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Diagnostic Performance Evaluation of the One Step HBV (Blue CROSS Bio-Medical Co.Ltd.) Rapid Test for the Detection of Hepatitis B Virus Serological Markers at the Dalal Jamm National Hospital Center (Senegal)

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ABSTRACT

Hepatitis B is a major public health problem in Senegal. This study aimed to evaluate the diagnostic performance and operational characteristics of the One step HBV (Blue CROSS Bio-medical Co.Ltd.) rapid test for the detection of HBV serological markers at the Dalal Jamm National Hospital Center (CHNDJ). An experimental study was conducted from April to June 2025 on 190 serum samples characterized by the ARCHITECT reference test. The test showed 100% specificity for HBsAg, anti-HBs, and anti-HBc. Sensitivity for HBsAg was 96.2% (Discordance Rate (DR): 2.1%), but was low for anti-HBs (50.9%, DR: 23.2%) and anti-HBc (58.3%, DR: 32.6%). The WHO operational score was 25/30, classifying the test as "Highly appropriate". In conclusion, the One step HBV (Blue CROSS Bio-medical Co.Ltd.) test is highly practical but has insufficient sensitivity for HBsAg according to WHO standards (>99%) and is particularly low for anti-HBs and anti-HBc. Its use should be cautious, especially for markers other than HBsAg, to avoid false negatives.

Keywords

Hepatitis B, Rapid Diagnostic Test, Diagnostic Performance, Senegal, HBsAg.

Introduction

Hepatitis B is a major public health problem worldwide. According to the World Health Organization (WHO), nearly 296 million people were living with chronic hepatitis B virus (HBV) infection in 2022, with over 820,000 annual deaths linked to complications such as cirrhosis and hepatocellular carcinoma [1,2]. Sub-Saharan Africa is among the highly endemic regions, with an average prevalence of chronic infection ranging between 6% and 12% [2]. In Senegal, several studies have confirmed this trend, estimating the prevalence of HBV in the general population between 8% and 11% depending on the cohorts studied [3,4].

In this context, early and reliable screening for HBV serological markers is essential to guide management, reduce transmission, and improve patient prognosis. Reference immunological methods, such as ELISA or automated chemiluminescence tests, offer excellent performance, but they require adapted infrastructure and are sometimes costly, which limits their accessibility in several hospital structures in resource-limited countries [5].

The availability of rapid diagnostic tests (RDTs) possessing the different biological markers of HBV could allow for better adaptation, from the first consultation, of the information delivered to the patient, depending on their HBV status, for efficient therapeutic or preventive management. RDTs and multiparametric combined tests thus represent an interesting alternative, as they allow simultaneous detection of several viral markers, saving time and simplifying the screening workflow. The One step HBV (BlueCROSS Bio-medical Co.Ltd.) Rapid Test is an immunochromatographic test that simultaneously detects five HBV markers: HBsAg, HBeAg, anti-HBs, anti-HBe, and anti-HBc.

However, as with any screening test, its use in routine clinical practice requires a local evaluation of its performance to determine its reliability, sensitivity, and specificity under real-world conditions of use [6]. In accordance with WHO recommendations, any test must be evaluated in its context of use before obtaining marketing authorization [7].

At the Dalal Jamm National Hospital Center (CHNDJ), where the management of viral hepatitis constitutes an important part of clinical activity, it remains essential to have high-performance tests for initial screening. It is in this perspective that the present study is inscribed, aiming to evaluate the diagnostic performance and operational characteristics of the OHNET HBV-5-1 Combo test for the detection of hepatitis B virus serological markers in the population consulting at CHNDJ.

Material and Methods

This was an experimental rapid test evaluation study conducted between April and June 2025. The study was carried out at the Bacteriology-Virology laboratory of the Dalal Jamm National Hospital Center, specifically in the Virology-Serology department. The study included subjects of all genders who came for HBV HBsAg screening or for the detection of HBV markers. The evaluation panel comprised 190 serum samples that had been previously characterized using a reference test (ARCHITECT®).

