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SARS-COV-2 Rapid Antigen Test in Comparison with RT-PCR for Laboratory Diagnosis of COVID-19 in a Southwest State of Nigeria

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Abstract

Objectives: Rapid and accurate identification of persons infected with SARS-CoV-2 which causes COVID-19 is key to managing the pandemic. The urgent need to scale up access to COVID-19 testing in Nigeria has led to the government's introduction of the use of COVID-19 Ag rapid diagnostic test (RDT) across various settings in the country. However, field performance evaluation of the rapid SARS-CoV-2 antigen detection test is required to be conducted periodically and compared with the gold standard real-time reverse transcription-polymerase chain reaction (RT-PCR) test for diagnosis of COVID-19 cases. **Design:** A prospective COVID-19 screening and un-blinded verification of the performance of the STANDARD Q COVID-19 Ag test kit. **Setting:** The rapid SARS-CoV-2 antigen detection test, Standard™ Q COVID-19 Ag kit was compared with the RT-PCR test for detection of SARS-CoV-2 in nasopharyngeal samples for COVID-19 screening from persons and personnel attending a national youth camp orientation exercise during the second wave of the COVID-19 outbreak (January to March 2021) in Ondo state, southwest Nigeria. **Participants:** Three hundred fifty-one persons and personnel were screened for COVID-19 infection. **Results**: Of 351 respondents screened, 68 (19.4%) were positive, and 264 (75.2%) were negative for both COVID-19 Ag RDT and RT-PCR assay. The rapid SARS-CoV-2 antigen detection test's sensitivity and specificity were 78.16% (95% CI = 68.02% - 86.31%) and 100.0% (95% CI = 98.61% - 100.0%), respectively and the diagnostic accuracy was

94.59% (95% CI: 92 - 97). Respondents that were symptomatic had a higher test sensitivity of 78.6% (49.2 - 95.3) compared to those without symptoms 78.1% (66.9 - 86.9) ($p < 0.05$). **Conclusions:** Our study shows evidence that Standard™ Q COVID-19 Ag kit can be an appropriate rapid antigen test that could be used to screen for positive COVID-19 tests to guide decision-making for clinical management of persons infected with COVID-19, especially for closed settings and other clinical care settings.

Keywords

SARS-CoV-2, COVID-19 Rapid Antigen, RT-PCR, Sensitivity, Nigeria

1. Introduction

Coronavirus disease-2019 (COVID-19) is an infectious disease caused by a newly discovered coronavirus called Severe Acute Respiratory Coronavirus 2 (SARS-CoV2) [1]. The SARS-CoV2 belongs to a family of viruses that cause illness with various symptoms such as pneumonia, fever, breathing difficulty and lung infections [2].

The Coronavirus disease 2019 (COVID-19) pandemic has spread worldwide since its first recorded case in December 2019 [3]. Since the report of the index case in Nigeria in February 2020 by the Nigeria Center for Disease Control (NCDC), daily records of confirmed cases have been reported in several states in the country, including Ondo State. As of 28th August 2020, a total of 53,477 cases and 1011 deaths have been reported in Nigeria, while Ondo state ranked 11th among the states with a high number of confirmed cases in the country [4].

The Federal Ministry of Health through the Nigeria Centre for Disease Control (NCDC) has prioritized testing as one of the key strategies for the COVID-19 response in Nigeria. To contain the outbreak, the Government of Nigeria plans to rapidly scale-up diagnostic testing to cover all states and cities in Nigeria (NCDC scaling up laboratory testing) [5].

As the Coronavirus disease 2019 (COVID-19) pandemic continues to spread across the states and cities in Nigeria, there is an urgent need for rapid, simple, and accurate tests to diagnose severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection [3] [6]. In September 2020, the World Health Organization (WHO) announced the emergency use authorization of two Antigen (Ag)-based rapid diagnostic tests (RDTs) kits namely SD Biosensor and Abbott for COVID-19 testing based on available data on both RDTs showing their ability to correctly identify individuals with the disease (sensitivity > 80%) and to accurately identify those who do not have the disease (specificity > 97%) [5] [7].

Rapid identification of infected subjects is a cornerstone for controlling a pandemic like the COVID-19 pandemic [8] [9]. Easy-to-handle antigen tests can easily be performed and provide timely results, which is of particular importance in primary care and outside the laboratory settings. [6]. However, concerns exist

regarding the sensitivity of these rapid diagnostic testing kits. Hence, the study evaluated the performance of the SARS-CoV-2 Ag-RDT compared with the real-time PCR for SARS-CoV-2 for COVID-19 screening at an orientation camp in a southwest state of Nigeria.

