

## Comparative Evaluation of Chromatographic Immunoassay and Enzyme-Linked Immunosorbent Assay in the Diagnosis of Hepatitis B Viral Infection in Pregnancy

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**Abstract:** Hepatitis B virus (HBV) is a serious liver infection that can be transmitted from mother to child. Early diagnosis of this infection is vital for efficient patient treatment management and in the prevention of perinatal transmission, therefore it is necessary to use the most sensitive and efficient diagnostic method in the detection of HBV among antenatal patients. The study was conducted to evaluate the performance of chromatographic immunoassay (CIA) against enzyme-linked immunosorbent assay (ELISA), in the detection of HBsAg among pregnant women in Northwestern Nigeria. Out of the 160 serum samples screened for HBsAg, 5.6% (2.99-10.35) and 6.9% (3.48-11.97) tested positive with CIA and ELISA respectively. Both diagnostic methods have 100% (97.55-100.00) specificity, however, the sensitivity of CIA was 81.8% (48.22-97.72) while its positive predictive value, negative predictive value and negative likelihood ratio were 100%, 98.7% (95.51-99.62) and 0.18 (0.05-0.64) respectively at 95% confidence level. The sensitivity of ELISA was 100% (71.51-100.00). The study revealed that ELISA was more sensitive than CIA, therefore rapid test kits are not sensitive enough to confirm hepatitis status among antenatal patients.

**Keywords:** CIA, ELISA, Diagnosis, HBV, Sensitivity, Specificity, Predictive value, Pregnancy

### 1. INTRODUCTION

Among the many viruses that cause human diseases, few are of greater global importance than hepatitis B virus (HBV). This virus causes acute and chronic liver diseases and it is endemic in many areas of the world. The risk of vertical transmission is about 10% if the mother is positive only for HBsAg. Likewise, approximately 90% of infants with HBV may develop chronic liver diseases. HBsAg is the marker used for diagnosing HBV infections or detecting carriers. It can be detected as early as 1 or 2 weeks and as late as 11 or 12 weeks after exposure to HBV when sensitive assays are used. The presence of HBsAg indicates that a person is infectious, regardless of whether the infection is acute or chronic [1].

Clinicians can promptly evaluate the status of HBV, if the infection is detected early using the best diagnostic methods. Different methods are available to diagnose HBsAg. In Nigeria, the most widely used diagnostic method in antenatal clinics is the chromatographic immunoassay

(CIA). It is a rapid diagnostic test procedure. Less frequently used methods include the enzyme-linked immunosorbent assay (ELISA) and the polymerase chain reaction (PCR) [2, 3]. ELISA and PCR are less common in Nigeria's clinical laboratories because they are time consuming and the kits are quite expensive. They also require certain equipment, technical expertise and power source which are not readily available in most clinics in northern Nigeria especially in rural areas. CIA kits are developed by different pharmaceutical, biotechnology and diagnostics companies and their mode of action is based on the principle of chromatography, whereby there is an interaction between antibodies present in the test serum, plasma or whole blood and the protein coated pad of the test device which has series of capillary beds. This pad has the ability to transport fluid spontaneously. During the interaction, the test sample moves laterally or vertically by capillary action through the pad membrane to react with recombinant antigen present on the pad, thereby generating a visible

colour line in the test region. Specific antibody is adsorbed onto a membrane (which can be porous paper, micro-structured polymer or sintered polymer) in the test line, and control antibody is adsorbed onto the same membrane as control line. CIA kits are cheap and readily available in pharmacy stores. It requires no electricity for storage or special training or equipment before use. The test strips manufactures often assert that these strips have relatively high sensitivity, specificity and accuracy but there are reports doubting these claims [4]. Originally, CIA is intended for home or field diagnostic testing and for emergency clinical use [5], however, they are widely used in most clinical laboratories in northwestern Nigeria, as they do not need well-equipped infrastructure which are lacking in some of these clinics.

