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Evaluating the Diagnostic Performance of Covid-19 Serological Assays with Sars-Cov-2 in a Healthcare Setting in Federal Capital Territory Abuja, Nigeria

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Abstract

Covid-19 is one of the most lethal infections, causing a global pandemic. An alternative serological test was developed in response to the increased demand for Covid 19 diagnosis. This study compared the diagnostic performance of Saytul and Global Access to the gold standard (Sars-COV-2) in Abuja, Nigeria. The diagnostic performance of Covid-19 serological assays was determined in a cross-sectional study (Saytul and Global access). All three tertiary health facilities in the FCT, as well as the Zankli Research Center, were purposefully chosen as Covid-19 referral laboratories, and all of the institutions selected provide medical student training. Quota sampling was used in the study. The data was analyzed using SPSS version 23.0, with statistical significance set at p<0.005. Eight hundred and six respondents participated in the study. Most of the respondents (71%) were age 16-30 years. The positivity rate is higher SarCov2 compared to Saytul and Global Access. Saytul shows a sensitivity of 47.2% and specificity of 98.0% while Global access shows a sensitivity of 43.8% and specificity of 98.0%. There was a statistically significant difference in the results between SarCOV2 PCR and Saytul (p=0.001) and Global Access (p=0.001). We discovered that the serological tests have low sensitivity but high specificity. Low sensitivity has implications for missing cases, which could lead to further infection spread. With improved technology and understanding of the virus, highly accurate and effective tests to help prevent coronavirus infection can be made available.

Keywords: *Serological test, Covid 19, Sensitivity, Specificity.*

Introduction

Late 2019 saw the emergence of coronavirus disease 2019 (Covid-19), one of the deadliest infections which was first discovered in Wuhan, China and later declared a pandemic following its alarming severity and spread across the world [1-3]. Known to be very contagious, infected persons present mainly with respiratory symptoms, but the disease may affect other parts of the body. Most infected people develop mild symptoms with a few having severe symptoms which has caused death of

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millions of people globally since its onset [4, 5].

The symptoms of Covid-19 include fever, cough, tiredness, loss of taste or smell. sore throat, headache, aches and pains, diarrhoea, a rash on the skin, or discolouration of fingers or toes and red or irritated eyes [6-8]. In severe cases SARS-CoV-2 infection leads to severe pneumonia, organ failure and even death. The coronavirus family has α CoV and βCoV, genera as the species that infect mammals [9]. Currently, seven members of the coronavirus family are pathogenic to human beings. Three are highly pathogenic coronaviruses (SARS-CoV, MERS-CoV, and SARS-CoV-2), the other four human coronaviruses (HCoV-229E, HCoV-OC43 [10], HCoV-NL63, and HCoV-HKU1) usually cause mild-to-moderate upper respiratory diseases in people [11].

Definitive diagnosis is by the reverse transcription polymerase chain reaction (RT-PCR) test where the viral gene is detected, and this test has been recognized as the gold standard for detecting Covid 19. With several measures put in place to contain the pandemic, the place of increased testing cannot be overemphasized [12]. The increased demand for tests and diagnosis necessitated development of alternative tests to detect Covid-19 many of which got Emergency Use Authorization (EUA) [13]. Among the tests used are the antigen based rapid diagnostic tests (Ag RDTs) and host antibody detection rapid diagnostic tests [14]. These tests can be used in screening people without symptoms of Covid-19 which is important in efforts to control the disease. Many antigen-based and antibody-based tests are available for use under the EUA [15, 16], however, caution is recommended in their use, so that people will not to be wrongly categorized after a test [15]. Therefore, their use is recommended mainly in research setting but may be used in a population after validation in such population and settings. This necessitated validation of two RDTs in Abuja, Nigeria where their use has been widespread owing to the unavailability, cost, and delay in getting results associated with RT-PCR.

This study therefore aimed to determine the diagnostic performance of Saytul and Global Access and compare their performance with the gold standard (Sars-COV) in Federal Capital Territory (FCT) Abuja, Nigeria.

