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## Comparison of Two Commercial Screening Kits for Detection of Anti-HCV Antibody among Adult Patients in Osogbo, Nigeria

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### Authors' contributions

*This work was carried out in collaboration between all authors. Authors MAM, VOM and CAA designed the study and did the literature search for writing the first draft of the manuscript. Authors CAA and PSM performed the statistical analysis and wrote the protocol. Authors OYA and AOH managed the laboratory analyses and quality controls of the study. All authors read and approved the final manuscript."*

Research Article

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### ABSTRACT

**Aims:** A commercial rapid test kit for anti-Hepatitis C Virus (anti-HCV) detection was evaluated and compared for diagnosis of hepatitis C by detection of immunoglobulin G(IgG) antibodies against a third generation Enzyme Immunoassay(EIA) as gold standard.

**Methodology:** A total of 560 patient serum samples were subjected to rapid screening with rapid test (immunochromatographic) strip supplied by Global Diagnostics and commercially prepared IgG capture EIA by DIA.PRO, Italy.

**Results:** Of the 560 samples, anti HCV was detected in 31(5.54%) by ELISA, whereas

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only 17(3.04%) by strip method. This gives 100% specificity as no false positive was observed, but with 68.8% sensitivity. The number of false negative results was 14. The positive and negative predictive values were 100% and 97.42% respectively.

**Conclusion:** The result pattern shows that sensitivity is compromised. It is therefore recommended that third generation ELISA is used for blood donors screening, to reduce transmission of hepatitis C virus through blood transfusion. When need arises to use strip for anti-HCV testing, such strip should be validated locally before its adoption because kits are directed against known range of strains of HCV and have minimum titer of antibody below which detection becomes impossible.

*Keywords: Rapid test kit; anti-HCV; EIA; evaluation; sensitivity.*

## 1. INTRODUCTION

HCV is a prominent cause of liver disease in the tropics; provoking chronic persistent infection progressively causing chronic hepatitis leading to liver cirrhosis and primary liver cell carcinoma (PLCC) [1,2]. According to a report by the World Health Organization Consultation Group in collaboration with the Viral Hepatitis Prevention Board, Antwerp, Belgium, it was specified that though representative prevalence data were not available from many countries, available data indicate that approximately 3% of the world's population is infected with HCV [3]. The Centre for Disease Control and Prevention estimated that there are up to 230,000 new hepatitis C infections in the U.S every year, resulting to 8,000 to 10,000 deaths per annum [4]. The prevalence rate in European countries varies between 0.1 and 5% [3,5].

Although HCV has been detected worldwide, it is more prevalent in developing countries (5, 6). In Nigeria, Egah et al. (2004) reported 6% prevalence among the 200 blood donors studied in Jos [6]. This is also similar to the 5.8% prevalence reported by Mutimer *et al.* among blood donors from southern Nigeria [7]. The seroprevalence rate found by the duo is however higher than the 2.8% found among blood donors in Ghana [8] and the 2.9% found among blood donors in Port Harcourt [9]; while it is lower than the 12.3% prevalence reported among Nigerian blood donors in Benin city [10] and the 15.8% recorded among Egyptian blood donors [11].

HCV is transmitted through parenteral, sexual and vertical routes. It is also transmissible through blood transfusion while tattooing and all forms of circumcision have been indicated as modes of acquisition of the disease [12-14]. Furthermore, HCV shares routes of transmission with both HIV and HBsAg, thus, co – infection is possible. HCV co-infection with HBV or HIV or both had been reported. It is estimated that 30% of HIV infected individuals also have HCV and 60-90% of persons who contracted HIV by intravenous drug use (IVDU) have HCV. Co- infection rate of 8% with HCV and HIV has been reported in Mumbai [15].

Several approaches have been applied for laboratory diagnosis of HCV infection. These methods include detection of the IgG antibodies against the virus in serum (IgM tests are not routinely used) and demonstration of the presence of HCV RNA in serum using a genome amplification technique such as reverse transcriptase-polymerase chain reaction assay [16,17].

However, this study was conducted to compare 2 commercially available anti-HCV antibody (IgG) screening kits with a view to evaluate the performance of the rapid immunochromatographic strips against the third generation EIA kit.

## 2. MATERIALS AND METHODS

A total of 560 human sera were used in this evaluation. These blood samples were collected from blood donors and outpatients of Ladoke Akintola University of Technology Teaching Hospital, Osogbo. Informed consent was obtained from every participant. Ethical clearance was given by the LAUTECH Teaching Hospital Ethics Review Committee.

HCV Test Strip for qualitative detection of anti-HCV, with control band incorporated supplied by Global Diagnostics was used. The method is a rapid, direct binding procedure, which visually determines antibodies to hepatitis C in the serum or plasma. The test is a membrane based immunoassay in which the membrane is coated with recombinant antigens on the test line region of the strip. During testing, the serum or plasma reacts with protein coated particles. The mixture migrates upward on the membrane chromatographically by capillary action to react with recombinant HCV antigen on the membrane and generate a coloured line. Presence of this coloured line indicates a positive result, while its absence indicates a negative result. A coloured line will always appear at the control region, to serve as procedural control. This is in consonance with the dictate of the manufacturer [18].

