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Evaluation of Performance Characteristics of the Standard™ Q IgM/IgG and the Wantai SARS-CoV-2 Ab Rapid Tests in Tanzania

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ABSTRACT

Background: Rapid diagnostic tests (RDTs) have played a critical role in the detection and monitoring of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infections globally. A number of RDTs are currently available, and their accuracy is dependent on several factors that include disease stage, circulating virus variants at the particular time, and the population being tested. This study aimed to evaluate the performance characteristics of two RDTs, the Standard™ Q IgM/IgG and the Wantai SARS-CoV-2 Ab Rapid Test, for the detection of SARS-CoV-2 antibodies in a Tanzanian population.

Methods: Plasma samples from a total of 80 individuals stored at the National Institute for Medical Research-Mbeya Medical Research Centre (NIMR-MMRC) biobank were tested. Of these, 37 (46.3%) were confirmed to have been exposed to the SARS-CoV-2 virus through either RT-PCR or Ag rapid tests from ongoing COVID-19 studies. The remaining 43 (53.6%) serving as negative controls, were stored samples from SARS-CoV-2 unexposed individuals obtained from an HIV cohort enrolled between 2014 and 2017. All the samples were tested using both the Standard™ Q IgM/IgG and the Wantai SARS-CoV-2 Ab Rapid Test. The sensitivity, specificity, and other performance characteristics of each test were determined.

Results: The Standard™ Q IgM/IgG test demonstrated a higher sensitivity of 100% (95% CI: 74–100%) for patients with acute COVID-19 (less than ten days since onset of symptoms). The Wantai SARS-CoV-2 Ab rapid test had a sensitivity of 75% (95% CI: 43–95%). Both tests revealed a specificity of 100% (95% CI: 74–100%). For patients with more than 30 days since the onset of symptoms, the Standard™ Q IgM/IgG test showed a sensitivity of 96% (95% CI: 80-100%), while the Wantai total Ab assay had a sensitivity of 92% (95% CI: 74-99%), and again both test kits revealed a specificity of 100% (95% CI: 74-100%).

Conclusion: The Standard™ Q IgM/IgG Rapid Diagnostic Test is recommended to be used as the primary test for COVID-19 survey screening purposes due to its higher sensitivity, while the Wantai total Ab RDT is recommended to be regarded as the second option.

BACKGROUND

Coronavirus Disease 2019 (COVID-19) is caused by Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2). The World Health Organization (WHO) declared it a pandemic on March 11, 2020.[1] Since then, the disease has caused a drastic change in human lifestyles and the global economy. [2-4] To date, over 600 million cases have been reported globally, with more than 6 million cumulative deaths.[5] In Tanzania, as of April 2022, a total of 33,851 cases and 851 deaths have been officially confirmed out of 500,930 hospital-suspected cases.[6] The implementation of prevention and control measures has contributed to the minimization of the burden of COVID-19. The development of point-of-care diagnostics, such as rapid antibody and antigen tests, has enabled extensive screening for SARS-CoV-2 exposure

The detection of exposure to the SARS-CoV-2 pathogen is essential in implementing the recommended strategic public health mitigating measures set by the WHO. These include case identification, isolation, and contact tracing as the best approaches to contain COVID-19.[7,8] However, identifying cases can be challenging since 40 to 45% of individuals who test positive for the virus remain asymptomatic,[9,10] and when symptomatic, the clinical signs of COVID-19 vary and may be similar to many other respiratory

diseases.[11] Therefore, it is important to identify individuals who have not been exposed to the virus through the deployment of rapid diagnostic tests (RDTs), especially in preventive SARS-CoV-2 vaccine trials.

It is crucial to evaluate the RDTs in order to determine their effectiveness in identifying asymptomatic infected individuals and measuring the spread of the virus in a population. This information is extremely important for public health officials to develop better strategies to contain the spread of the disease, particularly in low and middle-income countries.[12]

Antibody-based RDTs for COVID-19 are designed to detect antibodies in a person's blood. These antibodies are produced in response to viral antigens such as anti-spike protein or anti-nucleocapsid after SARS-CoV-2 infection. Some RDTs are capable of detecting both. However, the performance of these tests can vary depending on factors such as the type of recombinant proteins used to prepare the test kits, the time elapsed since infection, the individual's immune status, and the manufacturer's detection threshold.[13,14]