ELISA technique involves the linking of various label enzymes to either antigens or antibodies. The double antibody sandwich assay and the indirect immunosorbent assay are the two basic ELISA methods. Other types include the sandwich and the competitive ELISA. The double antibody immunoassay of the sandwich type employs specific antibodies against the disease to be tested. The monoclonal antibody immobilized at the bottom of the microtiter wells, and polyclonal antibodies are coupled with horseradish peroxidase as the conjugate solution. During the assay, existing antigens in the specimen reacts with the antibodies to form an “antibody-antigen-antibody-enzyme” immune-complex. After the unbound material is washed off during the assay procedure, substrate is applied to indicate the test result. Early generations of ELISA had a long incubation period that has been reduced in new generations [6-8].

Parameters used for diagnostic test evaluation and assessment include sensitivity, specificity, predictive values and likelihood ratio. The validity of a diagnostic test is defined as its ability to discern between patients who have a certain condition and those who do not. The sensitivity of a test is its ability to recognize correctly persons who have a disease or condition. In contrast the specificity of a test is the ability of a test to recognize correctly persons who do not have a disease or condition. Positive predictive value (PPV) is the proportion of patients testing positive who actually have the disease or condition in question while the negative predictive value (NPV) is the proportion of patients testing negative who

actually do not have the condition in question. Likelihood ratio (LR) is defined as the likelihood that a person who has a target disorder will have a positive test result [3, 9]. Although rapid tests are widely used in Nigeria, studies on specificity and sensitivity of CIA as against ELISA in the country are scarce. The study was aimed at assessing the validity and effectiveness of CIA against the gold standard, ELISA, by comparing specificity, sensitivity, predictive value and likelihood ratio of the two techniques in the diagnosis of HBV among pregnant women in some hospitals in Northwestern part of Nigeria.

## **2. MATERIALS AND METHODS**

### **2.1. Study Design, Size, Population and Setting**

This research is a comparative study with a population of 160 apparently healthy antenatal patients attending the antenatal clinics of some secondary healthcare centers situated in Kano State, Northwestern part of Nigeria.

### **2.2. Ethical Consideration**

Permission to carry out the study was obtained from the Kano State Ministry of Health through the Ethics Committee, Operational Research Advisory Council. Informed consent of each participant was obtained prior to sample and data collection by the issuance of a consent form.

### **2.3. Storage and Stability**

The CIA kits used for the study were kept sealed in pouch and packs and stored between 4-30 °C while the ELISA kits were kept around 4 °C until used. The expiry dates were observed at the point of purchase.

### **2.4. Blood Collection Procedure**

Five milliliter (5 ml) of venous blood was aseptically drawn from the antecubital vein of the participants into a plain sample bottle. Approximately 1ml of the whole blood was used for CIA test procedure and remaining was allowed to clot at room temperature before centrifuging for 10 mins at 2,500 rpm to obtain serum to be used for ELISA [10].

### **2.5. Chromatographic Immunoassay**

Micro point rapid screen test (USA) was employed for this study because it is the most widely used HBV kits in medical laboratories in Northwestern Nigeria. It is a one-step test strip for detecting HBV markers. Whole blood

samples were subjected to CIA for the qualitative detection of HBsAg in accordance with the manufacturer's instruction. The kit was removed from the pouch then placed horizontally on the work bench. Micropipette was used to draw the whole blood sample from each sample bottle. The micropipette containing the blood was held vertically above the CIA device and a drop of the whole blood was dispensed on the test pad, after all blood completely absorbed by the pad, a drop of blood diluent was immediately added and the appearance of the test and controlled lines were observed within 5-20 mins at room temperature<sup>[10]</sup>.

