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Comparative Assessment of Diagnostic Performance of RT-PCR and Rapid Diagnostic Test (RDT) Kits for the Detection of SARS-CoV-2

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Abstract

COVID-19 is an infectious respiratory disease that is caused by the SARS-CoV-2 virus. The outcome of this pandemic stemmed the interest for the development and validation of rapid diagnostic tests. This study assessed the diagnostic performance of real time (RT)-PCR and rapid diagnostic test (RDT) kit for the detection of SARS-Cov2 in Respiratory Samples. A total of one hundred (100) suspected Covid-19 patients who visited Sagamu Health Zone in Ogun State were recruited for this study. Nasopharyngeal (NP) and oropharyngeal (OP) swabs were collected from the patients in a universal transport medium and then analysed using the RT-PCR. Blood samples were also collected from the patients and analysed using diagnostic kit for 2019-Novel Coronavirus 2019-nCoV Antibody test. Diagnostic performance was determined by comparing the results obtained by Rapid Diagnostic Test RDT to Real Time Polymerase Chain Reaction (RT-PCR.). The results of this study revealed that out of a total hundred (100) suspected cases of Covid-19 recruited, sixty four (64) were RT-PCR positive and thirty six (36) were RT-PCR negative. The mean age of the patients was 36.54±12.06 while the median age was 37.5 years. The overall sensitivity and specificity were 64.5% (CI 95%; 60.5–70.6) and 70.7% (CI 95%; 65.7–74.6) respectively with diagnostic accuracy of 61.4%. Female patients had higher cases of SARS-Cov2 (65.5%) with a sensitivity of 68.2% and specificity of 71.4% while male patients had lower cases (63.4%) with a sensitivity of 60.7% and specificity of 70.0%. The results of this study revealed that the antigen-based RDT showed low to moderate sensitivity and specificity in the samples obtained from the patients in contrast to the high sensitivity and specificity obtained from RT-PCR. This study revealed that RT-PCR is an important tool for the early detection and diagnosis of SARS-CoV-2 and hence should still remain the gold standard for diagnosis of SARS-CoV-2 in order to prevent misdiagnosis and further guide the clinicians effectively.

Keywords

Diagnostic Performance, Coronavirus, SARS-CoV-2, COVID-19, Rapid Diagnostic Test

1. Introduction

Coronavirus 2 (SARS-CoV-2) disease is a severe acute respiratory syndrome that was first reported at the end of 2019 (December 2019) in Wuhan, China and subsequently termed a global pandemic [1, 2]. The SARS-CoV-2 virus is responsible for the infectious respiratory disease called COVID-19 (Corona Virus Disease). The rapidly emerging SARS-CoV-2 pandemic has resulted in tremendous public health challenges all over the world and has played a pivotal role in causing pneumonia and upper/lower respiratory tract infections [3]. The symptoms of COVID-19 infection manifests after an incubation period of approximately 5.2 days where the most common symptoms are fever, cough, and fatigue, headache, sore throat, acute respiratory distress syndrome which could lead to respiratory failure [4].

Furthermore, the Chinese health authorities and the World Health Organization (WHO) officially announced the discovery of a novel coronavirus on January 9th, 2020 where it was first named 2019-nCoV and then officially termed SARS-CoV-2. This virus belongs to the family of coronavirus which is different from the viruses SARS-CoV and MERS-CoV responsible for SARS outbreak in 2003 and the ongoing outbreak that began in 2012 in the Middle East respectively [4]. The WHO has declared this outbreak a global health emergency at the end of January 2020 since its emergence in China and since then it has caused a large global outbreak resulting to a major worldwide public health issue. The large global outbreak was strongly manifested when the World Health Organization (WHO) announced that the total global deaths from COVID-19 have surpassed 100,000 on April 12th, 2020 [5]. Also, there was a global report on April 28th, 2020 that 2,892,688 cases of COVID-19 have been confirmed and 210,193 patients have died and about 1.7 billion people have been ordered to remain at home as governments take extreme measures to protect her citizens [5].