2. Methods

2.1. Study Area

Nigeria is the most populous country in Africa, with an estimated population of over 160 million and a growth rate of 3.8% per annum [10]. Nigeria has six regional zones with varying ecologies, climates and population characteristics. The zones are divided into 36 states and the federal capital territory, which is further divided into 774 LGAs or districts and 8812 administrative wards [11]. Ondo state is one of the 36 states in the Federal Republic of Nigeria situated between longitudes 4˚15'E and 6˚00'E of the Greenwich meridian and latitudes 5˚45'N and 7˚45'N, which are to the North of the equator, in the Southwestern geopolitical zone of the country [12].

The state has 18 LGAs with three senatorial districts; Ondo North, Central and South and a 2021 projected total population of about 5,361,003 based on the 2006 population census. The climate of the areas is highly favored for agrarian activities and crops such as cocoa, kola nut, palm tree and arable crops like maize and tubers such as yam and cassava are grown annually [13]. The annual rainfall is between 1000 mm and 1500 mm with a high daily temperature of about 30˚C. Most of the population consists of peasant farmers cultivating food and cash crops at a small-scale level. Hunters and livestock keeping is also the major occupation of the population of Ondo state. Other economic activities in the state include trading and civil service [14]. The state has about 800 primary health facilities, 18 general hospitals, 6 tertiary health facilities and several private health facilities located across all LGAs in the state [14].

2.2. Study Setting and Participants

The study was conducted in an orientation camp for youth corps members from all parts of the country who were screened for COVID-19 before being admitted into a 3-week orientation exercise for mobilization for their one-year mandatory national youth service scheme in Ondo state, southwest Nigeria [15] [16]. The screening follows the national guideline on National Youth Service Corps (NYSC) Orientation Camp activities (NCDC guideline on NYSC). This is to facilitate the safe conduct of the NYSC orientation camp activities in all NYSC camps across the country during the COVID-19 pandemic [16]. The guideline mandates all corps members and camp officials to be tested for COVID-19 on arrival at the orientation camp [16].

2.3. Sampling Technique

A systematic sampling technique was used in the selection of 351 respondents

for the study from 3510 participants during 2 consecutive orientation camp exercises in January 2021 and March 2021 respectively. The sampling fraction/interval was calculated by dividing the total population of the participants (3510) for the two consecutive orientation camps by the sample size (351) giving an interval of 10, we randomly selected the fifth individual arriving at the NYSC camp by balloting and screened using RDT and RT-PCR simultaneously. Subsequently, one in every ten of the individuals arriving at the camp was selected using the sampling interval and were screened using RDT and RT-PCR simultaneously.

2.4. Sample and Data Collection Procedures

Two Nasopharyngeal respiratory swabs were collected per participant at the same time point from each nostril: one for RT-PCR testing and one for rapid antigen testing.

The specimens were collected from each client at the nasal cavity by sterile polyester flocked swabs stuck into a sterile 3 mL virus preservation solution, Viral (Universal) transport media V(U)TM. [6] While the sample for Ag-RDT was tested within the camp, that for the RT-PCR was transported on an ice pack to the designated national reference laboratory located within the state.

2.5. COVID-19 Antigen RDT Testing

The COVID-19 A-RDT screening was conducted using Standard™ Q COVID-19 Ag kit (SD Biosensor®, Republic of Korea). In Nigeria, Standard™ Q COVID-19 Ag kit (SD Biosensor®, Republic of Korea) is one of the two WHO emergency-approved Ag-RDTs recommended by the Federal Ministry of Health through the Nigeria Center for Disease Control for use in the country. It uses a conventional lateral flow format with colloidal gold or other visible dye as indicators. The indicators are used to enhance sensitivity and specificity but require a device to read and interpret the test results.

Assays were done at room temperature in a temporary mobile laboratory within the camp. The screening and interpretation of results were carried out according to the manufacturer's instructions for use (IFU). The sample was diluted in a sample inactivation medium and transferred to a test device. Where SARS-CoV-2 antigen was present above a threshold concentration, a visible line appeared in the test area and control of the test device (cassette kit) within 15 - 30 minutes.