### 2.6. Enzyme-Linked Immunosorbent Assay

Sera were screened with enzyme-linked immunosorbent assay (Monolisa HBsAg ULTRA, France) in accordance with the manufacturer's instruction. It is a one-step enzyme immunoassay technique of the sandwich type for the detection of the surface antigen of the Hepatitis B virus (HBsAg) in human serum. All reagents were allowed to reach room temperature before running the assay. The concentrated washing solution was diluted with distilled water in ratio 1 to 20. That is, 40 ml of the concentrated solution to 760 ml of water for each plate. The conjugate working solution was prepared by pouring the content of a conjugate diluent vial R6 (Tris HCl buffer pH 7.4 containing BSA, Tween 20, bovine immunoglobulins and mouse immunoglobulins with sample addition control reagent) into the lyophilized conjugate vial R7 (Mouse Monoclonal anti-HBs antibodies and Goat polyclonal anti-HBs antibodies bound to the peroxidase) and standing it for 10 mins while gently shaking and inverting from time to time for ease dissolution. The chromogen R9 (tetramethyl benzidine-TMB) was diluted in the Substrate Buffer R8 in ration 1:11 (that is, 1ml reagent R9 in 10 ml reagent R8) in the dark for 6 hrs. Sample distribution and identification plan were carefully established. Four of the wells A1, B1, C1 and D1 were used for negative controls; well E1 was used for positive control

and well H12 for the blank. Hundred micro liter (100 µl) each of the positive control, negative control and the serum samples to be analyzed were introduced into the corresponding wells. The blank well was left empty. Fifty micro liter (50 µl) of the conjugate (R6+R7) was immediately dispensed into the each wells. The plate was covered with adhesive film and incubated at 37°C for 30 mins. The film was removed and discarded. The content of the plate was aspirated and filled with 300 µl washing solution, mixed gently and also aspirated. The aspiration-washing procedure was repeated five times. After the last wash, the microtiter plate was blotted on absorbent tissue to remove any excess liquid from the wells. Hundred microliter (100 µl) of the freshly prepared development solution (R8+R9) was added be to each well except those used for the blank controls and incubated at 30°C for 30 mins in the dark. The reaction was stopped by adding 100 µl of 1 N sulphuric acid (stop solution) to the wells. ELISA plate reader was then be used to read the result 4 mins after the addition of the stopping solution. It was blanked at 450 nm with the blank well. The absorbance of each well was read within 30 mins using ELISA Plate Reader (Biotek ELx808).

### 2.7. Data Analysis

Data were analyzed using MedCalc statistical software (2017 Version, Ostend, Belgium). Disease prevalence, sensitivity, specificity, positive and negative predictive values were expressed as percentages. Confidence interval for sensitivity and specificity were exact Clopper-Pearson confidence intervals at 95% confidence level. Likelihood ratios were calculated using the Log method.

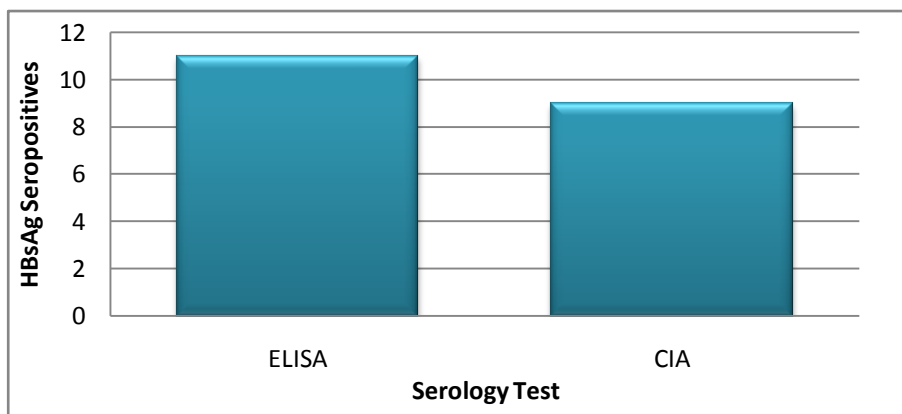
## 3. RESULTS

The study revealed that out of the 160 samples screened with Micro point chromatographic immunoassay (CIA), 9 tested positive for HBsAg with a prevalence of 5.6%, while 11 participants tested positive for HBsAg with the Monolisa enzyme-linked immunosorbent assay (ELISA) with a prevalence of 6.9% (Table 1).

