Performance of anti-SARS-CoV-2 IgG/IgM rapid diagnostic test in N'Djamena, Chad: evidence from a clinical perspective during an outbreak response

Amine Akouya,[1,2] Ezechiel Ngoufack Jagni Semengue,[3] Koutaya Dezoumbe,[1,2,4] Noubaramadji Yamti Suitombaye,[1,2] Aleyo Zita Nodjikouambaye,[1] Carla Montesano,[5,6] Carlo Federico Perno,[3,7] Vittorio Colizzi,[1,3,4] Giulia Cappelli,[1,8] Joseph Fokam[3,9-12]

[1]Laboratoire des Grandes Épidémies Tropicales, University Hospital Complex "Le Bon Samaritain", N'Djamena, Chad; [2]Doctoral School of Advanced Sciences for Sustainable Development, Evangelic University of Cameroon, Bandjoun, Cameroon; [3]Faculty of Medicine and Biomedical Sciences, University of Yaoundé 1, Cameroon; [4]Laboratory of Immunology, National Research Council, Rome, Italy; [5]Faculty of Sciences and Technology, Evangelical University of Cameroon, Bandjoun, Cameroon; [6]Department of Biology, Faculty of Sciences, University of Rome Tor Vergata, Italy; [7]Faculty of Medicine, University Hospital Complex "Le Bon Samaritain", N'Djamena, Chad; [8]National Public Health Emergency Operations Coordination Centre, Yaoundé, Cameroon; [9]Faculty of Health Sciences, University of Buea, Cameroon; [10]Bambino Gesù Pediatric Hospital, Rome, Italy; [11]National AIDS Control Committee, Ministry of Public Health, Yaoundé, Cameroon; [12]Virology Laboratory, Chantal Biya International Reference Centre for Research on HIV and AIDS Prevention and Management, Yaoundé, Cameroon

Correspondence: Joseph Fokam, Virology Laboratory, Chantal BIYA International Reference Center for Research on VIH/AIDS Prevention and Management, Yaoundé, Cameroon.
E-mail: josephfokam@gmail.com

Key words: COVID-19, rapid diagnostic test, ELISA, anti-SARS-CoV-2, antibody.

Conflict of interest: the authors have no conflict of interest to declare.

Ethics approval and consent to participate: the study protocol received authorization to conduct a COVID-19 seroprevalence survey under decision No. 001/PR/CGCS/CNRS COVID-19/2021, with the objective of monitoring the evolution of the pandemic in Chad. Participant confidentiality was strictly maintained throughout the study. Each individual was assigned a unique study identification number to ensure anonymity and to link their clinical samples without using personal identifiers.

Availability of data and materials: the datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Funding: the present study was supported by the MAGIS Foundation, the Italian Agency for Development Cooperation, and the European and Developing Countries Clinical Trials Partnership, EDCTP PERECT-Study RIA2020 EF3000.

Acknowledgments: we express our gratitude to the staff of the University Hospital Complex "Le Bon Samaritain" in Chad and the scientific team of the Cameroonian-Chad collaborative initiative under the EDCTP PERFECT-Study for their assistance in preparing for and responding to pathogens that have the potential to cause an epidemic or pandemic. Additionally, we would like to thank the Italian cooperation for giving additional help for the implementation of the project.

Received: 25 August 2025.
Accepted: 26 September 2025.