2.6. Polymerase Chain Reaction (PCR) Screening

Samples for RT-PCR were transported to designated reference laboratories in the national COVID-19 network operating within the state for testing. Upon the arrival of samples in the laboratory, the information about the sample and the patient was entered into the laboratory database with a sample identification code generated for sample tracking. The testing protocol begins with the inactivation of each sample, typically a nasopharyngeal swab in the same tube of viral

transport medium, in a biosafety cabinet using an external lysis buffer reagent, which accompanies the commercial RNA extraction kit. The sample was then moved to the RNA extraction room where RNA was extracted manually using an RNA isolation kit (Shanghai ZJ Biotech, Shanghai, China). Five microlitres (μL) of the extracted RNA were then added to 20 μL of the prepared master mix (composed of 19 μL supermix and 1 μL enzyme mix) in the reaction tube [16]. Polymerase chain reaction amplification was achieved using a novel coronavirus real-time multiplex reverse transcription-PCR kit (Liferiver, Shanghai ZJ Biotech, Shanghai, China) on a magnetic induction cycler real-time Dx48 PCR instrument (Biomolecular Systems, Upper Coomera, Queensland, Australia). Results were interpreted based on the detection of the envelope (E), nucleocapsid (N) and open reading frame 1ab (ORF1ab) genes. For a test to be considered positive, at least two of these genes, which must include the ORF1ab, must have been detected at the recommended cycle threshold (Ct) of less than 41 [17].

Due to the open nature of the test platform, we were able to use other commercial RNA extraction and detection kits, for instance, DAAN Gene (Da An Gene Co. Limited of Sun Yat-sen University, Guangzhou, China) was used when the Liferiver kit (Liferiver, Shanghai ZJ Biotech, Shanghai, China) was not available [17].

2.7. Data Management and Analysis

Descriptive statistics were used to describe the demographic and key clinical characteristics of the study population. A comparison of the RT-PCR and Ag-RDT results was conducted by characteristics of participants, and test period using Fisher's Exact test. All statistical tests were considered significant at a 95% confidence interval with a p-value less than 0.05. The primary outcome variable in this study was the detection rates of SARS-CoV-2 antigen by means of rapid diagnostic tests performed on nasopharyngeal swabs obtained from the upper airways. Secondary outcomes were related to local validation of the RDT kit with PCR testing.

Sensitivity

The sensitivity was calculated as the number of specimens identified as positive by the STANDARD Q COVID-19 Ag test divided by the number of specimens identified as positive by the RT-PCR reference assay and expressed as a percentage [18].

Specificity

The specificity was calculated as the number of specimens identified as negative by the STANDARD Q COVID-19 Ag test divided by the number of specimens identified as negative by the RT-PCR reference assay and expressed as a percentage [18].

Accuracy

The accuracy was calculated as the proportion of STANDARD Q COVID-19 Ag test results that agreed with the RT-PCR results (positive and negative) and

expressed as a percentage [18].

The sensitivity, specificity, and accuracy calculations were performed using the online statistical tool "medcalc's diagnostic test evaluation calculator" [19] which also generated the 95% confidence intervals (CIs) while the sociodemographic and clinical data of the respondents were analyzed using SPSS, version 20.0

2.8. Ethical Clearance and Participants' Informed Consent

The study was conducted as part of an outbreak control investigation hence ethical approval was obtained from the Ondo State Health Research Ethics Committee of the Ondo State Ministry of Health, Akure, Nigeria with protocol number OSHREC14/12/21/409. Also, Informed consent was obtained from the respondents. They were made to understand that participation is voluntary and there was no consequence for non-participation. All information obtained was kept confidential. Participants' confidentiality was respected and maintained by ensuring that no unauthorized person has access to the information on the laboratory test reports. Also, we ensure that information of each participant cannot be traced to them (as a coding system was used for the data analysis sheet instead of writing these participants' names on them), and unauthorized use of information was strictly prohibited and monitored during the research process by the principal investigator and co-investigators.

3. Results

3.1. Socio-Demographic Characteristics of COVID-19 Cases

A total of 351 respondents aged 20 years and above were screened for SARS-CoV-2, with a mean age of 28.2 ± 6.5 years. Slightly about two-thirds (211; 60.1%) of the participants were males, and 184 (52.4%) were from the Yoruba Ethnic group (Table 1). A majority (295; 84.0%) of the respondents were National Youth Service Corps (NYSC) members, while 56 (16.0%) were Camp officials at the orientation camp. Slightly above half (207; 59.0%) of the tests were conducted in January while 144 (41.0%) were conducted in March 2021.

Table 2 shows the clinical characteristics and outcomes of the Ag-RDT and PCR test results of the participants. Seventy-three (73; 20.8%) of the participants were symptomatic, with 48 (65.8%) and 33 (45.2) presenting with headache and tiredness respectively. Of the total of 351 COVID-19 samples tested using Ag-RDT, 68 (19.4) were positive, while 87 (24.8) were positive using real-time PCR. The sensitivity and specificity of the SARS-CoV-2 antigen detecting RDT compared to the RNA detection by RT-PCR assay to identify COVID-19 were 78.16% (95% CI = 68.02% - 86.31%) and 100.0% (95% CI = 98.61% - 100.0%) respectively (Table 3) and the diagnostic accuracy was 94.59% (95% CI: 92 - 97).

