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Diagnostic Performance of the Determine™ HBsAg Rapid Test for the Detection of Hepatitis B Surface Antigen in a Rural Population in Burkina Faso

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Abstract

Introduction: Hepatitis B virus (HBV) infection remains a major public health challenge in sub-Saharan Africa. In resource-limited settings, rapid diagnostic tests provide an alternative to automated assays. This study aimed to evaluate the diagnostic performance of the Determine™ HBsAg rapid test for the detection of hepatitis B surface antigen (HBsAg) in a rural setting in Burkina Faso. **Methods:** A cross-sectional diagnostic accuracy study was conducted from April to June 2021 in Moussodougou, Burkina Faso. The Determine™ HBsAg test results from 770 participants were compared with those obtained using the Architect® system (Abbott), which served as the reference standard. Sensitivity, specificity, positive and negative predictive values, diagnostic accuracy, and Cohen's kappa coefficient were calculated. **Results:** The prevalence of HBsAg was 8.70% with the Determine™ HBsAg test and 9.61% with the Architect® assay. The rapid test identified 67 true-positive, 696 true-negative, seven false-negative, and no false-positive results. Sensitivity was 90.54% (95% CI: 81.48 - 96.11), specificity was 100% (95% CI: 99.47 - 100), the positive predictive value was 100% (95% CI: 94.64 - 100), the negative predictive value was 99.00% (95% CI: 97.96 - 99.60), diagnostic accuracy was 99.09% (95% CI: 98.14 - 99.63), and Cohen's kappa coefficient was 0.9454 (95% CI: 0.8748 - 1.0000). **Conclusion:** The Determine™ HBsAg rapid test demonstrated excellent diagnostic performance and is a reliable tool for HBV screening in rural settings. Its excellent specificity and strong agreement with the Architect® assay

support its use in decentralized HBV screening strategies in resource-limited settings.

Keywords

Hepatitis B, HbsAg, Determine™ HbsAg, Architect®, Diagnostic Performance, Burkina Faso

1. Introduction

Hepatitis B virus (HBV) infection remains a major global public health challenge. According to the World Health Organization (WHO), an estimated 254 million people were living with chronic HBV infection in 2022, and approximately 1.1 million deaths each year are attributable to HBV-related complications, mainly cirrhosis and hepatocellular carcinoma [1]. Despite the availability of a safe and effective vaccine for several decades, HBV transmission remains high in many parts of the world, particularly in sub-Saharan Africa, where the infection remains highly endemic.

Burkina Faso is among the countries with a high HBV burden. Previous studies have reported hepatitis B surface antigen (HBsAg) prevalence rates ranging from 8% to 12% in the general population [2] [3]. This high prevalence poses a substantial challenge to the healthcare system because of the morbidity and mortality associated with chronic liver disease. Early identification of infected individuals is therefore essential to improve patient management, prevent ongoing transmission, and support the achievement of the WHO target of eliminating viral hepatitis as a public health threat by 2030 [4].

Detection of HBsAg is the cornerstone of chronic HBV diagnosis. Automated immunoassays, such as the Architect® system (Abbott), are considered the reference standard because of their excellent diagnostic performance. However, their implementation requires well-equipped laboratories, trained personnel, and substantial financial resources, limiting their availability in rural and peripheral healthcare facilities [5].

Rapid diagnostic tests (RDTs) offer a practical alternative in resource-limited settings. They are easy to use, affordable, and do not require sophisticated laboratory equipment, thereby expanding access to HBV screening in underserved populations. Among these, the Determine™ HBsAg rapid test (Abbott) has been widely used in several African countries. Nevertheless, the diagnostic performance of RDTs may vary according to the study population, field conditions, and epidemiological context. Consequently, international guidelines recommend local validation before large-scale implementation [6].

In the Cascades region of Burkina Faso, data on the field performance of the Determine™ HBsAg rapid test remain scarce. This study, therefore, aimed to evaluate the diagnostic performance of the Determine™ HBsAg rapid test for detect-

ing HBsAg, using the Architect® system as the reference standard, in a rural population from Moussodougou, Burkina Faso.