Sahelian Journal of Responsible One Health 2025; 1:557
doi:10.4081/sjroh.557

Abstract

The utility of rapid serological tests for anti-SARS-CoV-2 antibodies, particularly in a tropical context, is not well-defined. We evaluated the performance of the Genrui IgG/IgM rapid diagnostic test (RDT; Genrui Biotech Inc., Shenzhen, China) against an enzyme-linked immunosorbent assay (ELISA), which serves as the gold standard. This cross-sectional study was conducted in N'Djamena, Chad, in July 2022. A total of 198 samples from individuals attending a facility for COVID-19 diagnosis were tested using both the Genrui RDT and the DIATHEVA COVID-19 IgG ELISA kit (DIATHEVA S.r.l., Fano, Italy). IgG seropositivity with ELISA was 84.8%, significantly higher than the 54% found with the RDT, representing a 30.8% difference. The RDT showed a sensitivity of 60% and a specificity of 80%, with poor agreement with ELISA (Cohen's κ=0.22). Positive and negative predictive values (PPVs and NPVs) were 94% and 26%, respectively. The rapid IgM/IgG test from Genrui Biotech Inc. has a significantly suboptimal performance for detecting anti-SARS-CoV-2 antibodies. This highlights the need for performing ELISA on non-reactive RDT cases during serosurveys or post-vaccine response assessments.

Introduction

During the COVID-19 outbreak, the World Health Organization (WHO) recommended that health authorities systematically test all suspected cases of SARS-CoV-2 for case isolation and interruption of viral transmission and dispersal.[1] The gold standard for the diagnosis of COVID-19 is the detection of SARS-CoV-2 genetic material by real-time polymerase chain reaction (RT-PCR). However, many affected individuals never show symptoms of the disease, resulting in an underestimate of disease incidence and prevalence, which could be mitigated by implementing strategies to monitor viral exposure.[2]

Since the start of the COVID-19 pandemic in December 2019, SARS-CoV-2 has undergone several mutations, some of which have led to variants of concern, leading to various waves of COVID-19 at global, continental, and country levels. Since December 2020, five of them have been classified as a cause for

concern by the WHO: Alpha, Beta, Gamma, Delta, and, more recently, the Omicron variant. Some variants could negatively impact the efficacy of vaccines against COVID-19 and/or influence the performance of a diagnostic assay, leading to potential false negative results.[3] However, detecting viral exposure through immune response is less likely to give a false negative from each exposed or vaccinated individual, irrespective of the SARS-CoV-2 variant.[3]

The detection of anti-SARS-CoV-2 IgG antibodies is one of the most effective approaches available to determine the number of individuals affected in the community; this is clearly crucial for informing decision-making and public health policies. Therefore, evaluating commercial kits is essential. Tests that detect antibodies to the core (N) antigen are expected to be more sensitive since the majority of antibodies are produced against the most abundant protein in the virus, which is protein N.[4] On the other hand, antibodies against the spike glycoprotein receptor binding domain (RBD-S) would be more specific, since RBD-S is the host-binding protein, and these have been correlated with the severity of the disease.[5] Traditionally, antibody determination is performed using various techniques such as enzyme-linked immunosorbent assay (ELISA), chemiluminescent immunoassay (CLIA), rapid lateral flow (immunochromatographic) assays, or fluorescence immunoassays (FIA). ELISA and CLIA variants are the most reliable solutions, especially for COVID-19.[6,7] Common assay platforms include lateral flow assays, which can serve an important niche by offering low cost, rapid turnaround, and increased accessibility. Meanwhile, established laboratory platforms based on ELISA and CLIA extend existing technologies to SARS-CoV-2, providing throughput and quantification capabilities.[8] The market pressure generated by this pandemic has resulted in several new tests whose actual performance is uncertain.[9]

We aimed at determining the diagnostic concordance between the rapid anti-SARS-CoV-2 Genrui IgG/IgM test (colloidal gold; Genrui Biotech Inc., Shenzhen, China) and the COVID-19 ELISA IgG DIATHEVA test (DIATHEVA S.r.l., Fano, Italy), used as the reference test. Comparing anti-SARS-CoV-2 serological results measured by ELISA and the rapid test may be useful for ensuring the quality of results in a health emergency situation and for designing a pragmatic algorithm for routine screening in population-based serosurveys in tropical settings.

