 - 46.39	-	-
Likelihood ratio of negative test	0.6353	0.5221 - 0.773	0.3509	0.04929 - 2.498	0.0	-	0.3556	0.04987 - 2.535	1	-
Unweighted Cohen's kappa coefficient	0.4484	0.3164 - 0.5804	0.5343	0.239 - 0.8296	0.7727	0.3459 - 1.2	0.5249	0.1978 - 0.852	0.0	0.0 - 0.0

Table 5. Performance of the Standard ™ Q COVID-19 Ag Test versus RT-PCR by Ct value.

	Set			
	Ct ≤ 33		Ct >33	
PARAMETER	%	95%CI	%	95%CI
Sensitivity	66.67	35.42- 87.94	0.0	0.0- 35.43
Specificity				
Positive predictive value	100	60.97- 100	-	-
Negative predictive value				
Accuracy of diagnosis	66.67	35.42- 87.94	0.0	0.0- 35.43

Discussion

This study evaluated the performance of the "Standard™ Q COVID-19 Ag Test" in a healthcare setting to guide their use in local settings. The performance results showed an overall low sensitivity (37.5% (CI95%: 18.48- 61.36)) and high specificity (98.38% (CI95%: 95.34- 99.45)). In a previous study conducted under the same conditions (health care site, population with clinically suspected (symptomatic) of COVID-19) in Mozambique, the Standard™ Q COVID-19 Ag Test had low sensitivity and a high specificity of 45.0% (95% CI: 39.9-50.2%) and 97.6% (95% CI: 95.3-99.0%) respectively. A higher sensitivity of 49.4% was observed in symptomatic cases [22]. In Uganda, the sensitivity and specificity of the "Standard™ Q COVID-19 Ag Test" were even higher at 70.0% (95% CI: 60-79) and 92% (95% CI: 87-96), respectively. But, the authors concluded that the "Standard™ Q COVID-19 Ag Test" did not perform optimally in their evaluation. However, the test may have an important role in early infection when RT-PCR is not available [23]. In addition, in Thailand, results showed that this rapid antigen detection test

had a sensitivity of 47.97% (95% CI: 36.10-59.96%) and specificity of 99.71% (95% CI: 99.15-99.94%) compared with RT-PCR [24]. in Korea, the sensitivity and specificity of the "Standard™ Q COVID-19 Ag Test" were 89.2% (58/65) and 96.0% (96/100) respectively, making it suitable for diagnostic use [25].

Taking into account the symptoms, ours results showed that the sensitivity and specificity of the "Standard ™ Q COVID-19 Ag Test" were 66.67% (IC95%: 20.77- 93.85) and 95% (IC95%: 83.5- 98.62) respectively. Based on these results, the Standard™ Q COVID-19 Ag Test did not perform optimally in this evaluation. Despite their low overall sensitivity, rapid tests are useful for improving the accessibility of diagnosis of symptomatic SARS-CoV-2 infections during periods of high transmission. Nevertheless, in Mozambique a lower sensitivity of 49.4% was observed in symptomatic cases [22] compared to 72.8% (CI95% 62.4-81.3), and specificity of 99.4% (CI95% 99.0-99.7) in a meta-analysis [26].