Simultaneously, third generation ELISA that determines presence of anti-HCV (IgG) in human serum or plasma was used as a gold standard in this work. Patient's serum or plasma sample was added to the microwell together with a second antibody conjugated with the enzyme horseradish peroxidase (the HRP-Conjugate) and directed against a different epitopes of HCV. During incubation, the specific immunocomplex formed in case of presence of anti-HCV in the sample, was captured on the solid phase which generates an optical signal that is proportional to the amount of anti-HCV antibodies present in the sample. The commercially prepared positive and negative controls were treated alongside the specimens. A cut-off value was determined and results were interpreted as positive and negative according to manufacturer's instructions [19].

The sensitivity, specificity, efficiency, positive predictive value (PPV), and negative predictive value (NPV) for the strip method were calculated based on the third generation ELISA kit as the gold standard and using the following formula:

$$\text{Percentage Sensitivity} = a / (a+c) \times 100\%$$

$$\text{Percentage Specificity} = d / (b+d) \times 100\%$$

$$\text{Efficiency} = (a+d) / (a+b+c+d) \times 100\%$$

$$\text{Percentage Positive Predictive Value} = a / (a+b) \times 100\%$$

$$\text{Percentage Negative Predictive Value} = d / (c+d) \times 100\%$$

Where

a = number of true positives

b = number of false positives

c = number of false negatives

d = number of true negatives

### 3. RESULTS

A total of 560 samples collected from participants who are all adults include 280 samples from blood donors and 280 samples from outpatients. The prevalence of anti-HCV among the participants reflects that 31(5.54%) and 17 (3.04%) were positive by ELISA and strip methods respectively. This is depicted in Table 1. Hence, the comparison of rapid screening (strip) method to ELISA method (as gold standard for this work) reveals number of true positives, number of false positives, number of false negatives and number of true negatives to be 31, 0, 14 and 529 respectively (Table 2). Table 3 reveals the percentage specificity, sensitivity, efficiency, PPV and NPV of the rapid screening strip calculated based on samples that were considered truly seropositive for anti- HCV ( $N = 560$ ) by 3<sup>rd</sup> generation ELISA kit. The specificity of 100% observed correlates with the 100% PPV recorded. The specificity and NPV are 68.8 and 97.42 respectively.

**Table 1. Prevalence of anti-HCV by the strip and ELISA screening methods**

Outcome	ELISA Freq (%)	Strip Freq (%)
Positive	31(5.54%)	17(3.04)
Negative	529(94.46)	543(96.96)
Total	560(100.00)	560(100.00)

**Table 2. Comparison of the strip to ELISA anti-HCV screening using ELISA as gold standard**

	Positive	Strip Methods Negative	Total
ELISA Positive	17	14(c)	31(a)
ELISA Negative	0(b)	529	529(d)
Total	17	543	560

**Table 3. Evaluation of the screening strip using 3<sup>rd</sup> generation ELISA as gold standard**

	Percentage
Sensitivity	68.8
Specificity	100.0
Efficiency	97.56
PPV	100.0
NPV	97.42

### 4. DISCUSSION

Accurate and precise laboratory result in respect of serological screening for anti-HCV is key to safe blood transfusion service; clinical diagnosis of suspected cases and preemptive diagnosis of healthy individuals during routine screening exercise (6-12). A reasonable turnaround time (TAT), reduced cost of kit and simplicity of technology required are prominent factors to be considered while choosing kits or methods for laboratory tests, especially in resource-limited settings, albeit, without compromising accuracy of results [20]. Hence, at present, the most commonly used techniques in the laboratory for anti-HCV detection is rapid screening strip. Third generation ELISA is more accurate and sensitive; though, expensive and time consuming [9,19]. Moreover, these facilities are not widely

available in the clinics and hospital settings. Hence, a rapid test kit would be useful to provide early diagnosis.

In this study, we evaluated the performance of the Global rapid test strip for the detection of anti-HCV antibody (IgG) using the 3<sup>rd</sup> generation ELISA kit (DIA.PRO, Italy) as gold standard. The sensitivity of the strip (68.8%) was very low as compared to 99.0% stated by the manufacturer [18]. This may be due to presence of different HCV genotypes in the community where the research was conducted. It is equally possible that the antibody titers in some of the true positive subjects were lower and not detectable by strips method. We therefore recommend that all strips should be evaluated before being considered for use in diagnostic laboratories. More stringent approach, by way of 3<sup>rd</sup> generation ELISA is recommended for HCV screening, especially for blood transfusion practice.

## **ACKNOWLEDGMENTS**

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## **CONSENT**

All 560 participants who are all adults comprising of 280 blood donors and 280 outpatients gave written informed consent. The Consent form were filled and signed by all who participated in the study.

## **ETHICAL APPROVAL**

Ethical clearance was obtained from the Research committee of the LAUTECH Teaching Hospital research committee (LTH/REC/2013/01/29/127).

## **COMPETING INTERESTS**

Authors have declared that no competing interests exist.

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