Methods

Study Settings and Area

This was a cross-sectional study carried out from September 2021 to December 2021 in Federal Capital Territory. Federal capital territory (FCT), being the seat of the government of an emerging national economy, experiences an influx of people from diverse backgrounds. The estimated total population is 5,338,550 with a landmass of 1769 km^2. It has 6 Area Councils (AC) and 62 political wards [17].

FCT operates a 3-tier health system, comprising of primary, secondary, and tertiary levels of care that spread over rural and urban areas. There are 254 public health facilities which are disaggregated into 237 primary health facilities, 14 secondary health facilities, and 3 tertiary hospitals. The three tertiary hospitals are owned and funded by the Federal Government og Nigeria, while the FCT's Hospitals Management Board (HMB) manages the secondary facilities, and its Primary Health Care Board (PHCB) manages the PHC facilities. The private health facilities consist of hospitals, maternity homes, faith-based hospitals and clinics, diagnostic centers, and pharmacies. The private sector provides healthcare for a substantial proportion of the population [18].

Study Design

A cross-sectional study to evaluate the diagnostic performance of Covid-19

serological assays (Saytul and Global access). The tests are rapid chromatographic immunoassays for qualitative detection of specific SARS-Cov-2 antigens present in human nasal cavity.

Sample Size and Sampling Technique

The minimum sample size was calculated using the formula for a cross-sectional study. The confidence interval was placed at a 95%, and power of 80% using prevalence from a similar previous study. Sample collected was well above the estimated sample size to increase the power of the study [19].

All the three tertiary health facilities in FCT, Abuja and Zankli Research Center was selected purposively being one of the Covid-19 referral laboratory and all the selected institutions provide training for medical students. A purposive sampling techniques was utilized to recruit symptomatic and asymptomatic individuals in the study.

The study population consisted of individuals with symptom(s) of Covid-19, attending health facilities and residing in the FCT for at least six months who consented for the study. The asymptomatic participants were people attending the health facilities who reported no symptom(s) of Covid 19 were recruited. Those who declined consent for the study were excluded.

Sample Collection and Analysis

A semi- structure questionnaire adapted from a study done in Nigeria was used to obtained data. Sample was collected from individual with symptoms of suspected Covid-19 (fever, cough, tiredness, loss of taste or smell. sore throat, headache, aches and pains, diarrhoea, a rash on skin, or discolouration of fingers or toes and red or irritated eyes) for symptomatic individuals [14, 20]. Those without the symptoms were classified as asymptomatic.

PCR Assay: we used three types of automatic extractors to obtain viral RNA from clinical samples, i.e., MagCore HF16 (RBC bioscience, Taipei, Taiwan), Nimbus MicrolabSeegene (Hamilton Company, Bonaduz, Switzerland) and m2000 system (Abbott Molecular Inc. Des Plaines, IL). RNA amplification was made using two real-time PCR platforms, i.e., qCOVID-19 (Genomica, Madrid, Spain) and Allplex 2019-nCoV assay (Seegene, Seoul, South Korea) and we used the CFX96™ (Bio-Rad) real-time detection system. PCR did not have a human extraction control gene target. The extraction control gen target was a phage. These kits were used according to the manufacturer´s instructions for both the handling and the interpretation of the results.

Rapid Diagnostic Test: SARS-CoV-2 antibody test (lateral flow method) is an immune chromate graphic assay used for rapid qualitative detection of IgM/IgG in human whole blood serum or plasma samples against SARS-CoV2 infection. All index test results are for research purposes and was not used for patient care. The diagnostic tests that is easy to perform for preliminary or emergency medical screening of SARS-CoV-2 within 20 minutes. The test was performed according to leaflets manufacturers-protocol provided from the manufacturer in the test kit packet.