However, accurate, rapid and reliable diagnostic methods becomes pertinent considering the rapid spread and increasing number of COVID-19 cases caused by this new coronavirus SARS-CoV-2 as this will help to monitor infection rates and prevent the progression of the disease. There is need to also reduce the rates of transmission of infection to health care workers through early detection of SARS-CoV-2 which however forms the basis of comprehensive health care. The best methods that have been mostly employed to curtail the spread of this pandemic are timely detection and isolation of cases and their contacts [6]. Therefore, there is an urgent need for diagnostic procedures that are robust, rapid, and easy-to-perform and can test large numbers of samples within a short period of time [7].

In order to respond swiftly to the growing COVID-19 pandemic, Rapid Diagnostic Tests (RDTs) have been developed which is based on the detection of antibodies (Ig G and IgM) to SARS-CoV-2 virus. In January, 2020, the real-time reverse-transcription polymerase chain reaction (RT-PCR) was introduced as the standard recommended diagnostic method for SARS-CoV-2 infection (known as Covid-19) [8], and is currently applied using WHO or CDC protocols [9-11].

The large gap between the large number of patients/contacts and the laboratory capacities to perform RT-PCR in a timely manner is a major limitation of the current public health containment strategies [12]. Hence, there are stringent and concerted efforts in search of alternative assays such as antigen detection test which has the capacity to detect the presence of the virus itself in respiratory samples [12]. Therefore, tests detecting SARS-CoV-2-specific antigen have recently been developed and many of them are now commercially available [10].

Also, there are some uncertainties on the actual performance of these assays which makes the validation of such assays essential [13]. According to WHO, [12] and ECDC, [13], there are other serological tests that can be used but they are not well efficient for detecting early infections and as such are not recommended for case detection but pro-confirmation. In line with the above, rapid diagnostic tests (RDTs) should be made pivotal in detection considering the fact that they are timely, easy to perform, and can serve as point-of-care testing (POCT) [14].

Sequel to the aforementioned on the critical need for a rapid and easy to perform diagnostic assays, this study is therefore set to comparatively assess the diagnostic performance of Real Time (RT)-PCR and Rapid Diagnostic Test (RDT) kit for the detection of SARS-Cov2 in Respiratory and blood samples from suspected COVID-19 cases in Ogun State, Nigeria.

2. Materials and Methods

In this study we conducted analytical comparison of the diagnostic accuracy of a rapid SARS-CoV-2 antigen detection test compared to RT-PCR

2.1. Ethical Approval

The study was approved by the Head of Zone, Sagamu Health Zone in Ogun State, on July 23rd 2020 and informed consent was obtained from each patient after properly explaining the purpose of the study and confidentiality assured.

2.2. Study Population

The study population consisted of patients who visited the Ogun State Isolation Centre, General Hospital, Iperu-Remo, Ogun State from April 18th, 2020 to June 10th, 2020. This Isolation Centre receives patients whose symptoms, such as

headache, fatigue, fever or respiratory signs suggest a COVID infection, and for whom diagnosis and isolation is requested. The date of onset of symptoms and other information (age, gender, travel history) as declared by the patients and age were collected and recorded appropriately. Information that could not be made available by the patients was obtained from the compulsory national Covid-19 notification forms. Patients who are positive for RT-PCR were followed up immediately either by admission in the isolation centre or booked for medical appointment with the consultants.

2.3. Specimen Collection

Nasopharyngeal (NP) and oropharyngeal swab (OP) specimens were collected by trained Medical Laboratory Scientists in the isolation center within 3 days after the onset of the disease. For nasopharyngeal swab specimens, the specimen collection tube was labeled with a barcode. The swab was used to measure the length between apex nasal and the earlobe and marked with a finger. The swab was inserted into the nasal cavity in a direction perpendicular to the nose. The swab was inserted half of the length from the earlobe to the nasal apex. Swab stops were made in the nasal for 15-30 seconds and rotated gently between 3-5 times. The swab was immediately placed into specimen collection tube containing 2ml lysis buffer and sample storage reagent containing RNA enzyme inhibitor and then the swab rod near the top lighten blue cap was broken and sealed with sealing film. For oropharyngeal swab specimens, a sterile flocking swab was used to wipe the posterior pharyngeal wall while avoiding touching the tongue. The swab was placed in the collection tube and the swab rod near the top lighten blue cap was broken and sealed with sealing film.