The One step HBV (BlueCROSS Bio-medical Co.Ltd.) test is a rapid Hepatitis B screening test presented in a cassette format. It allows for the detection of 5 markers: HBsAg, anti-HBs, HBeAg, anti-HBe, and anti-HBc. The kit contains 25 tests to be stored between 2°C and 30°C.

The test uses two immunomarking principles depending on the markers to be detected:

- Sandwich immunomarking principle for HBsAg, HBeAg, and anti-HBs.
- Competition immunomarking principle for anti-HBc and anti-HBe.

Usage conditions require bringing the test cassette and samples to room temperature (20 to 30°C). One to two drops of sample (serum, plasma, or whole blood) are deposited into each of the 5 wells of the cassette. Results are observed and recorded after 15 minutes and before 30 minutes. The presence of a purple line in the control zone "C" indicates that the test is valid and that the protocol has been followed correctly. The interpretation of results was as follows:

- Sandwich Markers (HBsAg, anti-HBs, HBeAg): The appearance of a purple line in the test zone (T) indicates a positive result.
- Competition Markers (anti-HBe, anti-HBc): The absence of a purple line in the test zone (T) indicates a positive result. The presence of a purple line in the test zone indicates a negative result.

Data analysis

Determination of technical performance

Technical performance (sensitivity (Se), specificity (Sp), positive predictive value (PPV), negative predictive value (NPV), and discordance rate (DR)) were calculated from the contingency table.

Study of operational characteristics

Operational characteristics were estimated using certain criteria proposed by WHO [8]. The test is considered:

- **Highly appropriate** if the total score is strictly greater than 23.
- **Appropriate** if the total score is between 17 and 23.
- **Less appropriate** if the total score is strictly less than 17.

Results and Discussion

Technical performance

The technical performance of the One step HBV (Blue CROSS Bio-medical Co.Ltd.) test was evaluated for the three screening markers: HBsAg, anti-HBs, and anti-HBc.

HBsAg detection

For HBsAg, sensitivity, specificity, PPV, and NPV were 96.2%, 100%, 100%, and 95.7%, respectively. The discordance rate (DR) was 2.1%.

Table 1: Technical Performance of the One step HBV (Blue CROSS Bio-medical Co.Ltd.) Test for HBsAg Detection

ARCHITECT ABBOTT HBsAg	Positive	Negative	Total
One step HBV **Positive**	100	0	100
One step HBV **Negative**	4	90	94
Total	104	90	194

Anti-HBs detection

Performance for anti-HBs antibody detection showed a sensitivity of 50.9% and a specificity of 100%. PPV and NPV were 100% and 10.3%, respectively. The discordance rate was 23.2%.

Table 2: Technical performance of the One step HBV (Blue CROSS Bio-medical Co.Ltd.) test for anti-HBs detection.

ARCHITECT ABBOTT Anti-HBs	Positive	Negative	Total
One step HBV **Positive**	27	0	27
One step HBV **Negative**	26	3	29
Total	53	3	56

Anti-HBc detection

Performance for anti-HBc antibody was 58.3% for sensitivity and 100% for specificity. PPV and NPV were 100% and 40%, respectively. The discordance rate was 32.6%.

Operational characteristics

The study of operational characteristics showed that the One step HBV (BlueCROSS Bio-medical Co.Ltd.) test is relatively simple to use. It can be performed in all community screening posts and its implementation requires neither qualified personnel nor a laboratory. Its execution time was 15 minutes, confirming that it is a rapid test according to WHO criteria [7].

The total score obtained was 25, which classifies the test as Highly appropriate according to WHO criteria (score > 23).

HBV infection is widespread globally and remains a public health problem [2] due to its endemicity. It is therefore important to have effective and rapid diagnostic tools for prompt patient management to avoid complications related to this viral infection.

Table 3: Performance of the One step HBV (Blue CROSS Bio-medical Co.Ltd.) test for Anti-HBc detection.