3.2. RT-PCR and Ag-RDT Results by Characteristics, Period of Test and Symptomatic Status of Respondents

Table 4 below shows the sensitivity, specificity and negative predicted value by

Table 1. Socio-demographic characteristics of respondents (n = 351).

Variables	Frequency	Percentage (%)
Gender		
Male	211	60.1
Female	140	39.9
Age group		
20 - 29	282	80.3
30 - 39	43	12.3
≥40	26	7.4
Ethnicity		
Yoruba	158	45.0
Igbo	118	33.6
Hausa	49	14.0
Others*	26	7.4
Occupation		
Camp official	56	16.0
NYSC members	295	84.0
Period of test		
January	207	59.0
March	144	41.0

*Others include other ethnic groups in Nigeria.

Table 2. Clinical characteristics of respondents (n = 351).

Variables	Yes n (%)	No n (%)
Symptom status		
Symptomatic	73 (20.8)	278 (79.2)
Types of symptoms (multiple responses allowed) (n = 73)		
Headache	48 (65.8)	25 (34.2)
Tiredness	33 (45.2)	40 (54.8)
Runny nose	25 (34.2)	48 (65.8)
Diarrhea	23 (31.5)	50 (68.5)
Fever	22 (30.1)	51 (69.9)
Sore throat	11 (15.1)	62 (84.9)
Cough	13 (17.8)	60 (82.2)
Vomiting	12 (16.4)	61 (83.6)
Red eyes	9 (12.3)	64 (87.7)
Loss of smell	13 (17.8)	60 (82.2)
Results	**Positive**	**Negative**
PCR result	87 (24.8)	264 (75.2)
Ag-RDT result	68 (19.4)	283 (80.6)

Table 3. The sensitivity and specificity of the COVID-19 Ag-RDT.

	PCR test results		
	Positive	**Negative**	**Total**
Ag-RDT results			
Positive	68	0	68
Negative	19	264	283
Sensitivity	78.16% (95% CI = 68.02% - 86.31%)		
Specificity	100.0% (95% CI = 98.61% - 100.0%)		
PPV	100.0%		
NPV	94.59% (95% CI = 90.33% - 95.39%)		

Table 4. RT-PCR and Ag-RDT results by characteristics, period of test and symptomatic status of respondents.

	True positive n (%)	False negative n (%)	False positive n (%)	True negative n (%)	Sensitivity (95% CI)	Specificity (95% CI)	NPV	Total	*p*-value
Age group in years									
20 - 29	53 (100.0)	11 (4.8)	0 (0.0)	218 (95.2)	82.8 (71.3 - 100.0)	100 (98.3 - 100.0	95.2 (95.1 - 97.1	282	<0.001
30 - 39	8 (100.0)	5 (14.3)	0 (0.0)	30 (85.7)	61.5 (31.6 - 86.1)	100 (88.4 - 100.0)	85.7 (75.1 - 92.3)	43	<0.001*
≥40	7 (100.0)	3 (15.8)	0 (0.0)	16 (84.2)	70.0 (34.8 - 93.3)	100.0 (79.4 - 100.0)	84.2 (67.4 - 93.2	26	<0.001*
Gender									
Male	49 (100.0)	11 (94.7)	0 (0.0)	151 (93.2)	81.7 (69.6 - 90.5)	100.0 (97.6 - 100.0)	93.2 (88.9 - 95.9)	211	<0.001
Female	19 (100.0)	8 (6.6)	0 (0.0)	113 (93.4)	70.4 (49.8 - 86.3)	100.0 (96.8 - 100.0)	93.4 (88.8 - 96.2)	140	<0.001
Period of test									
January, 2021	37 (100.0)	14 (8.2)	0 (0.0)	156 (91.8)	72.6 (58.3 - 84.1)	100.0 (97.78 - 100.00)	98.80 (97.7 - 100.0)	207	<0.001*
March, 2021	31 (100.0)	5 (4.4)	0 (0.0)	107 (85.6)	86.1 (70.5 - 95.3)	100.0 (96.6 - 100.0)	95.5 (90.5- 97.9	144	<0.001*
Symptomatic									
Yes	11 (100.0)	3 (4.8)	0 (0.0)	59 (95.2)	78.6 (49.2 - 95.3)	100.0 (93.9 - 100.0)	95.2 (87.8 - 98.2)	73	0.002*
No	57 (100.0%)	16 (7.2)	0 (0.0)	205 (92.8)	78.1 (66.9 - 86.9)	100.0 (98.2 - 100.00)	92.8 (89.3 - 95.2)	278	<0.001*

*Fisher's Exact Test.