The IgM/IgG Standard™ Q test kits use recombinant spike and nucleocapsid proteins conjugated with colloidal gold particles, while the Wantai SARS-CoV-2 test uses recombinant proteins from the Spike Region Bound Domain (SRBD) conjugated with colloidal gold particles. It is worth noting that the Standard™ Q COVID-19 IgM/IgG rapid test was authorised for emergency use in Korea in March 2020[15], and the Wantai SARS-CoV-2 antibody (Ab) RDT was authorised by the U.S. Food and Drug Administration (FDA) in March 2021.[16]

This study aimed to evaluate the performance of Standard™ Q IgM/IgG (SD Biosensor, Republic of Korea) and Wantai SARS-CoV-2 Ab Rapid Test (Wantai Biological Pharmacy Enterprise Co. Ltd., Beijing, China) rapid diagnostic tests (RDT) as point-of-care screening diagnostic test kits in a Tanzanian population.

MATERIALS AND METHODS

Study design and Participants

In this study, we evaluated the performance characteristics of the Standard™ Q IgM/IgG and Wantai SARS-CoV-2 Ab Rapid Tests through a retrospective and prospective cross-sectional analysis that was not blinded. We gathered serum samples from individuals who were confirmed to have been exposed to the SARS-CoV-2 virus through either RT-PCR or Ag rapid tests from ongoing COVID-19 studies (n = 37). These were obtained from ongoing COVID-19 studies (assessing host and viral factors for COVID-19 disease outcomes in Tanzania (AAS study) and the Epidemiological and Immunological Attributes for the Progress and Outcomes of COVID-19 Disease in Tanzania (ELICIT study)).

We also tested serum samples from individuals who were not exposed to SARS-CoV-2, which were obtained from the HIV cohort study, which was investigating the targeted virological treatment failure monitoring in HIV-infected antiretroviral treatment-experienced patients at the Mbeya Referral Hospital HIV Care and Treatment Centre, Tanzania (ALISA cohort) conducted between 2014 and 2017 (before the declaration of the COVID-19 pandemic) at the NIMR-Mbeya Medical Research Centre in Tanzania (n = 43) as indicated on figure 1.

Sample size Estimation

The sample size was determined using the formula for estimating the diagnostic accuracy of the of the sample size in experimental studies. [17] This calculation took into account the sensitivity and specificity specified by the manufacturers, which were equal to or greater than 95%. Additionally, it considered a disease prevalence of 50% for the community-based population based on a study conducted in 2021.[18] Furthermore, assuming approximately 6% of indeterminate results and considering the precision of 7%, a sample size of 80 was attained for evaluating the specificity and sensitivity of both the Wantai Biopharm IgG and Standard Q™ IgG/IgM rapid kits. The evaluation of these kits will include reporting corresponding 95% confidence intervals (with a corresponding z-score of 1.96).

$$n = \frac{Z^2_{\frac{\alpha}{2}} Se(1 - Se)}{d^2 x Prev}$$

Where:
n=Sample size
Se=Sensitivity
Prev=Prevalence
α = 0.05
Z_(α/2)=1.96

$$n = \frac{1.96^2 x 0.95 x 0.05}{0.07^2 x 0.5} = 75$$

Including 6% of possible indeterminate results will raise the sample size to 80, i.e.

$$The\ total\ sample\ size\ (n)\ will\ be = \frac{75}{(1 - 0.06)} \approx 80$$

Exclusion and Inclusion Criteria

Inclusion Criteria

Plasma samples from patients with a confirmed SARS-CoV-2 infection were collected by either RT-SARS-CoV-2 PCR or SARS-CoV-2 antigen rapid tests.

Plasma samples were taken from patients enrolled in the studies two years before the declaration of the COVID-19 pandemic.