2. Methods

2.1. Study Design and Setting

A cross-sectional diagnostic accuracy study was conducted from April to June 2021 in the rural municipality of Moussodougou, located in the Comoé Province of the Cascades Region, southwestern Burkina Faso. Community sensitization, participant recruitment, and blood sample collection were carried out at the primary healthcare centers (Centres de Santé et de Promotion Sociale, CSPS) of the four main villages: Moussodougou, Mondon, Kolokolo, and Diamon. Laboratory analyses were performed at the Immunology Laboratory of the National Centre for Malaria Research and Training (CNRFP) in Banfora for Determine™ HBsAg rapid test and the Hematology and Immunology Laboratory of Souro Sanou University Teaching Hospital (CHUSS) in Bobo-Dioulasso for Architect® Ci4100 analysis.

2.2. Study Population

The study population consisted of residents of Moussodougou who voluntarily participated in a community-based hepatitis B screening campaign. Community awareness sessions on HBV infection were organized before participant recruitment. Individuals who agreed to participate received individual pre-test counselling before enrollment.

Eligible participants were residents of the study area who provided informed consent. For participants younger than 18 years, consent was obtained from a parent or legal guardian. Participants were consecutively enrolled throughout the study period. No prior sample size calculation was performed, and all eligible volunteers were included, resulting in a final sample of 770 participants.

2.3. Sample Collection

Approximately 4 mL of venous blood was collected from each participant into dry tubes. Blood samples were transported from the collection sites to the laboratory of the National Centre for Malaria Research and Training (CNRFP), Banfora, under a controlled temperature of +4˚C to +8˚C. Following centrifugation at 5,000 rpm for 10 minutes, serum was aliquoted into two cryovials (a primary and a backup aliquot) for each participant. The primary aliquots were stored at −80˚C at the CNRFP laboratory and were used for the Determine™ HBsAg analyses. The backup aliquots were transported under refrigerated conditions (+4˚C to +8˚C) to the laboratory of the Souro Sanou University Hospital (CHUSS), where they were stored at −80˚C until quantitative HBsAg testing was performed using the Abbott ARCHITECT immunoassay system.

2.4. HBsAg Detection Using the Determine™ Rapid Test

HBsAg was qualitatively detected using the Determine™ HBsAg rapid test (Ab-

bott, Japan), an immunochromatographic lateral-flow sandwich assay. Briefly, 50 µL of serum was applied to the sample pad, and results were interpreted within the manufacturer's recommended reading time. A test was considered positive when both the control and test lines were visible, negative when only the control line appeared, and invalid when the control line was absent.

2.5. HBsAg Quantification Using the Architect® Assay

All serum samples were also analyzed using the Architect® HBsAg assay (Abbott Diagnostics), which served as the reference standard. HBsAg was quantified using a chemiluminescent microparticle immunoassay (CMIA). In this assay, HBsAg binds to anti-HBs-coated paramagnetic microparticles and is subsequently detected using an acridinium-labeled conjugate. The emitted chemiluminescent signal is proportional to the HBsAg concentration and is automatically measured by the analyzer. For internal quality control, one negative control and one positive control were analyzed with each analytical run on the Abbott ARCHITECT Ci4100 system. The analytical run was considered valid only when the control results fell within the acceptable ranges specified by the manufacturer. The unit of measurement was the International Unit per milliliter (IU/mL). The analytical measuring range was 0.05 - 250 IU/mL (50 - 250,000 mIU/mL). An automatic dilution system was used to analyze samples with concentrations exceeding the analytical measuring range. Samples with HBsAg concentrations ≥ 0.05 IU/mL were classified as positive, whereas those with HBsAg concentrations < 0.05 IU/mL were classified as negative. All analyses were performed according to the manufacturer's instructions and the laboratory's standard operating procedures.

2.6. Statistical Analysis

Data were entered into Microsoft Excel, and statistical analyses were performed using R software version 4.5.1 (R Foundation for Statistical Computing, Vienna, Austria). Quantitative variables were summarized as means ± standard deviations, medians, and ranges, whereas qualitative variables were presented as frequencies and percentages.