Materials and Methods

Study design, location, and duration

This cross-sectional laboratory-based study was conducted at the *Laboratoire des Grandes Épidémies Tropicales* (LAGET; Laboratory for Major Tropical Epidemics) in N'Djamena, Chad, within the frame of the quality control of serological tests performed during the month of July 2022 on plasma samples obtained from whole blood individuals tested for COVID-19.

Study population and sample

The study population involved 198 samples, which represent about 10% of the samples from individuals tested for COVID-19 in N'Djamena. The enrolled participants completed a survey form containing socio-demographic characteristics (age, sex, gender, occupation, place of residence) and clinical characteristics.

Following a consecutive sampling method, whole blood was collected from consenting participants by trained phlebotomists, and serum/plasma were separated and stored in the biobank of the *Institut de Recherche sur l'Elevage pour le Développement* (IRED; Livestock Research Institute for Development) of N'Djamena, Chad.

Laboratory procedures

Rapid test procedure

The Genrui IgG/IgM rapid test kit was processed according to the manufacturer's instructions. The test sample and reagents required for storage were brought to room temperature. The test card was then removed from its packaging and placed flat on a dry surface. For the serum/plasma sample, 10 µL of serum or plasma was added to the sample well, followed by the vertical addition of 4 drops (approximately 100 µL) of sample diluent. After adding the sample, the results were reported within 15 minutes as either reactive (presence of anti-SARS-CoV-2 antibody) or non-reactive (absence of anti-SARS-CoV-2 antibody).

ELISA test procedure

For the ELISA processing, 100 µL/well of negative control was distributed into duplicate wells, 100 µL/well of positive control into a single well, and 100µL of sample diluent (buffer A) into duplicate wells. For the dilution of the samples, 2 µL of sample was distributed into 198 µL of buffer A (1:100) in sterile tubes, and the whole of the dilution was transferred into the appropriate wells; the plate was covered with aluminum foil and incubated at 37±1°C for 60±5 minutes; the microtiter plates were automatically washed five times with 350 µL of reconstituted buffer B. Before starting the wash phase, the washer was equilibrated with wash buffer B, and the plate was covered with aluminum foil and incubated at 37±1°C for 60±5 minutes. The second automatic washing of the microtiter strips was done five times as previously described, then 100 µL/well of ABTS™ solution was added and the plate incubated at room temperature (22-27°C) for 20±2 minutes. The absorbance was measured at a wavelength of 405±5 nm using a microplate reader, following a 3-second shaking of the plate prior to measurement. According to the manufacturer, the DIATHEVA COVID-19 IgG ELISA kit has a sensitivity of 98.80% with a positive predictive value (PPV) of 97.06% and a specificity of 98.02%.

Statistical analyses

The collected data were entered into Excel software and exported to SPSS_18.0 software for analysis. Proportions were estimated with confidence intervals. The p-value was calculated in order to determine the existence of a statistically significant link between the study variables. The results of the different tests were analyzed in a 2×2 table for the calculation of performance indicators such as sensitivity, specificity, and predictive values (positive and negative). The p-value ($p<0.05$) was calculated to determine the existence of a statistically significant relationship between the study variables.

Results

Socio-demographic data

In the 198 samples of the study, the female sex was the most represented, with a rate of 53.53% and 46.46% for men. According to age, the most represented population was between 16 and 60 years old (86%). All 198 samples were tested at LAGET using rapid diagnostic tests (RDTs) and ELISA. Most participants in the study were non-vaccinated (98.5%). People who have been in contact with a COVID-19 patient represented 25.3% (50/198),

and fever was the only COVID-19-related symptom observed in the study population.

Reactivity of ELISA IgG DIATHEVA on tested samples

The reference ELISA test gave a seropositivity of 84.8% (95% confidence interval [CI]: 79-89) (Table 1). This outcome indicated a high rate of anti-SARS-CoV-2 antibody reactivity within the study population.