Exclusion Criteria

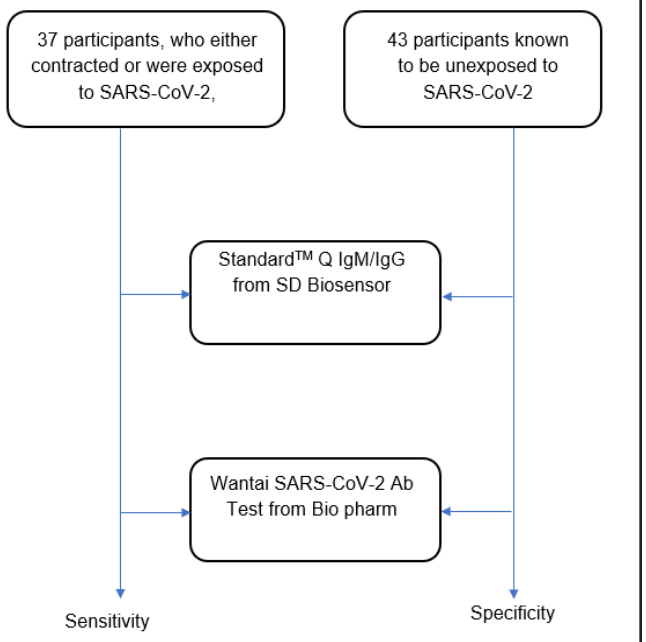
All cryopreserved plasma samples with more than two freeze-thawing cycles

SARS-CoV-2 Rapid Test Evaluation

Test Procedures

During the evaluation experiment, two different kits were used: the Standard™ Q IgM/IgG kit by SD Biosensor from the Republic of Korea and the Wantai SARS-CoV-2 Ab rapid test kit by Beijing Wantai Biological Pharmacy Enterprise Co., Ltd., China. The experiment was carried out at the NIMR-Mbeya Medical Research Centre laboratory.

FIGURE 1: Study Schema Depicting the Two Groups of Participants and Performance Evaluation Undertaken



A total of 80 plasma samples were used in this experiment. These samples were collected from individuals who were either exposed or unexposed to the SARS-CoV-2 virus. The plasma samples were thawed, and then 10µl of plasma from both exposed and unexposed individuals were tested using the Standard™ Q IgM/IgG and Wantai SARS-CoV-2 Ab rapid test kits, following the instructions provided by the manufacturers.

Further testing of the kits was conducted by utilising samples obtained from participants who had recovered from illness, with a period of over 30 days from symptom onset. According to the manufacturer, the Standard™ Q COVID-19 IgM/IgG rapid test works by detecting the presence of antibodies against SARS-CoV-2 in a person's blood. The test uses 20µl of blood sample or 10µl of plasma, which is added to the specimen window of the test cassette along with 3 drops of the respective buffer solution. If antibodies to the virus are present in the sample, they will bind to specific antigens on the test strip and produce a visible result within 10 to 15 minutes. It detects both IgM and IgG antibodies against both the spike and nucleocapsid protein regions of the virus, which are produced at different stages of infection. The test can thus provide information on whether a person has recently been infected or has previously been exposed to the virus.

The Wantai SARS-CoV-2 Ab rapid test works by detecting the presence of antibodies against SARS-CoV-2 in a person's blood. The test requires a small sample of blood or plasma (10µl), which is added to the specimen window of the test cassette along with 2 drops of the respective diluent buffer solution. The test is based on immunochromatographic assays that use gold nanoparticle-labelled SARS-CoV-2 antigens to detect antibodies in the blood sample. It detects total antibodies against S-RBD, which are produced at different stages of infection, and can provide information about the exposure status of a person. Spike SARS-CoV-2 antigens are bound at the test zone (T), and the antibodies are bound at the control zone (C). When the specimen is added, it migrates by capillary diffusion, rehydrating the gold conjugate, and then antibodies will bind to the gold-conjugated spike proteins and continue to diffuse to the test zone (T) to be visualised as the red line if the test is positive. Results are obtained after 15 minutes from when the sample was applied to the specimen window of the cassette.

Data Analysis

A laboratory form was used to document all RDT results according to the manufacturer's manual and NIMR-MMRC standard operating procedures. Subsequently, the recorded results were entered into an MS Excel spreadsheet and thoroughly verified for accuracy and completeness. Data were analysed using Stata version 14 (StataCorp LLC, Texas, USA). Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and accuracy were calculated and presented as percentages.[19] The sensitivity and specificity of both the Wantai SARS-CoV-2 Ab test and Standard ™ Q IgM/IgG RDT were determined by comparing them with reverse transcriptase PCR or SARS-CoV-2 antigen results as a gold standard for the exposed group.

Ethical Statement

Samples utilised in this study were obtained from previous and ongoing studies after obtaining written informed consent of participants to participate and storage of samples for future use in studies that were conducted at the National Institute for Medical Research in Mbeya and Dar es Salaam with ethical approvals from the National Health Research Ethics Committee (TANCoV-1: NIMR/HQ/R.8a/Vol.IX/3831; AAS COVID: NIMR/HQ/R.8a/Vol.IX/3754, ELICIT: SZEC-2439/R.A/V.1/116, ALISA: NIMR/HQ/R.8a/Vol.IX/1569) of the National Institute of Medical Research, Tanzania. To maintain confidentiality, specimens were not linked to personal identifiers, and the findings were not attributable to specific patients.