2.4. Real-Time RT-PCR Assays for the Detection of SARS-CoV-2

RT-PCR testing of SARS-CoV-2 was performed in the Virology unit of General Hospital, Iperu-Remo, Ogun State. Samples were initially examined for SARS-CoV-2 by Novel Coronavirus (2019-nCov) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing) (Sansure Biotech, Hunan Province, China). Samples showing an exponential growth curve and a Ct value ≤40 were considered as positive. This assay included 2019-nCov-pCR negative and positive controls (internal controls) and used as a means of validating the test results. Amplification was performed on an ABI 7900 134 Sequence Detection System (Applied Biosystem). The amplification results of 2019-nCov-pCR positive was taken as the presence of a typical S-shape amplification curve with Ct values ≤40 while the negative results was taken as absence of a typical S-shape amplification curve with no Ct values or Ct values >40.

2.5. Rapid Diagnostic Tests (RDT) for the Detection of SARS-CoV-2

Both positive and negative RT-PCR samples were evaluated using the Diagnostic Kit for 2019-Novel Coronavirus 2019-nCoV Antibody Test (Colloidal Gold) (INNOVITA Tangshan Biological Technology Co., Ltd). This was used for the qualitative detection of IgM and IgG antibodies against 2019 Novel Coronavirus (2019-nCoV) in human venous whole blood specimen. The kit detects 2019-nCoV IgM and IgG antibodies by immuno-capture method. The nitrocellulose membrane is coated by mouse-anti human monoclonal IgM antibodies, mouse-anti human monoclonal IgG antibodies, and goat-anti-mouse IgG antibodies. The recombinant 2019-nCoV antigen and mouse IgG antibodies are labeled with colloidal gold as a tracer. After addition of the specimens, if 2019-nCoV IgM antibodies are present, the antibodies will bind to colloidal gold-coated 2019-nCoV antigens to form compounds, which are further captured by pre-coated mouse-anti human IgM antibodies to form new compounds, and generate purple line (T). If 2019-nCoV IgG antibodies are present in specimen, the antibodies will bind to colloidal gold-labeled 2019-nCoV antigens to form compounds and further form new compounds by binding to pre-coated mouse-anti human monoclonal IgG antibodies, which give rise to purple line (T). The binding of colloidal gold-labeled mouse IgG antibodies with goat-anti-mouse IgG antibodies will present purple line, which is used as the control line(C). The test, specimen diluents and the controls were allowed to get to room temperature of 30℃ (86 ℉) before testing. The testing device was removed from the sealed pouch and placed on a clean and level surface. 20μL of venous whole blood was added into each specimen well from the top of the specimen well while 80μL of specimen diluents was added into each specimen well from the bottom of the specimen well. The results were read within 15 minutes after the visible appearance of the coloured lines. The Medical Laboratory Scientists that performed this procedure was blinded to the results of RT-PCR and standard laboratory practice for handling all specimens was strictly adhered to [15].

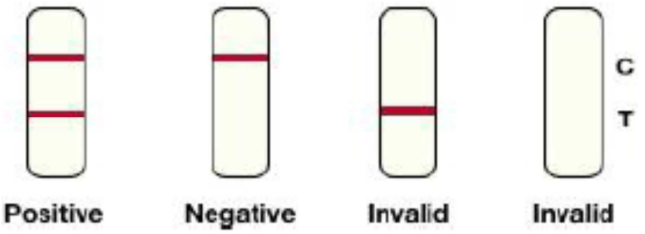

Figure 1. *Results interpretation for Rapid Diagnostic Tests.*

2.6. Statistical Analysis

The statistical analysis was done using statistical package for social sciences SPSS software (version 21). Socio demographic profile and prevalence were calculated using frequencies at 95% confidence intervals. Chi-square test was used to determine the significant differences in the prevalence of SARS-Cov2 as determined by RT-PCR and RDT in relation to gender and age. The sensitivity, specificity, diagnostic accuracy, predictive values, Diagnostic Likelihood Ratios (DLR) and Diagnostic Odd Ratios (DOR) were calculated to evaluate the diagnostic performance. RT-PCR was used as the reference standard and p-values less than 0.05 ($p<0.05$) were considered to be statistically significant.

