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Evaluation of a Rapid Diagnostic Test, Boson Biotech SARS CoV-2 Ag, for the Detection of SARS-CoV-2 in Gabon

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Abstract

1) Background: Rapid and acurate diagnostic testing for case identification, quarantine, and contact tracing is essential for managing the COVID 19 pandemic. Rapid antigen detection tests are available, however, it is important to evaluate their performances before use. We tested a rapid antigen detection of SARS-CoV-2, based on the immunochromatography (Boson Biotech SARS-CoV-2 Ag Test (Xiamen Boson Biotech Co., Ltd., China)) and the results were compared with the real time reverse transcriptase-Polymerase chain reaction (RT-PCR) (Gold standard) results; 2) Methods: From November 2021 to December 2021, samples were collected from symptomatic patients and asymptomatic individuals referred for testing in a hospital during the second pandemic wave in Gabon. All these participants attending "CTA Angondjé", a field hospital set up as part of the management of COVID-19 in Gabon. Two nasopharyngeal swabs were collected in all the patients, one for Ag test and the other for RT-PCR; 3) Results: A total of 300 samples were collected from 189 symptomatic and 111 asymptomatic individuals. The sensitivity and specificity of the antigen test were 82.5% [95%CI 73.8 - 89.3] and 97.9 % [95%CI 92.2 - 98.2] respectively, and the diagnostic accuracy was 84.4% (95% CI: 79.8 - 88.3%). The antigen test was more likely to be positive for samples with RT-PCR Ct values ≤ 32, with a sensitivity of 89.8%; 4) Conclusions: The Boson Biotech SARS-CoV-2 Ag Test has good sensitivity and

can detect SARS-CoV-2 infection, especially among symptomatic individuals with low viral load. This test could be incorporated into efficient testing algorithms as an alternative to PCR to decrease diagnostic delays and curb viral transmission.

Keywords

SARS-CoV-2, Rapid Diagnostic Test, Evaluation, COVID-19, Antigen, Performance

1. Introduction

In Gabon, the detection of SARS-CoV-2 commenced in March 2020 with the report of the first case in Libreville, the capital city of Gabon [1]. The RT-PCR remained the gold standard for laboratory confirmation of infection [2] [3] [4]. To increase the testing capacity in the country, all the public hospitals were equipped for the detection of SARS-CoV-2 by RT-PCR. However, the diagnostic period of 24 to 72 H and the huge demand in the country, prolong the period of isolation and also increases the risk of transmission of the virus in the population.

To control the COVID-19 pandemic, improvement of detection with easy, rapid, and cost-efficient approaches is urgently required [5] [6]. Thus, the national strategy was modified and antigenic testing was included. However, doubts about the quality of the rapid test result are one of the obstacles to its acceptance and the emergence of new SARS-CoV-2 strains, has promoted the development of several antigenic tests for SARS-CoV-2 detection [7]. According to the World Health Organization (WHO) a test should be verified in a given population and setting before its implementation [8] [9]. In Gabon, the evaluation of the performance of the SARS-CoV-2 antigenic testing is obligatory before its introduction and use in the country. The Boson Rapid SARS-CoV-2 Antigen Test Card (Xiamen Boson Biotech Co. Ltd, Fujian, P.R. China) is designed for the rapid qualitative detection of SARS-CoV-2 virus antigen in nasal swabs (NS) at 15 to 20 minutes, from individuals suspected of COVID-19.

This study was designed to evaluate the performance characteristics of the Boson Biotech SARS-CoV-2 Ag Test (Xiamen Boson Biotech Co., Ltd., China) compared with RT-PCR using nasopharyngeal swabs.

2. Materials and Methods

2.1. Specimen Collection and Selection Criteria

From November 2021 to December 2021, samples were collected from symptomatic patients suspected of having SARS-CoV-2 infection and from asymptomatic individuals, those without clinical signs, during the second pandemic wave in Gabon. All these individuals were coming for mass diagnosis at "CTA An-

gondjé", a field hospital set up as part of the management of COVID-19 in Gabon.

Two nasopharyngeal swabs were collected, one in each nostril by trained personnel. The first swab was immediately tested using the Boson Biotech Ag Test according to the manufacturer's guidelines and the second sample was placed in a 3mL of viral transport medium, stored and transported at 4˚C to the PCR laboratory "Professeur Daniel Gahouma", located at the same town, for extraction and RT-PCR test. The team conducting the Ag test was different from that carrying out the molecular tests.

The criteria for including participants were: a) Symptomatic individuals (within 7 days of onset) who were suspected of COVID-19. b) Asymptomatic individuals without a known SARS-CoV-2 exposure. The main criteria for exclusion from the study were: 1) individuals with nose-bleeds; 2) Unable to provide an informed consent form due to various disabilities.

2.2. Rapid Antigen Test

Boson Biotech Ag Test is a qualitative membrane-based immunoassay for the detection of nucleocapsid protein of SARS-CoV-2 in the nasopharyngeal samples. The results are available within 15 min.