RESULTS

Demographic Characteristics of Study Population

Samples from 80 participants were tested. Their demographic characteristics are as depicted in Table 1. Of these, 37 plasma samples were from patients known to be exposed to or infected with SARS-CoV-2, and 43 samples were from healthy, unexposed participants. Out of the 37 participants who were exposed, 12 (32.4%) had a recent infection with the onset of SARS-CoV-2 clinical symptoms within 10 days. Meanwhile, 25 (67.6%) of the exposed participants had recovered from SARS-CoV-2 infections (more than 30 days since the onset of clinical symptoms) (Table 1).

Performance Characteristics of the Tested Kits

Twelve of the 37 (32.4%) exposed individuals had an active SARS-CoV-2 infection at the time of sample collection, which was confirmed by reverse transcriptase

PCR (RT PCR). Without categorising the samples depending on the number of days for the onset of SARS-CoV-2 symptoms, the Standard™ Q IgM/IgG rapid test demonstrates a higher sensitivity of 97% (95% CI: 86–100%) compared to the Wantai SARS-CoV-2 Ab rapid test, which shows a sensitivity of 86% (95% CI: 71–95%). However, both tests maintain a specificity of 100% (95% CI: 74–100%). But once evaluating both the rapid test kits using samples from patients with acute SARS-CoV-2 infections with onset of symptoms less than 10 days, Wantai SARS-CoV-2 Ab rapid tests had a lower sensitivity of 75% (95% CI: 43–95%) (9/12) compared to Standard™ Q IgM/IgG with a sensitivity of 100% (95% CI: 74–100%) (12/12) (Table 2).

After further testing of the kits using samples obtained from participants who had recovered from illness, with a period of over 30 days from symptom onset, the sensitivity of the Wantai SARS-CoV-2 Ab rapid test increased from 75% to 92% (95% CI: 74-99%) (23/25). On the other hand, the StandardTM Q IgM/IgG displayed a sensitivity of 96% (95% CI: 80-100%) (24/25), while both rapids test kits maintained a specificity of 100% (95% CI: 74-100%) (Table 2).

Negative Predictive Value (NPV) and Positive Predictive Value (PPV)

Both the Wantai SARS-CoV-2 Ab rapid test and the StandardTM Q IgM/IgG test exhibited a positive predictive value (PPV) of 100% (95% CI: 74–100%) and a negative predictive value (NPV) of 100% (95% CI: 74–100%).

Accuracy and False Negative Rate

When evaluating participants who had confirmed exposure to SARS-CoV-2 by either RT-PCR or SARS-CoV-2 antigen test before sample collection and had experienced symptoms for either less than 10 days or had recovered from COVID-19, the Standard™ Q IgM/IgG test demonstrated an accuracy of 99% (95% CI: 93-100%), whereas the Wantai SARS-CoV-2 Ab rapid test showed an accuracy of 94% (95% CI: 86-98%). The false negative rate was 2.7% (95% CI: 0-14.2%) for the Standard™ Q IgM/IgG test and 13.5% (95% CI: 4.5-29%) for the Wantai SARS-CoV-2 Ab rapid test.

TABLE 1: Characteristics of study participants (N=80)

	Unexposed (n=43)	Exposed (n=37)
Demographic Data		
Participants, N (%)	43 (53.8)	37 (46.3)
Median Age, years (Range)	43 (21-64)	32(25-85)
Sex		
Male, n (%)	16 (37.2)	23 (62.2)
Female, n (%)	27 (62.8)	14 (37.8)

TABLE 2: Performance Characteristics of SARS CoV-2 Antibody Rapid Tests at 95% Confidence Interval (CI)

Number of Days since exposure to SARS CoV-2	Standard ™ Q IgM/IgG Rapid test performance (95% CI)	Wantai SARS-CoV-2 Ab Rapid test performance (95% CI)
Overall performance		
Sensitivity	97% (86%, 100%)	86% (71%, 95%)
Specificity	100% (74%, 100%)	100% (74%, 100%)
PPV	100% (74%, 100%)	100% (74%, 100%)
NPV	100% (74%, 100%).	100% (74%, 100%).
< 10 days		
Sensitivity	100% (74%, 100%)	75% (43%, 95%)
Specificity	100% (74%, 100%)	100% (74%, 100%)
>30 days (Recovered patients)		
Sensitivity	96% (80%, 100%)	92% (74%, 99%)
Specificity	100% (74%, 100%)	100% (74%, 100%)