The diagnostic performance of the Determine™ HBsAg rapid test was assessed using the Architect® assay as the reference standard. Sensitivity, specificity, positive predictive value, negative predictive value, and overall diagnostic accuracy were calculated with their corresponding 95% confidence intervals (95% CI). Agreement between the two methods was evaluated using Cohen's kappa coefficient and interpreted according to the Landis and Koch classification as poor ($\kappa < 0.20$), fair (0.21 - 0.40), moderate (0.41 - 0.60), substantial (0.61 - 0.80), or almost perfect ($\kappa > 0.80$). Statistical significance was set at $p < 0.05$.

2.7. Ethical Considerations

The community screening activities carried out in 2021 were conducted under

administrative authorizations issued by the competent health authorities. For the subsequent scientific use of the collected data, authorization to use the data was requested from and granted by the Ethics Committee of the Souro Sanou University Hospital prior to the conduct of this study (Approval No. CEI/CHUSS-2025/2026, issued on April 10, 2026).

Participation was entirely voluntary and was subject to the provision of informed consent. For participants younger than 18 years, informed consent was obtained from a parent or legal guardian.

To ensure confidentiality, each participant was assigned a unique, anonymous identification code. All collected data were used exclusively for scientific research purposes.

Individual test results were communicated confidentially to each participant. Participants who tested negative received counselling on hepatitis B prevention and were referred for hepatitis B vaccination. Those who tested positive for HBsAg were referred to appropriate healthcare facilities for further clinical evaluation and management.

3. Results

3.1. Characteristics of the Study Population

A total of 770 participants were enrolled in the study. The mean age was 33.6 years ± 19.6 years (range: 1 - 85 years), with a median age of 33 years. Females accounted for 60.9% (469/770) of the study population, yielding a male-to-female ratio of 0.64. More than half of the participants (53.8%) were recruited from Moussodougou village, and housewives represented the largest occupational group (45.8%) (Table 1).

Table 1. Sociodemographic characteristics of the study participants.

Variables	n	Frequency (%)
Age Group (Years)		
<15	176	22.86
15 - 50	**428**	**55.58**
51 - 70	139	18.05
>70	27	3.51
Sex		
Male	301	39.09
Female	**469**	**60.91**
Place of Residence		
Diamon	147	19.09
Kolokolo	111	14.42
Mondon	98	12.73
Moussodougou	**414**	**53.77**

Continued

Occupation		
Housewife	**353**	**45.84**
Farmer	197	25.58
Student	163	21.17
Other	57	7.40

Mean age (years): 33.59221; Age range (years): 1 - 85; Median age (years): 33; Standard deviation (years): 19.58789.

3.2. HBsAg Prevalence

The Determine™ HBsAg rapid test detected HBsAg in 67 of the 770 participants, corresponding to a prevalence of 8.70% (95% CI: 6.81 - 10.92). Using the Architect® assay as the reference standard, 74 participants tested positive, giving an HBsAg prevalence of 9.61% (95% CI: 7.62 - 11.91) (Table 2).

Table 2. Prevalence of HBsAg positivity according to the diagnostic method.

Diagnostic Method	n	Frequency (%)	95% CI
Determine™ HBsAg Rapid Test			
Negative	703	91.29	89.08 - 93.19
Positive	67	**8.70**	6.81 - 10.92
Total	**7**70	100	
Architect® Assay			
Negative	696	90.39	88.09 - 92.38
Positive	74	**9.61**	7.62 - 11.91
Total	**7**70	100	

3.3. Agreement between Determine™ HBsAg and the Architect® Assay

Among the 770 samples analyzed, 67 tested positive, and 696 tested negative with both methods. Seven samples that were positive with the Architect® assay were not detected by the Determine™ HBsAg rapid test, corresponding to false-negative results. No false-positive results were observed (Table 3).

Table 3. Agreement between the Determine™ HBsAg rapid test and the Architect® assay.