age, gender, period of test and symptomatic status of respondents. Significantly, the sensitivity of the tests was highest among those 20 - 29 years [82.8% (71.3 - 100.0)] compared to 30 - 39 years [61.5% (31.6 - 86.1)] and ≥40 years [(70.0% (34.8 - 93.3)] ($p < 0.005$). Similarly, higher test sensitivity was found among the males [81.7% (69.6 - 90.5) compared to the females [70.4% (49.8 - 86.3)]. The test sensitivity increased with the months of the year, with 86.1% sensitivity (70.5 - 95.3) found in March compared to 72.6% (58.3 - 84.1) in January 2021 ($p < 0.005$). Respondents that were symptomatic had a higher test sensitivity (78.6%; 49.2 - 95.3) compared to those without symptoms (78.1% (66.9 - 86.9) ($p < 0.001$).

4. Discussion

Our study recorded more males as respondents than females. This is consistent with the study in a similar setting by Arinze [20] titled "entrepreneurship education on entrepreneurial intention of fresh graduates: A study of NYSC orientation camp, Umunya" who reported 67.9% of respondents were males. This finding is also in consonance with the study of Odega and Mofolorunsho [15] where more males were reported than females in their study in the NYSC orientation camp in Delta state southern Nigeria. Although this phenomenon cannot be readily explained, as it is dependent on the unbiased deployment process by the federal government system of graduates from higher learning institutions for mandatory one-year national service exercise.

Also, most of the respondents in this study were below 30 years of age. This is consistent with the federal government of Nigeria's NYSC deployment policy where graduates who graduated at less than 30 years of age from polytechnics or universities either in Nigeria or outside Nigeria are deployed for the NYSC scheme [15] [21]. Furthermore, most of the respondents in this study were corps members than the NYSC camp officials. This can be attributed to the fact that the deployed NYSC members were more than the NYSC camp officials during NYSC orientation camp exercises [15].

The sensitivity and specificity of the Standard Q COVID-19 Ag test for rapid detection of SARS-CoV-2 antigen in our study revealed a moderate sensitivity (78.16%) and good Specificity (100%). Previous studies have documented and reported a much higher sensitivity and specificity for COVID-19 Ag RDT. For Panbio, other studies have reported sensitivity ranging from 73.3% - 91.7% with specificity in the range of 94.9% - 100% [22] [23] [24] [25]. Notably, the highest reported sensitivity of 91.7%/98.9% was reported by Alemany *et al.* [22]. Chaimayo *et al.* [3] in a similar study in Thailand using Standard™ Q COVID-19 Ag kit (SD Biosensor®, Republic of Korea) showed a higher sensitivity of 98.33% and a specificity of 98.73%.

Similarly, the manufacturer of Standard™ Q COVID-19 Ag kit (SD Biosensor®, Republic of Korea) has reported a sensitivity and specificity of 84.38% (95% CI, 67.21% - 94.72%) and 100.00% (95% CI, 97.85% - 100%), respectively (total n = 202; positive n = 32; negative n = 170). The manufacturer evaluated the sensitivity of the kit at a trial site in Malaysia using 32 RT-PCR-positive nasopharyngeal swabs from symptomatic patients. The specificity of this test was evaluated by the R&D team of SD Biosensor using 170 RT-PCR-negative samples. The monoclonal antibody specific to SARS-CoV-2 N antigen coated on the Standard Q COVID-19 Ag test was produced from the WUHAN-01 strain, which is genetically closely related to the SARS-CoV-2 strains detected in Thailand [3] [26] [27].

However, some studies where SD Biosensor COVID-19 Ag RDT was validated have reported lower sensitivity than our study. Treggiari *et al.* [28] in their study titled "SARS-CoV-2 rapid antigen test in comparison to RT-PCR targeting dif-

ferent genes: a real-life evaluation among unselected patients in a regional hospital of Italy" reported a sensitivity of 66.82% and specificity of 99.89%.

The lower sensitivity recorded in our study compared to previous studies such as Chaimayo *et al.* [3] might be attributed to the use of a mixed population of symptomatic and asymptomatic persons as study participants, with the asymptomatic participants representing more than three-quarters of the study participants in our study. This is consistent with the previous studies reporting an overall sensitivity within the range of 60% - 70% in heterogeneous patients [28] [29] [30]. This could also be due to other factors such as the sample quality, sample handling and processing techniques.