Table 1. Product Information's

Manufacturer Name	**Global Access Diagnostics Ltd**	**Institut Pasteur de Dakar**
Test name	Covios®Ag kits (Covid-19 rapid antigen test kits)	SAYTU Covid-19 Ag TEST (DAITROPIX)
Device batch No:	CA25K-130-1	19O1DO22S
Pack size(s)	25 tests per kit	25 tests per kit

Content of kit	Covid-19 lateral flow device, swab extraction buffer tube, specimen collection swab, instructions for use	Test device, extraction buffer bottle, tube, nozzle cap, nasal swab, paper stand, instructions for use
Product storage (temperature range)	2-30ºC / 36-86ºF	2-30ºC / 36-86ºF
Product expiry (months, year)	October, 2022	24 months
Manufacturing site (country)	Bedford Technology Park Thurleigh, Bedfordshire, United Kingdom	Institut Pasteur de Dakar – Senegal

Measurement of Variables

The dependent variable was presence of SARS-CoV-2 while independent variables were sociodemographic characteristics and the diagnostic used.

Data Analysis

All the data generated were entered and analyzed using the IBM Statistical Package for Social Sciences (SPSS) version 23. A $p < 0.05$ was considered significant for all statistical tests. Mean and standard deviations were used to appropriately summarize the quantitative variables. Chi-square was done to describe associations between sociodemographic SARSCoV-2.

Ethical Consideration

Ethical approval for the study was obtained from the FCTA Health and Research Ethics Committee (FCTHERC). Written informed consent was obtained from each study participant. Respondents were free to withdraw anytime during the study if they so desired. The participants were assured of the confidentiality of their information. All methods were carried out in accordance with relevant guidelines and regulations.

Results

Table 2: Five hundred and seventy-two (71%) of the respondents were within the age range of 16-30 years with 7 (0.9%) being over 60 years. Males constituted 47.5% (383) while females were 52.5% (423) of the respondents. Two hundred and twenty-six (28.0%) were married.

Table 2. Sociodemographic Characteristics of Participants

Parameter	Frequency	Percentage
Age Group		
<16	24	3.0
16-30	572	71.0
31-45	154	19.1
46-60	49	6.1
>69	7	0.9
Sex		
Male	383	47.5
Female	423	52.5
Highest Educational Level		

None/No formal	26	3.2
Primary	28	3.5
Secondary	570	70.7
Tertiary	182	22.6
Marital Status		
Single	577	71.6
Married	226	28.0
Widow	3	0.4
Religion		
Christianity	749	92.9
Islam	56	7.0
Others	1	0.1
Occupation		
Employed	304	37.7
Unemployed	502	62.3

Table 3 shows 89 (11.0%), 56 (6.9%) and 53 (6.6%) positive results for SarCOV, Saytul and Global Access tests respectively.

Table 4 shows a sensitivity of 47.2% and specificity of 98.0% for Saytul. It also shows a sensitivity of 43.8% and specificity of 98.0% for Global Access. There was a statistically significant difference in the results between SarCOV 2 PCR and Saytul (p=0.001) and Global Access (p=0.001).

Table 3. Test Results by Different Test Methods

Variable	**Frequency**	**Percentage**
SarCOV		
Negative	717	89.0
Positive	89	11.0
Saytul		
Negative	750	93.1
Positive	56	6.9
Global Access		
Negative	753	93.4
Positive	53	6.6

Table 4. Comparison of Serological Assays with the Gold Standard SarCOV 2 PCR

SarCOV 2 PCR					
Variable	**Negative**	**Positive**	**OR (95% CI)**	χ^2	**p-value**
	Freq (%)	**Freq (%)**			
Saytul					
Negative	703 (98.0)	47 (52.8)	44.87 (22.89-87.96)	250.617	0.001
Positive	14 (2.0)	42 (47.2)	-	-	-
Global access					
Negative	703 (98.0)	50 (56.2)	39.17 (19.95-76.90)	225.907	0.001
Positive	14 (2.0)	39 (43.8)	-	-	-

Table 5 shows that age was statistically associated with SARCoV -2 (p=0.002). Higher positivity to SARCoV -2 was found among respondents over 30 years and was highest among age group greater than 60 years. Marital status (p=0.002) and religion (p=0.010) were found to be associated with SARCoV 2.