DISCUSSION

We evaluated the performance of two commercially available and widely used serological tests for the detection of anti-SARS-CoV-2 antibodies. Our results show that the Standard™ Q IgM/IgG test from SD Biosensor had excellent performance in terms of sensitivity (100%) and specificity (100%) for patient samples with acute infection (up to less than 10 days from the onset of symptoms). On the other hand, the Wantai SARS-CoV-2 Ab kits revealed a relatively lower sensitivity (75%), but excellent specificity (100%). However, according to the manual inserts, Wantai SARS-CoV-2 Ab from BioPharm has been reported to have excellent performance on tested samples from Chinese and other populations in the world[20,21] and has received emergency approval by the US FDA.[16]

While both nucleocapsid protein and spike protein are used in COVID-19 rapid antibody diagnostic tests, studies have suggested that rapid test kits prepared using recombinant nucleocapsid protein can provide a more accurate diagnosis of SARS-CoV-2 infection, particularly in the early stages of infection. [22,23] This is because the nucleocapsid protein is highly conserved and less prone to mutations compared to spike proteins.[24,25] As a result, antibodies to the nucleocapsid protein are more likely to detect a broader range of SARS-CoV-2 strains, including those with mutations in the spike region of the virus genome.[26,27]

Moreover, anti-nucleocapsid antibodies are typically present at higher levels in the early stages of infection, which may make it easier to detect the virus using nucleocapsid-based tests during the acute phase.[22,23] However, it's worth noting that the spike protein is still an important target for COVID-19 vaccines and therapies, as it plays a critical role in the virus's ability to enter host cells.[28] Our data showed that the Standard Q™ IgM/IgG, which targets both anti-spike and anti-nucleocapsid antibodies, had a relatively higher sensitivity compared to the Wantai Ab rapid kits from BioPharm, which only target anti-spike antibodies.

Limitations of the study

The relatively small number of samples, especially for the SARS-CoV-2-exposed individuals, would be the limitation of our study. However, to our knowledge, this is the first study to report on the performance of the Standard™ Q IgM/IgG and Wantai Ab rapid kits in a Tanzanian population.

CONCLUSION

The diagnostic accuracies of both the Standard™ Q IgM/IgG and the Wantai SARS-CoV-2 Ab rapid test in detecting COVID-19 in a Tanzanian population are high. However, the sensitivity of Wantai SARS-CoV-2 Ab RDT was lower for samples collected from patients within 10 days after the onset of symptoms.

Our findings highlight the importance of evaluating Ab rapid tests during pandemics and also suggest that the Standard™ Q IgM/IgG test be superior for COVID-19 survey screening purposes due to its high sensitivity. However, in case this is not available or for budget reasons, the Wantai SARS-CoV-2 Ab RDT (which is cheaper) can still be used since the difference between the two is not huge. Therefore, the use of any of the two kits may help in understanding the extent of SARS-CoV-2 infection exposure in Tanzania.