Also, the sensitivity increased significantly with the time of testing in our study. Other possible explanations could be linked to different testing time, as the test could have been performed either at the early or late phase of infection. Because infection of SARS-CoV-2 occurs in a large proportion of the population with the asymptomatic presentation, precautions should be observed when interpreting the results of the Ag-RDT test in these subjects. Conversely, we found a high specificity (100%), demonstrating a low occurrence of false-positive outcomes of the antigen test. Similar specificity was also reported by other authors [28] [31]. Diagnostic accuracy measures of a test are strictly dependent on the prevalence of the disease. For our study, the calculated NPV was 94.59% and PPV was 100% respectively. This could be due to the fact the study was conducted during the second wave of the COVID-19 outbreak in Nigeria within which a high number of confirmed COVID-19 cases and deaths were recorded daily in the country. However, there is a need to interpret Ag-RDT results with caution especially in low prevalence settings, due to the possibility of false-positive result outcomes.

Also, our study showed that age and sex were significantly associated with the antigen test performance, a finding that requires further investigation.

Strengths and Limitations of the Study

A preliminary search revealed this is the first field evaluation of antigen RDTs for the COVID-19 screening test in Nigeria Also, the selection of participants was random irrespective of their health status whether they were symptomatic or asymptomatic resulting in understanding the performance of the rapid test kit among these different groups and generalization of the findings.

The limitation of our study includes two swabs taken from each subject, with one from each nostril. One was tested immediately with the antigen RDT and the other was placed in a transport medium for subsequent RT-PCR testing at a national reference laboratory. Thus, the two swabs could be regarded as two different samples from the same participant.

Also, the storage and transportation of the samples to the reference laboratory could have influenced the outcome of the results as on some occasions the samples were batched for at most a day or two before being transported to the labor-

atory.

Furthermore, the collection of swab samples was done by different scientists with varying background training which may have introduced variability into the content or yield of swab material, however, minimal training on sample collection was provided to the research team prior to implementation of the study.

However, the findings from the study will boost the confidence of healthcare practitioners in implementing the use of antigen RDTs for the COVID-19 screening test in Nigeria.

5. Conclusion

Our study shows evidence that Standard™ Q COVID-19 Ag kit (SD Biosensor®, Republic of Korea) showed comparable sensitivity and specificity with real-time RT-PCR assay and can be an appropriate rapid antigen test that could be used to screen for positive tests and reduce the laboratory turnaround time for the tests conducted to guide rapid decision-making for clinical management of persons infected with COVID-19 for especially in closed settings and other clinical care settings.

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Author's Contributions

Elvis Efe Isere and Matthew Temitope Oluwole conceived the study. Elvis Efe Isere, Matthew Temitope Oluwole and Moses Adewale Adejugbagbe conceived the statistical analysis plan. Elvis Efe Isere, Matthew Temitope Oluwole, Moses Adewale Adejugbagbe, Temitope Olajumoke Omoju, Oluwatosin Oni, Ikeoluwapo Ajayi, Nosa Eniye Omorogbe, Stephen Fagbemi and Tolulope Aderonke Fagbemi contributed to the statistical analysis, interpretation of the results and writing of the first draft of the manuscript. All authors reviewed and approved the final manuscript for publication.

Data Availability Statement

Data are available on reasonable request.

Ethics Approval and Consent to Participate

The study was conducted as part of an outbreak investigation and control hence ethical approval was obtained from the Ondo state Health Research Ethics Committee with protocol number OSHREC14/12/21/409. Also, Informed consent was obtained from the respondents. They were made to understand that participation is voluntary and there was no consequence for non-participation.

All information obtained was kept confidential.

Conflicts of Interest

The authors declare that no conflicts of interest exist in this work.

References

[1] World Health Organization (2020, January 12) Novel Coronavirus—China. https://www.who.int/emergencies/diseases/novel-coronavirus-2019

[2] Adhikari, S., Meng, S., Wu, Y.J., Mao, Y., Ye, R., Wang, Q., *et al.* (2020) Epidemiology, Causes, Clinical Manifestation and Diagnosis, Prevention and Control of Coronavirus Disease (COVID-19) during the Early Outbreak Period: A Scoping Review. *Infectious Diseases of Poverty*, **9**, Article No. 29. https://doi.org/10.1186/s40249-020-00646-x

[3] Chaimayo, C., Kaewnaphan, B., Tanlieng, N., Athipanyasilp, N., Sirijatuphat, R., Chayakulkeeree, M., Angkasekwinai, N., *et al.* (2020) Rapid SARS-CoV-2 Antigen Detection Assay in Comparison with Real-Time RT-PCR Assay for Laboratory Diagnosis of COVID-19 in Thailand. *Virology Journal*, **17**, Article No. 177. https://doi.org/10.1186/s12985-020-01452-5