ARCHITECT ABBOTT Anti-HBc	Positive	Negative	Total
One step HBV **Positive**	21	0	21
One step HBV **Negative**	15	10	25
Total	36	10	46

Performance Summary

Table 4: Summary of performance for hepatitis B screening markers.

Marker	Sensitivity	Specificity	Discordance Rate
HBsAg	96.2 %	100 %	2.1 %
Anti-HBs	50.9 %	100 %	23.2 %
Anti-HBc	58.3 %	100 %	32.6 %

The availability of rapid HBV tests with three to five markers could allow for better adaptation, from the first consultation, of the information delivered to the patient, depending on their HBV serological status, and thus guide them towards efficient therapeutic or preventive management. Due to the limitations of certain rapid screening tests, WHO recommends evaluating tests before their use in a given region [7]. WHO recommends that an ideal rapid test meet the **ASSURED** criteria: "affordable, sensitive, specific, user-friendly, rapid and robust, equipment-free, and deliverable to end-users" [9].

In a panel of 190 samples, the sensitivity of the One step HBV (Blue CROSS Bio-medical Co.Ltd.) test for HBs antigen detection was 96.2% in our study. This result is similar to that of Determine® HBsAg, which was 96.1% in Madagascar [8]. However, it is lower than the 100% sensitivity obtained by Dembélé et al. in Côte d'Ivoire [10]. Our sensitivity is also lower than that announced by the manufacturer (99.3%). In contrast, the specificity was **100%,** a very good specificity similar to those of Determine® HBsAg and the Vikia HBsAg test [9,10].

In accordance with WHO eligibility criteria for HBsAg test procurement, rapid tests must have a sensitivity and specificity of > 99% and > 98% respectively [11], with a surface antigen detection threshold of 4 IU/ml [12]. Thus, based on WHO standards, a sensitivity of 96.2%, despite a low discordance rate of 2.1% and an announced detection threshold of 5 IU/ml, does not allow for the diagnosis of all subjects truly infected with HBV. This situation could lead to false negative results for patients who are actually infected.

The sensitivity for the detection of anti-HBs antibody of the evaluated test was **50.9%,** compared to a 100% rate announced by the manufacturer. This sensitivity is low compared to those of the most commonly used RDTs in anti-HBs antibody detection.

This low sensitivity is corroborated by the observation that false negatives had antibody levels between 50 and 100 mIU/mL, which was discordant with the threshold announced by the manufacturer (30 mIU/ml). A study by Poiteau et al. showed a better sensitivity of 90% if the anti-HBs antibody titer was greater than 150 mIU/mL [13], thus verifying the results obtained in our study. The One step HBV (BlueCROSS Bio-medical Co.Ltd.) test, with low sensitivity for anti-HBs antibody detection despite good specificity, thus revealed numerous false negatives with a high discordance rate of 23.2%. The risk of using this test would be to wrongly vaccinate already immunized subjects or to incorrectly identify subjects requiring revaccination.

Similarly, the sensitivity for anti-HBc detection was **58.3%,** with a very high discordance rate of 32.6%. Anti-HBc is an essential marker for the diagnosis of past or chronic infection. Low sensitivity for this marker could lead to an underestimation of the prevalence of past or occult infection in the population [14].

Conclusion

The One step HBV (Blue CROSS Bio-medical Co.Ltd.) rapid test shows excellent specificity (100%) for the three evaluated markers (HBsAg, anti-HBs, anti-HBc) and very good practicality (score of 25/30). However, its sensitivity is insufficient for HBsAg (96.2%) according to WHO standards (> 99%) and particularly low for anti-HBs (50.9%) and anti-HBc (58.3%).

The use of this test for HBsAg screening in a highly endemic context like Senegal should be considered with caution, as the risk of false negatives could compromise transmission control efforts. The use of anti-HBs and anti-HBc markers is strongly discouraged for the evaluation of immunity or past infection due to the low sensitivity observed.

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