Performance of GENRUI IgM/IgG

Seropositivity with the Genrui IgM/IgG test was 54% (95% CI: 47-60) (Table 2). These results revealed a sensitivity of 60% (95% CI: 57-62%) and a specificity of 80% (95% CI: 79-89) (Table 3). However, the extrinsic characteristics of the RDT showed 94% of the PPV of positive results obtained with IgG antibodies and 26% of the negative predictive value (NPV) from antibody-negative samples and a poor agreement (κ=0.22; $p<0.0001$) with the reference ELISA test.

Comparison of SARS-CoV-2 seropositivity and lessons learned

Neither age, gender, vaccine status, nor previous contact with positive cases were found to be associated with RDT or ELISA positivity (all $p>0.05$). With a 30.8% difference in positivity results, the RDT reported missing diagnostic opportunities of anti-SARS-CoV-2 antibodies, thereby supporting an algorithm of antibody screening starting with RDT. If the result is reactive, the individual can be considered positive for anti-SARS-CoV-2 antibodies, given the high PPV of the RDT (94%). However, if the result is non-reactive, further testing with ELISA is warranted to confirm serological status, due to the low NPV of the RDT (26%).

Discussion

Strong clinical performance of COVID-19 diagnostic tests and management is essential to rapidly contain the COVID-19 outbreak globally. Thus, the development of serological tests, systematically used in clinical laboratories to determine recent infection or previous contact with viruses, constitutes a good complementary option to the real-time polymerase chain reaction (RT-PCR) method.[10] The DIATHEVA COVID-19 IgG ELISA test was employed as the reference to evaluate the lateral flow immunochromatographic test (Genrui IgG, colloidal gold test kit), a serological test for the detection of total anti-N SARS-CoV-2 antibodies.

The present study shows a high IgG seroprevalence of 84.8% (95% CI: 79-89) with the ELISA test and a lower IgG seroprevalence of 54% (95% CI: 47-60) with RDT in this population. This result is similar to a study conducted in Omdurman in 2021,[11] in which the anti-SARS-CoV-2 seroprevalence was 54%. This concordance may be explained by the fact that Moser *et al.* also used RDTs to determine prevalence, as was done in the present evaluation. The literature reports that most rapid serological tests have lower sensitivity than ELISA.[12,13] The sensitivity of COVID-19 ELISA tests for IgG/IgM or IgG and IgM ranged from 75 to 93% depending on studies, while for rapid tests they ranged from 36 to 100%.[12,13] Also, the sensitivity and specificity of this RDT were 60% (95% CI: 57-62%) and 80% (95% CI: 62-91), respectively. This study adds to the body of evidence that such serological tests have a limited role in the acute diagnosis of COVID-19.[14] The apparent low sensitivity of serological tests is more pronounced in asymptomatic subjects than in symptomatic subjects. This is due to the fact that the production of SARS-CoV-2 antibodies would be greater in symptomatic subjects due to the higher reactivity of the infection, which is frequently associated with a higher viral concentration, higher antigen stimulation, and immune response.[15] These results are similar to those of Vásárhelyi *et al.*, who obtained even lower sensitivities of 33.30% and 35.48%, respectively, for the Ahui Deepblue® and Clungene® test kits.[16]

The clinical specificity reported in our study indicates a higher probability of the RDT in detecting negative samples accurately, with fewer false positive results. This is in accordance with several studies revealing better specificities of serological RDTs despite some variabilities. It is worth noting that some studies have reported specificities close to 98% (*i.e.*, WONDFO®) while others have reported specificities as low as 50%.[17] The specificity of the RDT assessed in our study consequently strengthens the PPV, which was 94% (95% CI: 89-97). This PPV denotes the likelihood that an individual who tested positive for the test genuinely possesses SARS-CoV-2 antibodies. The NPV of 26% (95% CI: 20-30) indicates the likelihood that individuals who received a negative result from the RDT lack any anti-SARS-CoV-2 antibodies.

In 2020, Vásárhelyi *et al.* found PPVs of 7.28% and 13.13% for Ahui Deepblue® and Clungene®, respectively,[16] which were far lower as compared to our study findings. Concordance between

Table 1. Results obtained with ELISA.