Table 5. Sociodemographic Factors associated with SarCOV Test Result

	SarCOV			
Variable	**Negative**	**Positive**	χ^2	**p-value**
	Freq (%)	**Freq (%)**		
Age Group				
<16	20 (83.3)	4 (16.7)	19.109	**0.002**
16-30	526 (91.3)	46 (8.7)		
31-45	125 (76.8)	29 (23.2)		
46-60	41 (80.5)	8 (19.5)		
>60	5 (71.4)	2 (28.6)		
Sex				
Male	341 (89.0)	42 (11.0)	0.004	1.000
Female	376 (88.9)	47 (11.1)		
Highest Educational Level				
None/No formal	25 (96.2)	1 (3.8)	3.737*	0.288
Primary	23 (92.1)	5 (17.9)		
Secondary	510 (89.6.)	59 (10.4)		
Tertiary	158 (86.8)	24 (13.2)		
Marital Status				
Single	529 (91.7)	48 (8.3)	15.734*	**0.002**
Married	186 (82.3)	40 (17.7)		
Widow	2 (66.7)	1 (33.3)		
Religion				
Christianity	673 (89.9)	76 (10.1)	8.543	**0.010**
Islam	43 (76.6)	13 (23.2)		
Others	1 (100.0)	0 (0.0)		

Discussion

This study showed both Saytul and Global Access to have positive rates lower than SarCOV. There was a statistically significant difference in the diagnostic performance of Saytul and Global Access compared to the gold standard. Both Saytul and Global Access had sensitivity lower than average. This is unlike that reported in a study in California where above average figures were reported for sensitivity of rapid antigen detection tests. This disparity may be explained by the difference in the sociodemographic characteristics of the study populations and peculiarities of the test strips may explain the difference [19]. Specificity for both tests was almost a hundred percent when compared to SarCOV-2.

There is a possibility that these tests are not able to detect minute quantities of the viral antigen in test specimen and this is an indication the two tests have tendencies to miss out from picking people that have the disease. Missing out positive cases constitutes a threat to public health, and it

compromises efforts at controlling the diseases as people will be given false hope thereby spreading more of the diseases [11]. In as much as time is of essence, where a highly contagious and sometime fatal disease is being considered for control, sensitivity and specificity of rapid tests should not be compromised. The low sensitivity recorded is a wake-up call to health care providers to consider confirmatory test using SarCOV-2 to avoid giving false positive results to people which in turn defeats the efforts at containing Covid-19.

In this study, we found that age group was statistically significantly associated with Sars-CoV-2 infection. The numerous age-related changes in the older age group may be brought on by muscle atrophy and a decline in lung function, which in turn leads to physiological impairments such a decrease in lung reserve, airway clearance, and defensive barrier function. The primary cause of the elderly's increased susceptibility to viral infection is thought to be age-related immune system remodelling, also known as immunosenesscence [21-22]. Furthermore, older patients are more likely to have pre-existing comorbidities. Age group less than 30 years had lower positivity rate compared to age group over 30 years [21]. The SARCOV-2 positive rate was highest among the age group greater than 60 years. This finding supports the report that risk to Covid 19 was higher among the elderly compared to the young and mortality rate among the age group greater than 55 years was 8.1 times higher and 62 times higher among those ages 65 or older [23].

There were no gender differences among the responders. Also, we discovered that SARCOV 2 and married status were both statistically associated. A study with married women revealed a similar finding, saying that married women cope better because stable couples understand one another [23]. The study recommended greater policies on residents' education and sustainable living since it connected unequal socioeconomic distributions to a variety of Covid-19 transmission in the area [24].