The test was performed by two different trained personnel. The second reader doesn't know the result of the other. In the case of discrepant results, both of them re-interpreted the results and agreed on the final result. The test was considered positive if the control was reactive and any intensity was observed at the test band. No invalid Ag-RTD results occurred.

2.3. RNA Extraction and RT-PCR Analysis

Viral RNA was isolated from the specimens by using the MGISP-960 automatic system (Wuhan MGI Tech Co. Ltd., China). One-step RT-PCR was performed using the MA 6000 system (BGI, China) with the Novel Coronavirus (2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence probing, Sansure Bio Tech Inc.) targeting ORF 1ab and the N gene. According to this method, a sample was declared positive when the cycle threshold (Ct) value of the target ORF 1ab and/or N genes was ≤40.

2.4. Statistical Methods

2.4.1. Sensitivity, Specificity and Predictive Values

Ag-RDT sensitivity and specificity and their 95% confidence intervals (95% CIs) were calculated relative to RT-PCR results which was considered the gold standard for this evaluation and, expressed as a percentage. Sensitivity (Se) was the proportion of positive results among PCR-confirmed SARS-CoV-2 infections and specificity (Sp) was the proportion of negative results among participants tested negative by PCR. Accuracy, positive and negative predictive values were also calculated for the Gabonese population (for seroprevalence of SARS-CoV-2 in the country

of 86.1%) with MedCalc Statistical software v19.3.

2.4.2. Comparison of Ct with Antigen Assay Results

Ct values were categorized as strongly positive (Ct ≤ 32) and weakly positive (Ct = 33 - 37), and compared with the Boson Biotech Ag Test results. Fischer's exact test was used to compare the results obtained. Statistical significance was defined as $p < 0.05$.

3. Results

3.1. Global Performance of Boson Biotech Rapid SARS-CoV-2 Ag Test

A total of 300 participants were included in this study: 189 (63%) were symptomatic and 111 (37%) were asymptomatic. One hundred and three (34.3%) tested positive with our gold standard and 93 (31%) tested positive with the evaluated Ag-RDT.

The overall sensitivity and specificity of the evaluated Ag-RDT were 82.5% [95%CI 73.8 - 89.3] and 97.9 % [95%CI 92.2 - 98.2] respectively. The diagnostic accuracy for a prevalence of 86.1% according to the nationwide seroepidemiological study conducted in the country after the peak of the second wave in 2021 (not yet published) was 84.4% (95% CI: 79.8% - 88.3%). The positive predictive value was 99.2% (95% CI: 98.5% - 99.6%) and the negative predictive value was 47% (95% CI: 36.8% - 54.4%). Of the 189 symptomatic participants, 82 tested positive by PCR and 78 by antigen-based diagnostic test (**Table 1**). Sensibility and specificity among symptomatic patients were 85.4% [95%CI 75.8 - 92.2] and 92.5% [95%CI 85.8 - 96.7] respectively. The diagnostic accuracy was 86.4% (95% CI: 80.6% - 90.9%). The positive predictive value was 98.6% (95% CI: 97.3% - 99.3%) and the negative predictive value was 50.5% (95% CI: 37.6% - 63.3%).

For 111 asymptomatic individuals, 21 participants tested positive by PCR and 15 by antigen-based diagnostic test. Sensibility and specificity among asymptomatic patients were 71.4% [95%CI 47.8 - 88.7] and 100% [95%CI 96.0 - 100] respectively. The diagnostic accuracy was 75.4% (95% CI: 66.3% - 83.1%). The positive predictive value was 100% and the negative predictive value was 36.1% (95% CI: 22.3% - 52.6%).

Table 1. Diagnostic performance of the Boson Biotech Rapid SARS-CoV-2 Ag test, among symptomatic and asymptomatic groups.

BOSON Biotech Rapid SARS-CoV-2 Ag test	qRT-PCR test results				Total, N (%)
	Symptomatic group		Asymptomatic group		
	Positive, N (%)	Negative, N (%)	Positive, N (%)	Negative, N (%)	
Positive, N (%)	70 (85.4)	8 (7.5)	15 (71.4)	0 (0)	93 (31.0)
Negative, N (%)	12 (14.6)	99 (92.5	6 (28.6)	90 (100)	207 (69.0)
Total, N (%)	82 (43.4)	107 (56.6)	21(18.9)	90 (81.1)	300 (100.0)

Table 2. Boson Biotech Ag Test results compared with Ct value categories.