Results	Frequency	Percentage (%)
Negative	30	15.2
Positive	168	84.8
Total	198	100.0

Table 2. Distribution of RDT cases.

Results	Frequency	Percentage (%)
Negative	91	46.0
Positive	107	54.0
Total	198	100.0

Table 3. Evaluation of the RDT results according to the ELISA test.

RDT Result	ELISA Positive	ELISA Negative	Total	Sensitivity % (95% CI)	Specificity % (95% CI)
Positive	101	6	107	60 (57-62)	80 (62-91)
Negative	67	24	91		
Total	168	30	198		

RDT, rapid diagnostic test; ELISA, enzyme-linked immunosorbent assay; CI, confidence interval.

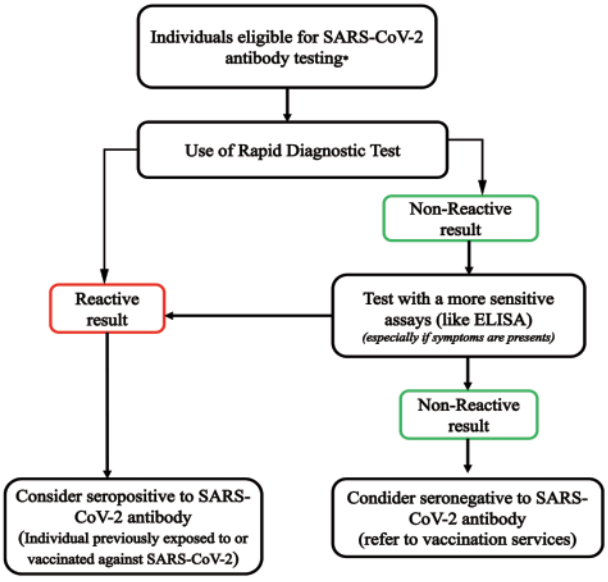

Figure 1. Diagnostic algorithm for SARS-CoV-2 during outbreak.*The proposed algorithm is valid to ascertain antibody circulation at the community level and could also be used for other emergent pathogens.

serological RDTs and the ELISA test was "moderate". This result was similar to that of an evaluation of two rapid tests whose κ-values are different (0.25, 0.1 and 0.03).[18]

This study emphasizes the potential role of RDTs in epidemic surveillance during an outbreak. It also revealed potential pitfalls in the interpretation of such RDT results while providing stronger evidence for the optimal utility of a reference assay like ELISA in a context of limited resources. Consequently, in standard clinical practice or epidemiological serosurveillance after virus exposure during an epidemic or post-vaccination, an evidence-based methodology for evaluating anti-SARS-CoV-2 antibodies in tropical environments should adhere to the subsequent algorithm: initiate testing with RDT; if a reactive result is obtained, interpret it as the presence of antibodies in the individual tested; if a non-reactive result is obtained, advance to a highly sensitive assay such as ELISA to confirm the individual's status (Figure 1).

Limitations of the study

The main limitation of this study was that serum samples were collected at one timepoint. As a result, the dynamics in antibody circulation per diagnostic assay could not be assessed over time. The intrinsic characteristics of the test obtained were lower compared with the performance presented by previous studies, hence calling for confirmatory investigations in tropical settings similar to the Central African region.

Conclusions

The Genrui IgM/IgG rapid test revealed a significantly lower performance for detecting anti-SARS-CoV-2 antibodies as compared to the gold standard ELISA. This highlights the necessity of employing ELISA on non-reactive RDT cases during serosurveys or post-vaccine response evaluation. Further studies in diverse tropical conditions will provide complementary or confirmatory findings.