3. Results

The results on demographic profile revealed that 71 (71.0%) were male patients while 29 (29.0%) were females. Majority of the patients were between 31-40 years (45.0%) and 41-50 years (22.0%). Among the negative cases, cough (33.3%) bitter taste (13.9%) and headache (13.9%) were the highest clinical symptoms reported. The positive patients reported more of sore throat and fever as compared to other symptoms such as cough, loss of smell and difficulty in breathing (Table 1).

The results on gender related prevalence of SARS-Cov2 using the RT-PCR at 48 and 96 hours included 71 males and 29 females and the results revealed that the prevalence of SARS-Cov2 were significantly higher ($p<0.05$) in female subjects (65.5%) as compared to the male subjects (63.4%) (Table 2).

The results on the prevalence of SARS-Cov2 as it relates to the age revealed that the prevalence of SARS-Cov2 were significantly higher ($p<0.05$) within the age range 51-60 years (87.7%) followed by 11-20 years (80.0%), 21-30 years (63.6%), 41-50 years (63.6%), 31-40 years (60.0%), 1-10 years (50.0%)and 61-70 years (33.3%) (Table 3).

The results on true positives/false positives and true negatives/false negatives values of RT-PCR and RDT methods in male and female SARS-Cov2 patients revealed that females had significant higher true positive values (68.2%) as compared to males (60.7%) while females (71.4%) had higher true negative values as compared to the males (70.0%) (Table 4).

The results on true positives/false positives and true negatives/false negatives values of RDT methods among age groups revealed that subjects within the age 21-30 years (100.0%) and 51-60 years (100.0%) had significant higher true positive values as compared to 11-20 years (75.0%), 31-40 years (92.3%) and 41-50 years (87.5%) (Table 5).

The result on the evaluation of diagnostic performance of RDT methods in male and female SARS-Cov2 patients revealed higher sensitivity in females (68.2%) than in males (60.7%) and low specificity in males (70.0%) as compared to and females (71.4%). The predictive values, likelihood ratios and diagnostic odd ratios were also presented (Table 6).

The result on the evaluation of diagnostic performance of RT-PCR and RDT methods of SARS-Cov2 patients with respect to age groups revealed higher sensitivity within 51-60 years (100.0%) and 21-30 years (100.0%) with low to moderate specificity in all age groups. The predictive values, likelihood ratios and diagnostic odd ratios were also presented (Table 7).

The results of time related diagnostic performance revealed higher sensitivity of RT-PCR within 48 hours (100.0%), 96 hours (100.0%), 192 hours (100.0%) and 240 hours (100.0%) of diagnostic testing while low sensitivity for RDT was recorded for 48 hours, 96 hours, 144 hours and 192 hours of diagnostic testing (Table 8)

Table 1. *Demographic and clinical features of the patients.*

Variables		Frequency	Percentages (%)
Gender (n=100)	Male	71	71.0
	Female	29	29.0
Age (years) (n=100)	1-10	2	2.0
	11-20	10	10.0
	21-30	11	11.0
	31-40	45	45.0
	41-50	22	22.0
	51-60	7	7.0
	61-70	3	3.0
Clinical features for negative cases (n=36)	Cough	12	33.3
	Bitter taste	5	13.9
	Body pain	3	8.3
	Sore throat	2	5.6
	Headache	5	13.9
	Fever	9	25.0
Clinical features for positive cases (n=64)	Cough	8	12.5
	Bitter taste	4	6.3
	Body pain	6	9.4
	Sore throat	15	23.4
	Headache	10	15.6
	Fever	12	18.8
	Difficulty in breathing	9	14.0