**Table 1.** Prevalence of HBsAg using Micro point Chromatographic Immunossay and Monolisa Enzyme-Linked Immunosorbent Assay among the study group

Test	Test Result	Frequency	Percentage	Prevalence
CIA#	Valid Positive	9	5.625	5.6
	Valid Negative	151	94.375	94.4
ELISA*	Valid Positive	11	6.875	6.9
	Valid Negative	149	93.125	93.1

n=160; reference test is denoted by \*; screening test is denoted by #



**Figure1.** Difference in the seropositivity of HBsAg using Monolisa ELISA and Micro point CIA among the study group

As shown in Figure 1, there was a slight increment of 1.3% in the seropositivity of HBsAg using Monolisa ELISA compared to Micro point CIA, as two more samples (false

negatives) tested positive for HBsAg out of the 151 samples that tested negative for HBsAg using Micro point CIA.

**Table2.** Diagnostic performance of Micro point CIA among the study group

Hepatitis B Viral Infection					
Test	HBsAg Present	No	HBsAg Absent	No	Total
<b>Positive</b>	True Positive	9	False Positive	0	9
<b>Negative</b>	False Negative	2	True Negative	149	151
<b>Total</b>		11		149	

n= 160

Table 2 shows the diagnostic performance of Micro point CIA. Out of the total sample, the false and true negatives were 2 and 149 respectively, while the true and false positives

were 9 and 0 respectively. As shown in Table 3, the true and false positives for Monolisa ELISA were 11 and 0 respectively, while the true and false negatives were 149 and 0 respectively.

**Table3.** Diagnostic performance of Monolisa ELISA among the study group

Hepatitis B Viral Infection					
Test	HBsAg Present	No	HBsAg Absent	No	Total
<b>Positive</b>	True Positive	11	False Positive	0	11
<b>Negative</b>	False Negative	0	True Negative	149	149
<b>Total</b>		11		149	

Table 4 shows that the sensitivity of Micropoint CIA and Monolisa ELISA were 81.82% (48.22-97.72) and 100% (71.51-100.00) respectively, while the specificity of Micropoint CIA and Monolisa ELISA were 100% (97.55-100.00). The table also shows that the negative predictive value of Micro point CIA and Monolisa ELISA

were 98.68% (95.51-99.62) and 100% respectively, while the negative likelihood of Micro point CIA and Monolisa ELISA were 0.18 (0.05-0.64) and 0.00 respectively. Statistically, these values were significant at 95% confidence level.

**Table4.** Sensitivity, specificity, predictive values and likelihood ratios of Micro point CIA and Monolisa ELISA among the study group

Parameter	TEST TYPE			
	MICROPOINT CIA <sup>#</sup>		MONOLISA ELISA*	
	Value in %	(95% CI)	Value in %	(95% CI)
Sensitivity	81.82	(48.22-97.72)	100.00	(71.51-100.00)
Specificity	100.00	(97.55-100.00)	100.00	(97.55-100.00)
Positive Likelihood Ratio	-	-	-	-
Negative Likelihood Ratio	0.18 <sup>^</sup>	(0.05-0.64 <sup>^</sup> )	0.00 <sup>^</sup>	-
Positive Predictive Value	100.00	-	100.00	-
Negative Predictive Value	98.68	(95.51-99.62)	100.00	-
Disease Prevalence	5.63	(2.99-10.35)	6.88	(3.48-11.97)

Confidence Interval (CI) at 95%; Values not expressed in percentages are denoted by <sup>^</sup>; reference test is denoted by\*; screening test is denoted by <sup>#</sup>