REFERENCES

1. Ciotti M, Ciccozzi M, Terrinoni A, Jiang W-C, Wang C-B, Bernardini S. The COVID-19 pandemic. Critical reviews in clinical laboratory sciences. 2020;57(6):365-88.
2. Sayyida S, Hartini S, Gunawan S, Husin SN. The impact of the COVID-19 pandemic on retail consumer behavior. Aptisi Transactions on Management (ATM). 2021;5(1):79-88.
3. Maital S, Barzani E. The global economic impact of COVID-19: A summary of research. Samuel Neaman Institute for National Policy Research. 2020;2020:1-12.
4. Fernandes N. Economic effects of coronavirus outbreak (COVID-19) on the world economy. 2020.
5. WHO Coronavirus (COVID-19) Dashboard. 2022.
6. Tanzania MOH. Taarifa Ya Hali Ya Uviko-19 Kuanzia Tarehe 02 Hadi Tarehe 08 April 2022.
7. Honein MA, Christie A, Rose DA, et al. Summary of guidance for public health strategies to address high levels of community transmission of SARS-CoV-2 and related deaths, December 2020. Morbidity and Mortality Weekly Report. 2020;69(49):1860.
8. Larsen D, Dinero R, Asiago-Reddy E, et al. A review of infectious disease surveillance to inform public health action against the novel coronavirus SARS-CoV-2. 2020.
9. Oran DP, Topol EJ. Prevalence of asymptomatic SARS-CoV-2 infection: a narrative review. Annals of internal medicine. 2020;173(5):362-7.
10. He J, Guo Y, Mao R, Zhang J. Proportion of asymptomatic coronavirus disease 2019: A systematic review and meta-analysis. Journal of medical virology. 2021;93(2):820-30.
11. WHO. Clinical management of severe acute respiratory infection when novel coronavirus (2019-nCoV) infection is suspected: interim guidance, 28 January 2020. World Health Organization; 2020.
12. Saluzzo F, Mantegani P, Poletti De Chaurand V, et al. SARS-CoV-2 antibody rapid tests: valuable epidemiological tools in challenging settings. Microbiology spectrum. 2021;9(2):e00250-21.
13. Padoan A, Sciacovelli L, Basso D, et al. IgA-Ab response to spike glycoprotein of SARS-CoV-2 in patients with COVID-19: A longitudinal study. Clinica chimica acta. 2020;507:164-6.
14. Theel ES, Harring J, Hilgart H, Granger D. Performance characteristics of four high-throughput immunoassays for detection of IgG antibodies against SARS-CoV-2. Journal of clinical microbiology. 2020;58(8):e01243-20.
15. KMFDS. List of COVID-19 In Vitro Diagnostic Devices for Export Only Approved by Korea Ministry of Food and Drug Safety (KMFDS). 2021 10.12.2021.
16. Emergency Use Authorisation of WANTAI SARS-CoV-2 Ab Rapid Test [Internet]. 2021
17. Akoglu H. User's guide to sample size estimation in diagnostic accuracy studies. Turkish Journal of Emergency Medicine. 2022;22(4):177.
18. Nyawale HA, Moremi N, Mohamed M, et al. High Seroprevalence of SARS-CoV-2 in Mwanza, Northwestern Tanzania: A Population-Based Survey. International Journal of Environmental Research and Public Health. 2022;19(18):11664.
19. Alford A, Nicoletti A, Derzon J, Trevethan R. Sensitivity, specificity, and predictive values: foundations, Pliabilities, and pitfalls in research and practice. Article 307 1. Public Health. 2017;5:307.
20. Saker K, Escuret V, Pitiot V, et al. Evaluation of commercial anti-SARS-CoV-2 antibody assays and comparison of standardized titers in vaccinated health care workers.

Journal of clinical microbiology. 2022;60(1):e01746-21.

21. Wang P. Combination of serological total antibody and RT-PCR test for detection of SARS-COV-2 infections. Journal of virological methods. 2020;283:113919.

22. Burbelo PD, Riedo FX, Morishima C, et al. Sensitivity in detection of antibodies to nucleocapsid and spike proteins of severe acute respiratory syndrome coronavirus 2 in patients with coronavirus disease 2019. The Journal of infectious diseases. 2020;222(2):206-13.

23. Burbelo PD, Riedo FX, Morishima C, Rawlings S, Smith D, Das S, et al. Detection of nucleocapsid antibody to SARS-CoV-2 is more sensitive than antibody to spike protein in COVID-19 patients. MedRxiv. 2020.

24. Ahlén G, Frelin L, Nikouyan N, Weber F, Höglund U, Larsson O, et al. The SARS-CoV-2 N protein is a good component in a vaccine. Journal of Virology. 2020;94(18):e01279-20.

25. Dutta NK, Mazumdar K, Gordy JT. The nucleocapsid protein of SARS–CoV-2: a target for vaccine development. Journal of virology. 2020;94(13):e00647-20.

26. Thakur S, Sasi S, Pillai SG, et al. SARS-CoV-2 mutations and their impact on diagnostics, therapeutics and vaccines. Frontiers in medicine. 2022;9.

27. Wu W, Cheng Y, Zhou H, Sun C, Zhang S. The SARS-CoV-2 nucleocapsid protein: its role in the viral life cycle, structure and functions, and use as a potential target in the development of vaccines and diagnostics. Virology Journal. 2023;20(1):1-16.

28. Ita K. Coronavirus disease (COVID-19): Current status and prospects for drug and vaccine development. Archives of Medical Research. 2021;52(1):15-24.

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