Table 2. *Gender related prevalence of SARS-Cov2 using the RT-PCR.*

Gender	Number Examined	Number Positive (%)	Number Negative (%)	χ^2 value	P value
Male	71	45 (63.4)	26 (36.6)		
Female	29	19 (65.5)	10 (43.5)		
Total	100	64 (64.0)	36 (36.0)	8.810	0.023

Chi-square (χ 2) showing significant association ($p<0.05$) between male and female prevalence

Table 3. *Age related prevalence of SARS-Cov2 using the RT-PCR.*

Age (years)	Number Examined	Number Positive (%)	Number Negative (%)	χ^2 value	P value
1-10	2	1 (50.0)	1 (50.0)		
11-20	10	8 (80.0)	2 (20.0)		
21-30	11	7 (63.6)	4 (36.4)		
31-40	45	27 (60.0)	18 (40.0)		
41-50	22	14 (63.6)	8 (36.4)		
51-60	7	6 (85.7)	1 (14.3)		
61-70	3	1 (33.3)	2 (66.7)		
Total	100	64 (64.0)	36 (36.0)	4.253	0.043

Chi-square (χ 2) showing significant association ($p<0.05$) within the age ranges of the subjects

Table 4. *True positives/false positives and true negatives/false negatives values of RDT in male and female SARS-Cov2 patients.*

Gender	True Positive (%)	False Positive (%)	True Negative (%)	False Negative (%)	Total
Male	37 (60.7)	24 (39.3)	7 (70.0)	3 (30.0)	71
Female	8 (68.9)	8 (40.0)	12 (60.0)	1 (11.1)	29
χ^2 value					6.552
P value					0.010

Chi-square (χ 2) showing significant association (p<0.05) in the diagnostic values

Table 5. *True positives/false positives and true negatives/false negatives values of RDT of SARS-Cov2 patients according to age.*

Age (years)	True Positive (%)	False Positive (%)	True Negative (%)	False Negative (%)	Total
1-10	(NC)	0 (0.0)	2 (100.0)	0 (0.0)	
11-20	3 (75.0)	1 (16.7)	5 (83.3)	1 (25.0)	
21-30	4 (100.0)	2 (28.6)	5 (71.4)	0 (0.0)	
31-40	12 (92.3)	17 (53.1)	15 (46.9)	1 (7.7)	
41-50	7 (87.5)	7 (50.0)	7 (50.0)	1 (12.5)	
51-60	3 (100.0)	1 (25.0)	3 (75.0)	0 (0.0)	
61-70	0 (0.0)	1 (50.0)	1 (100.0)	1 (50.0)	
χ^2 value					6.194
P value					0.013

Chi-square (χ 2) showing significant association (p<0.05) in the diagnostic values among age groups
NC: Not computed since there was no value was recorded for true positive

Table 6. *Evaluation of Diagnostic Performance of RDT in male and female SARS-Cov2 patients.*

Diagnostic Parameters	Male (n=71)	Female (n=29)	P value
Sensitivity	60.7	68.2	0.010
Specificity	70.0	71.4	0.120
Positive predictive value	65.8	67.5	0.150
Negative predictive value	82.8	88.2	0.009
Positive diagnostic likelihood ratio	1.50	1.48	
Negative diagnostic likelihood ratio	0.29	0.29	
Diagnostic odd ratio	5.2	5.3	

P value<0.05- Significant; P value>0.05- Not Significant

Table 7. *Evaluation of Diagnostic Performance of RDT in SARS-Cov2 patients according to age.*

Diagnostic Parameters	1-10 (n=2)	11-20 (n=10)	21-30 (n=11)	31-40 (n=45)	41-50 (n=22)	51-60 (n=7)	61-70 (n=3)	P value
Sensitivity	NC	75.0	100.0	92.3	87.5	100.0	0.0	0.747
Specificity	50.0	61.7	68.6	66.9	50.0	50.0	50.0	0.237
Positive predictive value	NC	37.5	44.4	41.4	50.0	50.0	0.0	0.382
Negative predictive value	100.0	50.0	100.0	93.8	87.5	100.0	50.0	0.167
Positive diagnostic likelihood ratio	NC	0.9	1.4	1.7	1.8	1.3	0.0	
Negative diagnostic likelihood ratio	NC	1.5	0.0	0.2	0.3	0.0	0.0	
Diagnostic odd ratio	NC	0.6	0.6	10.6	7.0	0.5	2.0	

P value<0.05- Significant; P value>0.05- Not Significant
NC: Not computed since there was no value was recorded for the age group.