	Determine™ HBsAg Rapid Test		
Architect® Assay (Reference Method)	Positive	Negative	Total
Positive	67	7	74
Negative	0	696	696
Total	67	703	770

3.4. Diagnostic Performance of the Determine™ HBsAg Rapid Test

Using the Architect® assay as the reference standard, the Determine™ HBsAg rapid test showed a sensitivity of 90.54% (95% CI: 81.48 - 96.11) and a specificity of 100% (95% CI: 99.47 - 100). The positive predictive value was 100%% (95% CI: 94.64 - 100), the negative predictive value was 99.00% (95% CI: 97.96 - 99.60), and the overall diagnostic accuracy was 99.09% (95% CI: 98.14 - 99.63). Agreement between the two methods was almost perfect, with a Cohen's kappa coefficient of 0. 9454 (95% CI: 0.8748 - 1.0000) according to the Landis and Koch classification (Table 4).

Table 4. Diagnostic performance of the Determine™ HBsAg rapid test compared with the Architect® assay.

Performance Measure	Determine™ HBsAg % (95% CI)
Sensitivity	90.54 (81.48 - 96.11)
Specificity	100 (99.47 - 100)
Positive Predictive Value (PPV)	100 (94.64 - 100)
Negative Predictive Value (NPV)	99.00 (97.96 - 99.60)
Overall Diagnostic Accuracy	99.09 (98.14 - 99.63)
Cohen's Kappa Coefficient	0. 9454 (95% CI: 0.8748 - 1.0000)

3.5. Distribution of Quantitative HBsAg Levels

Among the 74 HBsAg-positive participants identified by the Architect® assay, most (53/74; 71.6%) had HBsAg concentrations ≥ 1,001 units, whereas seven participants (9.5%) were classified in each of the following categories: [0.01 - 5.99], [6.00 - 100.99], and [101.00 - 1000.99] units. Overall, most infected participants had relatively high HBsAg concentrations. We also observed that the seven discordant subjects had antibody levels within the 0.01 - 5.99 IU/mL range.

4. Discussion

This study evaluated the diagnostic performance of the Determine™ HBsAg rapid test for detecting hepatitis B surface antigen (HBsAg) in a rural population in Burkina Faso, using the Architect® assay as the reference standard. Overall, the Determine™ HBsAg rapid test demonstrated excellent diagnostic performance, with high sensitivity (90.54%), perfect specificity (100%), high predictive values, an overall diagnostic accuracy of 99.09%, and near-perfect agreement with the reference assay (κ = 0.95). These findings support the World Health Organization (WHO) recommendations promoting the use of validated rapid diagnostic tests to expand hepatitis B screening in resource-limited settings [1] [4].

The sensitivity observed in this study indicates that the Determine™ HBsAg rapid test correctly identified more than nine out of ten HBsAg-positive individuals. Although slightly lower than the manufacturer's reported performance, this

value remains consistent with WHO recommendations and with findings from previous evaluations reporting sensitivities ranging from 85% to 100% and specificities above 98% for HBsAg rapid diagnostic tests [4] [7] [8]. The seven false-negative results observed in our study may be explained by low circulating HBsAg concentrations, a limitation previously described in diagnostic evaluation studies and acknowledged in WHO guidelines on hepatitis B testing [4] [7].

One of the main strengths of the Determine™ HBsAg rapid test was its perfect specificity. No false-positive results were identified among the 770 participants, indicating that every positive rapid test result was confirmed by the reference assay. This finding is consistent with previous studies conducted in highly endemic settings, which also reported excellent specificity for immunochromatographic HBsAg assays [7] [9]. High specificity is particularly valuable in community-based screening programs because it minimizes unnecessary confirmatory testing and reduces the psychological and economic consequences of false-positive diagnoses.

The positive predictive value of 100% further confirms the reliability of positive Determine™ HBsAg results, while the negative predictive value of 99.00% demonstrates the test's excellent ability to exclude HBV infection among individuals with negative results. These findings support the use of the Determine™ HBsAg rapid test in decentralized screening programs, particularly in rural and resource-constrained settings where access to automated laboratory platforms remains limited [1] [4].