In a pandemic situation associated with severe morbidity and mortality such as the world is witnessing with COVID-19, desperate measures need to be taken to contain the situation. These include correct identification of cases, made possible by tests with high sensitivity and specificity. More effort needs to be put in place to ensure that, especially when developing newer ways of testing to prevent misclassification of cases with its attendant consequences on the individuals, family, and the healthcare system. We also found that marital status is associated with.

Conclusion

We found that the RTKs have low sensitivity, though with high specificity. Low sensitivity of the RTKs has implication for the identification of coronavirus infection including missing cases and given individual false hope of being free form the infection and this could lead to more spread of the infection. The need to enhance diagnostic accuracy for RTKs is necessary. With improved technology and understanding of the virus, highly accuracy and effective RTKs can be made available to help prevent coronavirus infection.

Consent for Publication

Not applicable.

Availability of Data

The dataset generated or analyzed during this study is included in this published article and its supplementary information files uploaded.

Competing Interests

The authors declared no competing interest.

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Authors' Contributions

AS, JD, LEC, and OA contributed to the conceptualization and design. GD acquired articles for review, abstracted findings to tables, and contributed to analysis and interpretation. KIB carried out data analysis. All the authors participated in the review and critique process and revised it critically for intellectual content. All the authors read and approved the final manuscript.

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References

[1] Cucinotta D, Vanelli M. WHO Declares Covid-19 a Pandemic. Acta Biomed. 2020;91(1):157–60.

[2] World Health Organization. Archived: WHO Timeline - Covid-19. World Health Organization (WHO). 2020.

[3] Olum R, Chekwech G, Wekha G, Nassozi D. R, Bongomin F. Coronavirus Disease-2019: Knowledge, Attitude, and Practices of Health Care Workers at Makerere University Teaching Hospitals, Uganda. Front Public Heal. 2020 Apr 30;8.

[4] Labban L, Thallaj N, Labban A. Assessing the Level of Awareness and Knowledge of Covid 19 Pandemic among Syrians. Arch Med [Internet]. 2020 Apr 30 [cited 2021 Sep 7];12(3):8. Available from: https://www.archivesofmedicine.com/medicine/assessing-the-level-of-awareness-and-knowledge-of-Covid-19-pandemicamong-syrians.php?aid=26894.

[5] Kabito G. G, Alemayehu M, Mekonnen T. H, Wami S. D, Azanaw J, Adane T, et al. Community's perceived high risk of coronavirus infections during early phase of epidemics are significantly influenced by socio-demographic background, in Gondar City, Northwest Ethiopia: A cross-sectional -study. PLoS One [Internet]. 2020 Nov 1 [cited 2021 Sep 13];15(11): e0242654. Available from: https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0242654.

[6] WHO. Coronavirus [Internet]. [cited 2022 Dec 29]. Available from: https://www.who.int/health-topics/coronavirus#tab=tab_3.

[7] Atnafie S. A, Anteneh D. A, Yimenu D. K, Kifle Z. D. Assessment of exposure risks to Covid-19 among frontline health care workers in Amhara Region, Ethiopia: A cross-sectional survey. PLoS One [Internet]. 2021 Apr 1 [cited 2021 Sep 10];16(4): e0251000. Available from: https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0251000.

[8] Olum R, Chekwech G, Wekha G, Nassozi D. R, Bongomin F. Coronavirus Disease-2019: Knowledge, Attitude, and Practices of Health Care Workers at Makerere University Teaching Hospitals, Uganda. Front Public Heal. 2020 Apr 30; 0:181.

[9] Akyala A. I, Awayimbo J. R, Ogo AC, Chima NJ, Billyrose OMA, Engom AOG. Clinical diagnostic performance evaluation of five immunoassays for antibodies to SARS-CoV-2 diagnosis in a real-life routine care setting. Pan Afr Med J [Internet]. 2021 May 3 [cited 2022 Dec 28]; 39:3–3. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8197056.