#### 4. DISCUSSION

Our findings revealed that enzyme-linked immunosorbent assay (ELISA) gave a slightly higher HBsAg prevalence rate than chromatographic immunoassay (CIA) when used for the diagnosis of HBV among the antenatal patients recruited for this study. HBsAg is the most significant HBV marker and its presence indicates active HBV infection which may be acute or chronic, therefore a highly sensitive screening assay is very much needed to reduce mother to child transmission in endemic region such as Nigeria. Two out of the 151 that tested negative for HBsAg using CIA were false negatives when they were re-tested with ELISA. In a similar study conducted by Erhabor *et al.* [11] to screen donated blood for HBsAg, the 100 blood donor samples which tested negative with CIA were retested using ELISA. Out of 100 CIA negative blood donor samples tested, 9 (9.0%) tested positive with ELISA. Thirty (30) blood samples that tested positive with CIA were also retested using ELISA; all 30 samples (100.0%) tested positive. Zameer *et al.* [8] reported that out of 100 samples of blood donors showing negative results for Hepatitis C Virus (HCV) in their study, 1 (1.0%) sample showed positive results for HCV with ELISA. Similarly, 30 blood donor samples showing positive results by CIA technique were also analyzed by ELISA and 1 (3.3%) showed negative results with ELISA. Usually, rapid CIA kits that give more false positive results are better for diagnosis than those that give more false negative results. A positive result is usually followed by more accurate testing methods like ELISA to confirm the presence of infection. A negative test result is seldom retested, considering the costs of retesting in resource limiting settings such as in rural Northern Nigeria where this study was conducted. Hence, choosing a test with high sensitivity and negative predictive value (NPV) is more important than choosing a test with high specificity and positive predictive value (PPV) for routine use [5].

Our findings also revealed that *Monolisa* ELISA was more sensitive than *Micro point* CIA which is the most widely used HBV kit in most clinical laboratories in Northwestern Nigeria. However both tests have high specificity. This finding is similar to that of Zameer *et al.* [8]. They reported that by using ELISA technique as a gold standard for HCV screening, the specificity and sensitivity of CIA technique was 99.0% and

96.6% respectively. This study also conforms to the findings of Habibi *et al.* [12] where the sensitivity and specificity of fourth generation ELISA kits was 100%. Similarly, in a study conducted by Farooqui *et al.* [3], HBV specificity and sensitivity were 97% and 78% respectively using CIA technique. Likewise, in a study conducted by Mehra *et al.* [2] to screen HIV among a study group, the 787 sera tested at the voluntary counselling and testing facility employing a serial testing algorithm (based on SD Bioline HIV-1/2 3.0 as the first test) were subsequently tested with *Microlisa-HIV* for anti-HIV antibodies. The first test missed 9 HIV reactive samples and also registered 5 false positives. The sensitivity and specificity of the first test were 77.5% and 99.3% respectively, taking ELISA as the standard test. Likewise, Bibi *et al.* [13] reported that out of 206 sera tested using ELISA, anti-HBs was positive in 91(44.2%) sera and negative in 115(55.8%) sera. Using CIA, anti-HBs was positive in 85(41.3%) and negative in 121(58.7%) and the sensitivity and specificity of rapid test CIA was 83.5% and 92.2% respectively with overall accuracy of 88.5%. These figures fell to 70.8% sensitivity and 94.6% specificity with 81.5% accuracy when Centre for Disease Control and Prevention cut off of 10 mIU/ml was used. This study however contrasts the study by Mintsu *et al.* [14] where CIA showed no reactivity to HBsAg suggesting zero sensitivity. They found a sensitivity of 48% and specificity of 99.30% for the ELISA *Microscreen AgHBs*. The sensitivity and specificity observed in the present study were higher than those reported by Khan *et al.* [15]. In their study, among the 38 ELISA HBV positive sera, 20 were positive by HBsAg *One-Check* and 19 were positive by *Accurate*. The sensitivity for rapid HBsAg was found to be 53% and 50 % for *One-Check* and *Accurate* respectively. The variation in the sensitivity and specificity observed among the various studies may be due to differences in the diagnostic kits used for the assay and the variation in the size of the study population. Edman and Runge [16] indicated that the accepted minimal standard for the sensitivity of a screener is 70% and a specificity level of 80% is desirable. Therefore the 81.8% sensitivity and 100% specificity of CIA in this study is commendable.