Table 8. *Time related diagnostic performance of RT-PCR and RDT methods.*

Time (hours)	Number Examined	Sensitivity RT-PCR (%)	Sensitivity RDT (%)	χ^2 value	P value
48	100	100	68.8		
96	100	100	64.9		
144	68	83.3	52.6		
192	38	100	68.9		
240	18	100	50.0		
288	8	50	33.3		
336	NC	NC	NC		
384	NC	NC	NC	3.336	0.058

P value<0.05- Significant; P value>0.05- Not Significant.
NC: Not computed since there was no value recorded for the time.

4. Discussion

This real-life study was aimed at assessing the diagnostic performance of real time (RT)-PCR and rapid diagnostic test (RDT) kit for the detection of SARS-Cov2 in respiratory Samples. The diagnostic performance in this study was carried out in one hundred (100) patients. Considering the challenging nature of diagnosis for SARS-Cov2, rapid detection techniques such as the novel SARS-CoV-2 antigen test kit have been developed following the increasing nature of this pandemic in recent times.

The results revealed sensitivity of 68.2% in females and 60.7% in males. Also, specificity of 71.4% was reported in females and 70.0% in males. It was also observed that sensitivities of 75.0%, 100.0%, 92.3%, 87.5% and 100.0% was recorded for 11-20 years, 21-30 years, 31-40 years, 41-50 years and 51-60 years respectively. Female SARS-Cov2 patients had significant higher true positive values (68.2%) as compared to males (60.7%). Patients within the age 21-30 years (100.0%) and 51-60 years (100.0%) had significant higher true positive values as compared to 11-20 years (75.0%), 31-40 years (92.3%) and 41-50 years (87.5%). Higher sensitivity for RT-PCR was observed within 48 hours (100.0%), 96 hours (100.0%), 192 hours (100.0%) and 240 hours (100.0%) of diagnostic testing while low sensitivity was recorded for RDT. This is in agreement with the results of Liu *et al*., [16] where they carried out a retrospective study in 179 patients with SARS-CoV-2. They however reported the sensitivities of 18.8% and 100% accompanied with cases of false positive results. In another study, sensitivities of 11.1%, 92.9% and 96.8% were reported for patients with onset of the SARS-CoV-2 at the early, intermediated and late stages respectively [17]. In a study carried out by Prazuck *et al.*, [5] using COVID-DUO RDT, they reported sensitivity ranges between 35.71% and 100% in patients who had experienced first symptom from 0 to 5 days and more than 15 days respectively. However, they also reported sensitivities between 69.23% and 100% for patient who experienced symptoms from 11-15 days and more than 15 days respectively using COVID- PRESTO RDT.

The sensitivity and specificity as reported by Lorena *et al.,* [23] using RDT were 93.9% (CI95% 86.5–97.4) and 100% (CI95% 92.1–100), respectively. The reported higher sensitivity and specificity is higher than the results obtained from this study. Also, in a study carried out by Chen *et al*., [24] for the evaluation of nucleocapsid antigen in the early stages of infection of SARS-CoV reported a high sensitivity of 94.0%. According to Diao *et al.*, [18], they reported preprint information on a sensitivity value of 68% of RT-PCR positive nasopharyngeal swabs from patients from the Hubei province in China.