[10] Woo PCY, Lau SKP, Wong BHL, Chan KH, Chu CM, Tsoi HW, et al. Longitudinal Profile of Immunoglobulin G (IgG), IgM, and IgA Antibodies against the Severe Acute Respiratory Syndrome (SARS) Coronavirus Nucleocapsid Protein in Patients with Pneumonia Due to the SARS Coronavirus. Clin Diagn Lab Immunol [Internet].

2004 Jul [cited 2022 Dec 29];11(4):665. Available from: /pmc/articles/PMC440610/.
[11] Gong F, Wei HX, Li Q, Liu L, Li B. Evaluation and Comparison of Serological Methods for Covid-19 Diagnosis. Front Mol Biosci. 2021 Jul 23; 8:683.
[12] Yüce M, Filiztekin E, Özkaya KG. Covid-19 diagnosis —A review of current methods. Biosens Bioelectron. 2021;172.
[13] Centers for Disease Control and Prevention (CDC). Covid-19 Overview and Infection Prevention and Control Priorities in non-U.S. Healthcare Settings. 2021.
[14] World Health Organization (WHO). WHO lists two Covid-19 tests for emergency use. News. 2020.
[15] World Health Organization (WHO). Advice on the use of point-of-care immunodiagnostic tests for Covid-19. Scientific Brief. 2020.
[16] Centers for Disease Control and Prevention (CDC). Overview of testing for SARS-CoV-2, the virus that causes Covid-19. Cdc.Gov. 2022.
[17] Elleh N. Abuja: the single most ambitious urban design project of the 20th century. New World Encycl [Internet]. 2001 [cited 2021 Sep 13]; 97. Available from: http://www.newworldencyclopedia.org/entry/Abuja.
[18] Federal Capital Development Agency. Federal Capital Territory (Nigeria) [Internet]. City Population; [cited 2021 Sep 13]. Available from: http://www.citypopulation.de/php/nigeria-admin.php?adm1id=NGA015.
[19] Brihn A, Chang J, OYong K, Balter S, Terashita D, Rubin Z, et al. Diagnostic performance of an antigen test with RT-PCR for the detection of SARS-CoV-2 in a hospital setting —Los Angeles County, California, June–August 2020. MMWR Recomm Reports. 2021;70(19):702–6.
[20] Clinical diagnostic performance evaluation of five immunoassays for antibodies to SARS-CoV-2 diagnosis in a real-life routine care setting. | Pan Afr Med J; 39:3, 2021. | MEDLINE [Internet]. [cited 2022 Dec 28]. Available from: https://search.bvsalud.org/global-literature-on-novel-coronavirus-2019-ncov/resource/es/covidwho-1264683.
[21] Zhang H, Wu Y, He Y, Liu X, Liu M, Tang Y, et al. Age-Related Risk Factors and Complications of Patients with Covid-19: A Population-Based Retrospective Study. Front Med [Internet]. 2022 Jan 11 [cited 2023 May 4];8. Available from: https://pubmed.ncbi.nlm.nih.gov/35087843/.
[22] Mueller AL, Mcnamara MS, Sinclair DA. Why does Covid-19 disproportionately affect older people? Aging (Albany NY) [Internet]. 2020 May 5 [cited 2023 May 4];12(10):9959. Available from: /pmc/articles/PMC7288963/.
[23] Lawal AM, Alhassan EO, Mogaji HO, Odoh IM, Essien EA. Differential effect of gender, marital status, religion, ethnicity, education, and employment status on mental health during Covid-19 lockdown in Nigeria.
https://doi.org/101080/1354850620201865548
[Internet]. 2020 [cited 2023 Mar 21];27(1):1–12. Available from: https://www.tandfonline.com/doi/abs/10.1080/13548506.2020.1865548.
[24] Dowd JB, Andriano L, Brazel DM, Rotondi V, Block P, Ding X, et al. Demographic science aids in understanding the spread and fatality rates of Covid-19. Proc Natl Acad Sci U S A. 2020 May 5;117(18):9696–8.