[4] Isere, E.E., Adejugbagbe, A.M., Fagbemi, A.T., Fagbemi S., Famokun A.D., Omoju T.O., *et al.* (2021) Outcome of Epidemiological Investigation of COVID-19 Outbreak in a Southwest State of Nigeria, March to August 2020. *Open Journal of Epidemiology*, **11**, 163-177. https://doi.org/10.4236/ojepi.2021.112015

[5] Nigeria Center for Disease Control (NCDC) Guideline for the Use of Approved COVID-19 Ag RDTs in Nigeria for 2021. https://covid19.ncdc.gov.ng/media/files/Guidance_for_the_use_of_approved_COVID-19_Ag_RDTs_in_Nigeria.pdf

[6] de Campos-Stairiker, K., Pidathala, A.S., Gill, R.K., Gelimson, I., Varankovich, N., Gill, S.S., *et al.* (2021) Validation of Microchip RT-PCR COVID-19 Detection System. *Journal of Biosciences and Medicines*, **9**, 8-24. https://doi.org/10.4236/jbm.2021.99002

[7] Brummer, L.E., Katzenschlager, S., Gaeddert, M., Erdmann, C., Schmitz, S., Bota, M., *et al.* (2021) Accuracy of Novel Antigen Rapid Diagnostics for SARS-CoV-2: A Living Systematic Review and Meta-Analysis. *PLOS Medicine*, **18**, e1003735. https://doi.org/10.1371/journal.pmed.1003735

[8] Thommes, L., Burkert, F.R., Öttl, K.W., Goldin, D., Loacker, L., Lanser, L., *et al.* (2021) Comparative Evaluation of Four SARS-CoV-2 Antigen Tests in Hospitalized Patients. *International Journal of Infectious Diseases*, **105**, 144-146. https://doi.org/10.1016/j.ijid.2021.02.052

[9] Landaas, E.T., Storm, M.L., Tollånes, M.C., Barlinn, R., Bakken Kran, A.B., Bragstad, K., *et al.* (2021) Diagnostic Performance of a SARS-CoV-2 Rapid Antigen Test in a Large, Norwegian Cohort. *Journal of Clinical Virology*, **137**, Article ID: 104789. https://doi.org/10.1016/j.jcv.2021.104789

[10] National Population Commission (NPC) [Nigeria] and ICF International (2014) Nigeria Demographic and Health Survey 2013. NPC and ICF International, Abuja and Rockville, 1-2.

[11] Igbalajobi, O., Fatuase, A.I. and Ajibefun, I. (2013) Determinants of Poverty Incidence among Rural Farmers in Ondo State, Nigeria. *American Journal of Rural Development*, **1**, 131-137.

[12] National Population Commission. The Nigeria Population Census, 2006. https://nigeria.opendataforafrica.org/ifpbxbd/state-population-2006

[13] Amos, T.T. (2007) An Analysis of Productivity and Technical Efficiency of Smallholder Cocoa Farmers in Nigeria. *Journal of Social Sciences*, **15**, 127-133. https://doi.org/10.1080/09718923.2007.11892573

[14] Otu, A., Ebenso, B., Okuzu, O. and Osifo-Dawodu, E. (2016) Using a mHealth Tutorial Application to Change Knowledge and Attitude of Frontline Health Workers to Ebola Virus Disease in Nigeria: A Before-and-After Study. *Human Resources for Health*, **14**, Article No. 5. https://doi.org/10.1186/s12960-016-0100-4

[15] NCDC Guideline on 2020 National Youth Corp Orientation Camp Activities. https://covid19.ncdc.gov.ng/media/files/Guidelines_on_2020_National_Youth_Service_Corps_NYSC_Orientation_Camp_activities.pdf

[16] Odega, C.C. and Mofolorunsho, K.C. (2020) Prevalence of Ailments in a Youth Camp in Southern Nigeria. *Central African Journal of Public Health*, **6**, 346-350. https://doi.org/10.11648/j.cajph.20200606.15

[17] Osaigbovo, I.I., Igbarumah, I.O., Muoebonam, E.B. and Obaseki, D.E. (2021) Setting up a Molecular Diagnostic Laboratory for SARS-CoV-2 Testing: Experience of a Single Centre in a Resource-Constrained Setting. *African Journal of Laboratory Medicine*, **10**, Article No. 1326. https://doi.org/10.4102/ajlm.v10i1.1326

[18] Nalumansia,, A., Lutaloa, T., John Kayiwaa, J., Wateraa, C., Balinandia, S., Kiconcoa, J., *et al.* (2021) Field Evaluation of the Performance of a SARS-CoV-2 Antigen Rapid Diagnostic Test in Uganda Using Nasopharyngeal Samples. *International Journal of Infectious Diseases*, **104**, 282-286. https://doi.org/10.1016/j.ijid.2020.10.073

[19] Schoonjans, F. (2020) MedCalc's Diagnostic Test Evaluation Calculator. MedCalc. MedCalc Software. https://www.medcalc.org/calc/diagnostictest.php

[20] Arinze, S.A. (2019) Entrepreneurship Education on Entrepreneurial Intention of Fresh Graduates: A Study of NYSC Orientation Camp, Umunya. *IJAAS*, **5**, 1-10.