This study revealed that the PPV for both CIA and ELISA were high. This is expected since the prevalence of HBsAg in this study falls within

the high intermediate range of the World Health Organization standard set for monitoring of the severity and prevalence of HBV infection worldwide [17]. According to Carvajal and Rowe [9], the relationship between PPV and disease prevalence is important because the higher the disease prevalence, the higher the PPV. Although sensitivity and specificity are properties intrinsic to a test and are not affected by the prevalence of a particular disease or condition, the predictive values of a diagnostic test are influenced greatly by prevalence. This relationship means that knowing the predictive value of a test is most useful and efficient in populations in which the prevalence of a disease is high (high-risk populations). For a rare condition or one that has a much lower prevalence in the population, predictive values are lower and less useful. Further, if the prevalence of a disease is greater in the sample population than in the target clinical population, the predictive values are overestimated.

The high NPV for both tests in this study is understandable because the proportion of patients that were seronegative for HBsAg and who actually do not have the HBV were high. This finding is in line with that of Habibi *et al.* [12]. In their study, they reported that the PPV and NPV were 100%, whereas ELISA proves to be more sensitive than CIA as few more samples tested positive with ELISA. This finding is also in agreement with that of Mintsu *et al.* [14] where the PPV and NPV for the ELISA *Microscreen AgHBs* were 83.33% and 95.64% respectively. Likewise, Hayder *et al.* [18] reported that out of 100 positive and 100 negative tests for HBsAg confirmed on ELISA, all rapid kits showed comparable results with ELISA. The sensitivity and NPV of *Intec-China* (98%) and *Determine-Abbot* (98%) were similar to each other however; these were higher when compared to *Acon-USA* (95%). The rapid kit by *Intec-China* was cheaper to the other two rapid kits and was therefore, the most cost effective rapid kit. The specificity and PPV of all three HBsAg CIA kits was 100% and in agreement with ELISA. Out of 100 HCV positive and 100 HCV negative cases confirmed on ELISA, the rapid test by *Acon-USA* showed maximum sensitivity. The sensitivity and NPV of *Acon-USA* were higher (93%) as compared to *Membrane-Canada* (89%) and *Nobis-Germany* (86%). The specificity and PPV of *Acon-USA* were comparatively lower (93%) but did not significantly vary when compared with

*Membrane-Canada* (97%) and *Nobis-German* (96%). Also, in a study conducted by Farooqui *et al.* [3] to screen HBV, the PPV and NPV were 81% and 97% respectively using CIA. Their result was significant ( $p$ -value < 0.05). False positive was 2.34% for HBV false negative was 2.67% for HBV. In another study conducted by Khan *et al.* [15], the NPV for rapid HBsAg devices was 51% and 49% for *One-Check* and *Accurate* kits respectively. The PPV for HBV were 100% and 95% with *Accurate* and *One-Check* respectively.

This study revealed that the negative likelihood ratio (LR-ve) for *Micro point* CIA was close to zero (0.18) while that of *Monalisa* ELISA was zero. LR-ve is the probability of a negative outcome given a negative screening. It range from zero to one with values closer to zero representing a stronger likelihood that a test screening performance at that particular cut score accurately categorizes the patients. General interpretative guidelines indicate that an LR-ve from 0.0-0.2 provides relatively high probability of accuracy. Ideally, an LR-ve closest to zero is preferable [16]. Therefore the LR-ve values obtained for both tests were okay.

## 5. CONCLUSIONS

The study revealed that enzyme-linked immunosorbent assay (ELISA) showed more sensitivity than chromatographic immunoassay (CIA), also the negative likelihood ratio and negative predictive values of ELISA were slightly better than that of CIA. However, both tests have a very high specificity and positive predictive values. Due to the perinatal transmissibility of HBV, CIA is not sensitive enough to be use routinely as diagnostic test for hepatitis B screening among pregnant women. Where it can be afforded, ELISA should be used in the diagnosis of HBV instead of CIA in antenatal clinics because of its low likelihood ratio and very high sensitivity and specificity.

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**Citation:** Abulude Olatunji Ayodeji, Ahmed Ismai'la, Sadiu Farouk Umar. Comparative Evaluation of Chromatographic Immunoassay and Enzyme-Linked Immunosorbent Assay in the Diagnosis of Hepatitis B Viral Infection in Pregnancy. *ARC Journal of Hematology*. 2019; 4(1): 28-34

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