In addition, other factors related to viral load may influence the performance of antigenic tests including the duration of infection and the Ct value. Thus, authors had stated that antigenic testing is of particular clinical value in suspected cases during the first 5-7 days of symptoms [8]. According to our results, the sensitivity and specificity were respectively 100% (IC95%: 34.24-100) and 94.44% (IC95%: 74.24- 99.01) in symptomatic subjects with a delay of onset of symptoms from 1 to 5 days. This sensitivity decreased to 66.67% (CI95%: 20.77-93.85) in symptomatic subjects with a symptom onset time of 1 to 7 days and to 0.0% (CI95%: 0.0-29.92) in asymptomatic subjects of COVID-19. In contrast, specificity increased from 93.75% (CI95%: 79.85-98.27) in patients with a symptom onset time of 1-7 days and reached a value of 100% (CI95%: 97.4-100) in asymptomatic subjects. Also, previous studies have shown that antigenic testing is very useful in detecting patients who are symptomatic, preferably for less than 7 days and ideally for less than 5 days, and whose SARS-COV-2 viral load in throat or nasopharyngeal swabs is peaking [27]. However, some authors revealed in their study that the rate of samples with Ct ≤28.67 that was false negative for the test decreased from 18.2% to 9.4%. [13]. Therefore, they had recommended the use of the "Standard™ Q COVID-19 Ag Test" for samples taken ≤7 days after symptom onset. The relationship between turnaround time and sensitivity should be considered [13]. In Serbia, the "Standard Q COVID-19 Ag test" showed a sensitivity of 58.1% (95% CI 42.1-73.0), but it was higher in the first days of the disease, when the highest viral loads were detected. In the first 5 days after symptom onset, sensitivity ranged from 66.7% to 100%, and pooled precision and Kappa values were high (0.92 and 0.852). High agreement between the performance of the "Standard™ Q COVID-19 Ag Test" was observed during the first five days of illness, suggesting that this rapid antigenic test may be very useful for the diagnosis of COVID-19 in the early phase of the disease [28]. Finally, a recent study showed reduced sensitivity from 83.9% to 76.3% when samples are obtained ≤5 and ≤7 days after the onset of symptoms, respectively [29].

According to our results, based on Ct values, in subjects with symptom onset time of 1-7 days, and RT-PCR positive for SARS-Cov-2 with a Ct value ≤ 33, showed that the sensitivity of the "Standard ™ Q COVID-19 Ag Test" was estimated to be 0.0% (CI95%: 0.0-35.43). Overall, in all participants (symptomatic and asymptomatic) the sensitivity was 66.67% (95% CI: 35.42- 87.94) for Ct values ≤ 33, compared with 0.0% (95% CI: 0.0-35.43) when the Ct value was > 33. Of 9 asymptomatic participants testing positive on RT-PCR, eight (9) returned negative on the "Standard™ Q COVID-19 Ag Test" (100%). Of the 16 symptom-independent participants who tested positive for the "Standard™ Q COVID-19 Ag Test", 6 had a Ct value ≤ 33 and none had a Ct > 33, considered low contagious according to the literature [20,21].

In Uganda, the diagnostic accuracy was 84% (95% CI: 79-88). The antigenic test was more likely to be positive in samples with qRT-PCR Ct values ≤29, reaching a sensitivity of 92% [23]. In Korea, analysis of results using RT-PCR cycle thresholds of ≤ 30 or ≤ 25 increased the sensitivity to 26.9% (95% CI, 13.7-46.1%), and 41.1% (95% CI, 21.6-64.0%), respectively of the Standard Q COVID-19 Ag test, which was not an optimal clinical test because of its low sensitivity [12]. In contrast, another study in the same country found that the "Standard Q COVID-19 Ag test" could be used as an alternative in high prevalence settings [25]. The sensitivity of the test was higher in samples with Ct≤30 and those collected one to five days after symptom onset. [25]. In Uganda, the antigen test was more likely to be positive in samples with qRT-PCR Ct values ≤29, reaching a

sensitivity of 92% . [23]. Other authors found that the "Standard ™ Q COVID-19 Ag Test" could be used as an aid to early diagnosis of SARS-CoV-2 infection in terms of analytical and clinical sensitivity although the prevalence of samples with Ct ≤28.67 decreased from 81.8% to 79.9% when samples were obtained ≤5 and ≤7 days after symptom onset respectively [13]. On the contrary, in a meta-analysis based on 25 studies, the "Standard™ Q COVID-19 Ag Test" had higher sensitivity on samples with high viral load (ie, Ct <25; 97.6%; 95%CI 94.1-99.0), compared with those with low viral load (Ct ≥25; 43.6%; 95% 27.6-61.1). Therefore, the widespread use of antigenic testing in place of RT-qPCR may be questionable, and its deployment as a mass screening test may result in an intolerable proportion of missed diagnoses [26]. Finally, according to a recent metanalysis, samples from symptomatic patients showed a higher sensitivity of 82% (95% CI: 82-82) compared with asymptomatic patients at 68% (95% CI: 65-71), whereas a cycle threshold (Ct) value ≤25 had shown a higher sensitivity of 96% (95% CI: 95-97) compared with a higher Ct value [30].