BOSON Biotech Rapid SARS-CoV-2 Ag test result	RT-PCR Ct Value Category		Total
	Strongly positive (Ct ≤ 32)	Weakly positive (Ct = 33 - 37	
Positive, N (%)	79 (89.8)	06 (40)	85 (82.5)
Negative, N (%)	09 (10.2)	09 (60)	18 (17.5)
Total, N (%)	88 (85.4)	15 (14.6)	103 (100)

3.2. Associations between Ct Values and Boson Biotech Ag Test Results

Overall, the mean Ct value among positive people with PCR test was 26.1 (range, 17.5 - 35.2), among those who tested positive with both diagnostic tests (PCR and Ag), the mean Ct value was 25.0 (range, 17.5 - 31.6) and, in those who tested negative with Ag and positive with PCR, it was rather 31.3 (range, 29.3 - 34.9). The associations between the Ct values and Boson Biotech Ag Test results are shown in Table 2. When compared to the Ct values, sensitivity was significantly reduced in subgroup of samples with Ct values indicating lower viral loads, where only 40% of the specimens with weak positive qRT-PCR results were positive according to the Boson Biotech Ag Test. Among the strong positive qRT-PCR results, 89.8% of the specimens were positive with the antigen test ($p < 0.0001$).

4. Discussion

Mass testing is becoming increasingly important for the Gabon's strategy to fight against COVID-19. In this strategy, apart from sample pooling procedure which was used as a strategy to conserve diagnostic resources and to increase the testing capacity for Gabon [10], Ag testing for SARS-CoV-2 detection seems to be a credible alternative. Indeed, this procedure has main advantages including rapidity, ease of interpretation, limited technical skills and infrastructure required and could constitute an alternative to PCR. However, it is important to test the diagnostic performance of a rapid antigenic test before using it in a country [11] [12].

This study evaluated the diagnostic accuracy of the Boson Biotech Rapid SARS-CoV-2 Antigen Test against the reference reagent Novel Coronavirus (2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence probing, Sansure Bio Tech Inc.) targeting ORF 1ab and the N gene. The study was conducted on 300 individuals, both symptomatic and asymptomatic. To the best of our knowledge, this is the first study evaluating the performance of this test in Africa.

In this study, the Boson Biotech evaluated identified 82.5% of RT-PCR positive sample with a specificity of 95.9%. According to the WHO interim guidance [13] [14] regarding the use of antigen RDTs for patient management (sensitivity is ≥80% and specificity ≥ 97%), this test exhibits adequate performance. However, the sensitivity and the specificity of the Boson Biotech SARS-CoV-2 Ag test (Se: 82.5% and Sp: 97.9%) reported here were both lower than that reported by

the manufacturer (Se: 96.77% and Sp: 99.20%) [15]. The findings of this current study align with those reported in Greece (Europa) with a sensitivity and specificity of 98.18% and 100% respectively [16]. This fact highlighted the importance of independent evaluation before implementation.

In symptomatic individuals, the sensitivity (85.4%) was higher than that reported among asymptomatic counterparts (71.4%). A possible explanation could be that symptomatic patients do not systematically present themselves to the hospital or to a test center due to the absence of signs, unlike symptomatic patients. This could therefore favor the screening of this category of patients when the viral load is relatively low [17].

The VPN was lower in the two groups of participants with 50.5% for symptomatic individuals and 36.1% for asymptomatic counterparts. These findings suggest that individuals with negative antigen test results are likely to be infected with SARS-CoV-2 and would require confirmatory NAAT.

As might be expected, the performance of this antigen RDT diminished when the Ct was high. Indeed, most participants (40.0%) with high PCR Ct values tested negative using antigen-based rapid diagnostic testing. This finding is consistent with some studies that reported that the positivity of Rapid Ag test decreases as viral shedding decreases [17] [18] [19] [20]. However, in this study, the majority of participants (89.8%) with low Ct tested positive for antigen RDT. An important aspect is that antigen RDT is important and able to identify infected individuals that have high viral load and could spread the virus [21]. It appears that the performance characteristics (low-high) of Boson Biotech, would depend largely on the infectious status of the individuals (low-high viral loads) and the disease prevalence at the time of testing (low-high).

Moreover, the Boson Biotech test exhibited a 71.4% sensitivity ratio for asymptomatic patients. Improved diagnostic time is critically important, especially in remote locations.

It is important to mention some limitations of the current study, which could influence the interpretation of results. The current evaluation of the performance of Boson Biotech rapid test did not consider the variants circulation in Gabon during the study period. The variation in test sensitivity observed could be linked to the heterogeneity of the SARS-CoV-2 variants circulation in the country. However, we think that this limitation is counterbalanced by the inclusion of a large number of individuals according to the country's population.

5. Conclusions

Boson Biotech Ag Test can detect SARS-CoV-2 infection with high sensitivity particularly when performed on samples high viral load. However, our analysis also highlights the variability in results between tests (which is not reflected in the manufacturer-reported data), indicating the need for independent validations. Boson Biotech Ag Test can be used for the diagnosis of SARS-CoV-2 in our context and can be an important contribution in the context of mass screening

and screening in remote areas lacking diagnostic tools.

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Institutional Review Board Statement

The study was conducted in accordance with the Declaration of Helsinki, and approved by the Coronavirus Surveillance and Response Plan Committee (COPIL-Coronavirus), Ministry of Public Health (n°008/PM du 25 février 2020). To keep confidentiality all specimens were not tied to personal identity.

Informed Consent Statement

The objectives and benefits of the study were explained to all participants and their consent to participate in the study was obtained.

Conflicts of Interest

The authors declare no conflict of interest.

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