References

1. World Health Organization (WHO). COVID-19 Public Health Emergency of International Concern (PHEIC) Global research and innovation forum [Internet]. Available from: https://www.who.int/publications/m/item/covid-19-public-health-emergency-of-international-concern-(pheic)-global-research-and-innovation-forum
2. Foundation for Innovative New Diagnostics (FIND). SARS-CoV-2 diagnostic pipeline [Internet]. Available from: https://www.finddx.org/covid-19/pipeline/
3. Santé Canada. [Screening tools for COVID-19: Overview]. 2020. Available from: https://www.canada.ca/fr/sante-canada/services/medicaments-produits-sante/covid19-industrie/instruments-medicaux/depistage.html
4. Amrun SN, Lee CYP, Lee B, et al. Linear B-cell epitopes in the spike and nucleocapsid proteins as markers of SARS-CoV-2 exposure and disease severity. EBioMedicine 2020;58:102911.
5. Guery B, Alfandari S, Leroy O, et al. [Severe acute respiratory syndrome]. Med Mal Infect 2003;33:281□6.
6. Cohen JF, Korevaar DA, Altman DG, et al. STARD 2015 guidelines for reporting diagnostic accuracy studies: explanation and elaboration. BMJ Open 2016;6:e012799.
7. Dellière S, Salmona M, Minier M, et al. [Evaluation of rapid diagnostic test COVID-19 IgG/IgM (Orient Gene Biotech)]. Med Mal Infect 2020;50:S73-4.
8. Ernst E, Wolfe P, Stahura C, Edwards KA. Technical considerations to development of serological tests for SARS-CoV-2. Talanta 2021;224:121883.
9. Weitzel T, Legarraga P, Iruretagoyena M, et al. Head-to-head comparison of four antigen-based rapid detection tests for the diagnosis of SARS-CoV-2 in respiratory samples. bioRxiv 2020;2020.05.27.119255.
10. Yongchen Z, Shen H, Wang X, et al. Different longitudinal patterns of nucleic acid and serology testing results based on disease severity of COVID-19 patients. Emerg Microbes Infect 2020;9:833-6.
11. Moser W, Fahal MAH, Abualas E, et al. SARS-CoV-2 Antibody Prevalence and Population-Based Death Rates, Greater Omdurman, Sudan. Emerg Infect Dis 2022;28:1026-30.
12. Lisboa Bastos M, Tavaziva G, Abidi SK, et al. Diagnostic accuracy of serological tests for covid-19: systematic review and meta-analysis. BMJ 2020;370:m2516.
13. Deeks JJ, Dinnes J, Takwoingi Y, et al. Antibody tests for identification of current and past infection with SARS-CoV-2. Cochrane Database Syst Rev 2020;6:CD013652.
14. Teymouri M, Mollazadeh S, Mortazavi H, et al. Recent advances and challenges of RT-PCR tests for the diagnosis of COVID-19. Pathol Res Pract 2021;221:153443.
15. Al-Jighefee HT, Yassine HM, Al-Nesf MA, et al. Evaluation of Antibody Response in Symptomatic and Asymptomatic COVID-19 Patients and Diagnostic Assessment of New IgM/IgG ELISA Kits. Pathogens 2021;10:161.
16. Vásárhelyi B, Kristóf K, Ostorházi E, et al. [The diagnostic value of rapid anti IgM and IgG detecting tests in the identification of patients with SARS CoV-2 virus infection]. Orv Hetil 2020;161:807-12.

17. Montolio Breva S, Molina Clavero C, Gómez Bertomeu F, et al. Evaluation of five immunoassays and one lateral flow immunochromatography for anti-SARS-CoV-2 antibodies detection. Enferm Infecc Microbiol Clin (Engl Ed) 2021;40:489-94.
18. Ngaba GP, Kalla GCM, Assob JCN, et al. [Evaluation of two COVID-19 antigen diagnostic tests: BIOSYNEX® COVID-19 Ag BSS and BIOSYNEX® COVID-19 Ag+ BSS compared to PCR AmpliQuick® SARS-CoV-2]. Pan Afr Med J 2021;39:228.