The Kappa agreement between the "Standard™ Q COVID-19 Ag Test" and the reference test RT-PCR was highly variable depending on the type of subject tested. The best concordances between the antigenic RDT and the RT-PCR were observed during the first 5 days of symptoms. Indeed, the concordance between antigenic RDT and RT-PCR is a "substantial concordance" (kappa=0.7727) in subjects with a delay of onset of symptoms between 1 and 5 days, and "moderate" in subjects with a delay of onset of symptoms between 1 and 7 days (kappa=0.5343). In asymptomatic subjects, there was no agreement between ("moderate" respectively (kappa=0.00)) antigenic RDT and RT-PCR). These results show that the use of the "Standard™ Q COVID-19 Ag Test" in asymptomatic subjects significantly reduces the diagnostic sensitivity of the test compared to RT-PCR.

Despite their low overall sensitivity, rapid tests are useful for improving the accessibility of diagnosis of symptomatic SARS-CoV-2 infections during periods of high transmission. A meta-analysis showed that the overall pooled sensitivity and specificity of COVID-19 antigen tests were 70% (95% CI: 69-71) and 98% (95% CI: 98-98), respectively. In subgroup analyses, nasal swabs had the highest sensitivity, 83% (95% CI: 80-86), followed by nasopharyngeal swabs 71% (95% CI: 70-72), throat swabs 69% (95% CI: 63-75), and saliva 68% (95% CI: 59-77). Although the sensitivity of antigenic testing needs to be improved, it may still be a viable option in locations where laboratory facilities are lacking for diagnostic purposes [30]. This "Standard™ Q COVID-19 Ag Test" is on the WHO emergency use list for in vitro diagnostics (IVD) detecting SARS-CoV-2 and may be useful in the above conditions [31].

Conclusion

The "Standard™ Q COVID-19 Ag Test" kit could be used for the detection of COVID-19 in subjects with a delay in the onset of symptoms of less than 07 days. Also, the results showed that the antigenic RDT was not suitable for the detection of COVID-19 in asymptomatic subjects such as travelers, nor in subjects with a delay in the onset of suspected symptoms for more than 7 days.

Limitations of the study

The limitations of this study could be the small number of positive cases, which would result in a widening of the confidence intervals of the different estimated parameters. Secondly, more than half of the samples were taken from asymptomatic individuals. Finally, overall, the distribution of patients may not reflect the general population in low-prevalence settings, and the results of the performance evaluation may vary considerably by patient group. Despite these difficulties and limitations, the study was able to provide useful information for assessing the performance of the test being evaluated that could guide its use in the local context in Burkina Faso.

Author contributions

AAZ: Data curation, Writing- Original draft preparation. **HGO**: Conceptualization, Methodology, Investigation. **STS**: Visualization, Software. **TRC**: Writing - review &editing , **SZ**: Writing - review &editing. **OO**: Writing - review &editing. **DK**: Writing - review &editing. **DZ**: Conceptualization, Methodology, Investigation. **CD**: Methodology, **AK**: Methodology, **CS**: Conceptualization, Methodology, Investigation. **ZY**:Conceptualization, Methodology, Investigation., **TS**: Methodology, Investigation, Writing - review &editing. **LS**: Conceptualization, Methodology, Investigation.

Ethical approval

This evaluation is a contribution to the improvement of COVID-19 diagnosis. All participants gave their free consent and all information was processed with strict respect for anonymity and confidentiality.

Disclosure of potential conflicts of interest

The authors report no conflicts of interest..

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