Furthermore, the results revealed that the sensitivity of RT-PCR increased after 48 hours (2days), 96 hours (4days), 192 (8days) hours and 240hours (10days) of testing while that of RDT presented low sensitivities at the different testing time of diagnostic testing. However, this could be attributed to different methods employed in handling the samples coupled with inaccurate and precise reporting of the symptoms. The lower sensitivity observed in this study as compared to the results from China may also be due to the fact that most samples from this study were not obtained from the first week of onset of the symptoms and quarantine considering the difficulty in contact tracing and reporting of COVID-19 cases. The high sensitivity obtained during the early stages (between 0-10 days) for RT-PCR could be a pointer to develop timely RDT diagnostic protocols and algorithms which is essential for developing nations with low health resources coupled with the prevalence of other diseases.

There were some limitations in this study and which the first included the inability to test and follow up all the patients with symptom from the 48 hours (2days) to 384 hours (16 days). This however resulted in insufficient samples at this period and hence no basis for further comparison. The Laboratory Scientists being continuously exposed coupled with the stress and fatigue experienced during sample collection and testing could affect data collection and diagnostic performance. Also, this study was carried out during the rainy season in Nigeria when there are low chances of having other respiratory symptoms; it is possible that the antigen-based RDT kits could perform differently in different epidemiological outbreak and situations.

This study recorded high values of false positive result and this reveals moderate diagnostic performance of the tests. According to Laferi *et al*., [19] and Grobusch *et al*., [20], there are a number of factors that could be responsible for the false positive but the involvement of IgG with IgM in recent products has contributed significantly in avoiding this problem. The low sensitivity recorded among the patients is attributed to the high rate of false negative test results. However, it is pertinent to note that exposure of RDT kit to high temperatures could result to poor diagnostic performance in the tropics [21], which is the case for this study.

Furthermore, the study revealed a positive predictive value of 65.8% for males and 67.5% in females. This therefore connotes that the proportion of test reported as positive were actually true and sensitive. In the vein, negative predictive values of 82.8% and 88.2% were reported for males and females respectively. This supports the fact that the proportion of test reported as negative were actually negative and specific for all negative results reported. The results also recorded a high positive diagnostic likelihood ratio in both males and females and within the age range of 31-40 years and 41-50 years. This could be as a result of low false positive results within the groups. The RDT showed a high percentage of good likelihood of presenting a positive test in both males and females and this is couple with the high positive diagnostic and low negative diagnostic likelihood ratios. Based on this, it may suffice to say that detection of SARS-Cov2 would be more apt if RDT is developed to serve as a useful diagnostic tool that will help reduce testing time and severity of disease associated with prolonged diagnosis. Also, the diagnostic odd ratios were seen to be high in both

male and female patients and within the age range of 31-40 years. This is a pointer to good diagnostic test performance within the groups [22].

5. Conclusion

The results of this study revealed that the antigen-based RDT showed low to moderate sensitivity and specificity in the samples obtained from the patients in contrast to the high sensitivity and specificity obtained from RT-PCR. The results also showed that RT-PCR had a high sensitivity at 48 hours (2days), 96 hours (4days), 192 (8 days) hours and 240 hours (10 days) while RDT had low sensitivity between those hours of diagnostic testing. Therefore, this study revealed that RT-PCR is an important tool for the early detection and diagnosis of SARS-CoV-2 and hence should still remain the gold standard for diagnosis of SARS-CoV-2 in order to prevent misdiagnosis and further guide the clinicians effectively.

Conflict of Interest

The authors declare no conflicts of interest. The authors alone are responsible for the content and the writing of the paper.

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Authors' Contributions

Omisakin Ibukun Akinsola, Ajayi Folake Olubunmi, Bisiriyu Adeniyi Hakeem, Animasaun Olawale Sunday and Salako Risquat Oluremi conceptualized the laboratory work, Iyevhobu Kenneth Oshiokhayamhe and Obodo Basil Nnaemeka designed and wrote the manuscript; Omolumen Lucky Eromosele, Uhomoibhi Oserefuamen Trinitas, Usoro Edidiong Raphael, Okobi Tobechukwu Joseph and Ogundare Stephen Olusegun conducted experiments while Festus Oloruntoba Okojie, Amaechi Rose Akubueziuka and Turay Ahmadu Adjin provided scientific guidance.

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