[21] Maori, L., Jimoh, A., Shittu, A.N., Raji, A.A., Eigege, E, Anaryu, J.J., *et al.* (2017) Prevalence of Malaria Parasite among NYSC Corps Members, Staff, Military and Paramilitary Who Reported at NYSC Orientation Camp Amada in Gombe State. *Greener Journal of Epidemiology and Public Health*, **5**, 6-10. https://doi.org/10.15580/GJEPH.2017.2.031317035

[22] Alemany, A., Baro, B., Ouchi, D., Rodó, P., Ubals, M., Corbacho-Monné, M., *et al.* (2021) Analytical and Clinical Performance of the Panbio COVID-19 Antigen-Detecting Rapid Diagnostic Test. *Journal of Infection*, **82**, 186-230. https://doi.org/10.1016/j.jinf.2020.12.033

[23] Albert, E., Torres, I., Bueno, F., Huntley, D., Molla, E., Fernández-Fuentes, M.A., *et al.* (2020) Field Evaluation of a Rapid Antigen Test (PanbioTM COVID-19 Ag Rapid Test Device) for COVID-19 Diagnosis in Primary Healthcare Centres. *Clinical Microbiology and Infection*, **27**, 472.e7-472.e10. https://doi.org/10.1101/2020.10.16.20213850

[24] Linares, M., Perez-Tanoira, R., Carrero, A., Romanyk, J., Pérez-García, F., Gómez-Herruz P., *et al.* (2020) Panbio Antigen Rapid Test Is Reliable to Diagnose SARS-CoV-2 Infection in the First 7 Days after the Onset of Symptoms. *Journal of Clinical Virology*, **133**, Article ID: 104659. https://doi.org/10.1016/j.jcv.2020.104659

[25] Fenollar, F., Bouam, A., Ballouche, M., Fuster, L., Prudent, E., Colson, P., *et al.* (2020) Evaluation of the Panbio Covid-19 Rapid Antigen Detection Test Device for the Screening of Patients with Covid-19. *Journal of Clinical Microbiology*, **59**, e02589-20. https://doi.org/10.1128/JCM.02589-20

[26] Tang, X., Wu, C., Li, X., Song, Y., Yao, X., Wu, X., *et al.* (2020) On the Origin and Continuing Evolution of SARS-CoV-2. *National Science Review*, **7**, 1012-1023. https://doi.org/10.1093/nsr/nwaa036

[27] Ceraolo, C. and Giorgi, F.M. (2020) Genomic Variance of the 2019-nCoV Coronavirus. *Journal of Medical Virology*, **92**, 522-528. https://doi.org/10.1002/jmv.25700

[28] Treggiari, D., Piubelli, C., Caldrer, S., Mistretta, M., Ragusa, A., Orza, P., *et al.* (2021) SARS-CoV-2 Rapid Antigen Test in Comparison to RT-PCR Targeting Different Genes: A Real-Life Evaluation among Unselected Patients in a Regional Hospital of Italy. *Journal of Medical Virology*, **94**, 1190-1195. https://doi.org/10.1002/jmv.27378

[29] Bulilete, O., Lorente, P., Leiva, A., Carandell, E., Oliver, A., Rojo, E., *et al.* (2020) Evaluation of the Panbio™ Rapid Antigen Test for SARS-CoV-2 in Primary Health Care Centers and Test Sites. https://doi.org/10.1101/2020.11.13.20231316

[30] Masiá, M., Fernández-González, M., Sánchez. M., Carvajal, M., García, J.A., Gonzalo-Jiménez, N., *et al.* (2021) Nasopharyngeal Panbio COVID-19 Antigen Performed at Point-of-Care Has a High Sensitivity in Symptomatic and Asymptomatic Patients with Higher Risk for Transmission and Older Age. *Open Forum Infectious Diseases*, **8**, ofab059. https://doi.org/10.1093/ofid/ofab059

[31] Dinnes, J., Deeks, J.J., Adriano, A., Berhane, S., Davenport, C., Dittrich, S., *et al.* (2020) Rapid, Point-of-Care Antigen and Molecular-Based Tests for Diagnosis of SARS-CoV-2 Infection. *Cochrane Database of Systematic Reviews*, **8**, CD013705. https://doi.org/10.1002/14651858.CD013705