Agreement between the Determine™ HBsAg rapid test and the Architect® assay was almost perfect ($\kappa = 0.95$) according to the Landis and Koch classification [10]. Similar levels of agreement have been reported in studies conducted in sub-Saharan Africa, confirming the reliability of the Determine™ HBsAg rapid test under routine field conditions [11] [12]. Minor differences in diagnostic performance reported across studies may reflect variations in HBV prevalence, circulating viral genotypes, HBsAg concentrations, and test storage or operating conditions [7] [13].

Beyond its diagnostic performance, the Determine™ HBsAg rapid test offers several practical advantages, including ease of use, rapid turnaround time, affordability, and the absence of sophisticated laboratory requirements. These characteristics make it particularly suitable for peripheral health facilities and community-based screening campaigns in rural Burkina Faso. Expanding access to reliable HBV screening is one of the key pillars of the WHO strategy for eliminating viral hepatitis as a public health threat by 2030, especially in low-resource settings where automated diagnostic platforms remain scarce [1] [14].

This study has some limitations. First, the study was conducted in a single rural municipality, and participants self-selected for community screening following awareness campaigns, which could limit the generalizability of the results. Second, only HBsAg detection was evaluated, without additional serological or molecular markers that could have provided a more comprehensive assessment of HBV infection. Finally, factors associated with the discordant results between the two as-

says were not investigated. Nevertheless, this study provides valuable evidence on the field performance of the Determine™ HBsAg rapid test in a rural African setting, where data remain limited [11] [12].

Overall, our findings demonstrate that the Determine™ HBsAg rapid test is a reliable tool for HBV screening in rural settings. Its excellent specificity, high sensitivity, outstanding predictive values, and almost perfect agreement with the Architect® assay support its integration into HBV screening and surveillance programs in Burkina Faso and other resource-limited countries.

5. Conclusions

This study demonstrated that the Determine™ HBsAg rapid test has excellent diagnostic performance for the detection of hepatitis B surface antigen (HBsAg) in a rural population of Burkina Faso. Compared with the Architect® assay, used as the reference standard, the Determine™ HBsAg rapid test achieved a sensitivity of 90.54%, a specificity of 100%, a positive predictive value of 100%, a negative predictive value of 99.00%, and an almost perfect diagnostic agreement (κ = 0.95).

These diagnostic performances, combined with the simplicity, affordability, and rapid turnaround time of the Determine™ HBsAg rapid test, support its use in community-based screening programs and peripheral healthcare facilities where access to automated diagnostic platforms remains limited.

Expanding decentralized HBV screening through the use of reliable rapid diagnostic tests could improve the early identification of infected individuals and accelerate progress toward the World Health Organization's 2030 hepatitis elimination targets. Nevertheless, multicentre studies incorporating molecular confirmatory methods are warranted to further assess the diagnostic performance of the Determine™ HBsAg rapid test across different epidemiological settings in Burkina Faso.

Declarations

1) What Is Known about This Topic

Hepatitis B virus infection remains highly endemic in sub-Saharan Africa.

Rapid diagnostic tests are recommended by the World Health Organization to improve access to hepatitis B screening in resource-limited settings.

The diagnostic performance of HBsAg rapid tests may vary according to epidemiological and field conditions.

2) What This Study Adds

This study provides evidence of the excellent diagnostic performance of the Determine™ HBsAg rapid test in a rural community in Burkina Faso.

The Determine™ HBsAg rapid test demonstrated perfect specificity and almost perfect agreement with the Architect® reference assay.

These findings support the use of the Determine™ HBsAg rapid test for decentralized HBV screening in resource-limited settings.

Author Contributions

1) Study Conception and Supervision: Adrien Marie Gaston Belem, Yacouba Sourabié.

2) Sample Collection and Laboratory Analyses: Mafama Siribié; Aristide Ouattara; Aboubacar Sanou; Gertrude Marilyse Sawadogo; Yacouba Sourabié.

3) Data Analysis and Interpretation: Adrien Marie Gaston Belem, Yacouba Sourabié; Réné Kinda; Bienvenu Ouoba; Adama Kaboré; Mafama Siribié.

4) Drafting of the Manuscript, Critical Revision, and Final Approval of the Version to Be Published: All authors.

5) Accountability for All Aspects of the Work: All authors.

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Conflicts of Interest

The authors declare that they have no competing interests.

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