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# Evaluation of Three Rapid Test Kits for the Detection of Hepatitis C Virus Antibodies in Nigeria: An Observational Study

**Georgina C. Duru[1] , Ahaneku I. Osuji*[2], Hauwa Kinjir[3]**
*1.Department of Hematology and Blood Transfusion, University of Abuja Teaching Hospital, Gwagwalada, Abuja, Nigeria. 2. Department of Microbiology and Immunology, University of Abuja Teaching Hospital, Gwagwalada, Abuja. 3. Department of Hematology, Federal College of Veterinary and Medical Laboratory Technology, Vom. Plateau State, Nigeria.*

## ABSTRACT
**Objectives:** Hepatitis C Virus (HCV) infection misdiagnosis has become a common finding in many hospitals and blood transfusion centres in Nigeria. This observational, cross-sectional study determined the performance characteristics of three rapid test kits for the detection of HCV antibodies. **Methods:** Three anti-HCV rapid diagnostic tests (RDTs) kits, Aria®, LabAcon® and GLOBAL® were evaluated using a panel of known anti-HCV positive and negative samples obtained from consenting blood donors (n= 365) attending University of Abuja Teaching Hospital, Gwagwalada Abuja. The positive (n=53) and negative (n=36) samples were obtained by using ELISA and polymerase chain reaction (PCR). The sensitivity, specificity, positive predictive values (PPV) and negative predictive values (NPV) of the 3 RDTs were assessed. **Results:** The sensitivity and specificity of Aria, LabAcon and GLOBAL were 83%, 81%, 75% and 64.9%, 86.1% and 86.1%% respectively. The PPV and NPV of Aria, LabAcon and Global were 77.2%, 88.6%, 88.9% and 71.9%, 68.9% and 70.5% respectively. The study observed no statistically significant difference in the sensitivity ($p=0.343$) but significant difference in the specificity ($p<0.0001$) comparing the 3 RDTs in the detection of hepatitis C virus antibodies. **Conclusion:** The sensitivities and specificities of the 3 rapid test kits evaluated were low indicating the superiority of ELISA over the 3 rapid test kits. The use of these 3 rapid test kits in testing blood donors and patients in hospitals could lead to false positive or negative results. This necessitates for evaluation of other rapid test kits for the detection of HCV antibodies in Nigeria.

**Keywords:** Hepatitis C virus, antibodies, RDTs, evaluation, Nigeria

***Corresponding author:** ahanekuos@gmail.com; +2348033507775; **ORCID**: 0000-0002-8124-3674

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## INTRODUCTION

Hepatitis C virus infection is serious public health problem in developing countries due to its ability to develop chronic infections and most of the times, it is asymptomatic [1, 2]. Hepatitis C virus infection presents a diagnostic challenge in Nigeria as most laboratories use different kinds of rapid test kit in the detection of the virus [3]. One important measure to establish the burden of HCV infection is the diagnosis of acute and chronic cases. Primary diagnosis of HCV infection is made by using serological tests for the detection of antigens and antibodies against the virus. To confirm the primary diagnosis, to quantify viral load, to determine genotypes and resistance mutants for antiviral treatment, qualitative and quantitative molecular tests are used [4]. It is noteworthy to mention that Enzyme-linked Immunosorbent assay (ELISA) has been adjudged as a very sensitive method of detection and molecular methods very sensitive and specific platform of detection of HCV [5]. Laboratory-based immunoassay including automated platforms or manual enzyme immunoassay (EIAs) has proven accuracy in the detection of HCV antibodies. However, they require standard laboratory set up, skilled and competent staff and have longer turnaround times (TAT) [6]. This may not be available or cost-effective in testing patients and blood donors in resource constraint countries like Nigeria.

Rapid diagnostic tests (RDTs), eliminate the need for highly trained medical laboratory personnel, sample transport, and provide fast TAT [6]. Also, they are simple, accessible and affordable by most people [7]. Several commercial RDTs are available in the Nigerian market for the detection of HCV antibodies, however, their post marketing performance characteristics have not been determined in our facility for routine use. Additionally, there are RDTs available globally that have not been approved for use in Nigeria by the Federal Ministry of Health and Medical Laboratory Science Council of Nigeria (MLSCN). Evaluating the performance characteristics of RDTs kits will help in decisions about approval of RDTs by MLSCN and preventing misdiagnosis of HCV infection.

Rapid diagnostic tests (RDT) device, Aria®, is being used for the screening of blood donors in the blood bank at the University of Abuja Teaching Hospital, Gwagwalada, Abuja. Other blood banks in Gwagwalada Abuja and environs use different brands of the rapid test device and blood units are sourced from those private medical laboratories for some patients in the Teaching Hospital. There is a need for evaluation and validation of rapid test kits being used for screening of blood donors. The aim of this study is to evaluate the performance characteristics of three rapid diagnostic test kits for detection of HCV antibodies. The specific objectives of this study include: i. To assess the sensitivity of the 3 rapid diagnostic test kits with HCV ELISA as a reference panel. ii.To compare the specificity of the 3 rapid diagnostic test kits with HCV ELISA as a reference panel. Iii.To determine and compare the positive and negative predictive values for the 3 rapid test kits with HCV ELISA. It is anticipated that the outcome of this study will provide valuable information in the selection of rapid test kits for screening of patients and blood donors in Nigeria. This will ultimately aid to control the transmission of hepatitis C viral infection in Nigeria.

## MATERIALS AND METHODS

### Study Site, Design and Population

This observational, cross-sectional study was conducted at the University of Abuja Teaching Hospital Gwagwalada, Abuja. The target population of the study was healthy blood donors attending UATH between the period of 1st August 2019 and 31st January 2020. A total of 365 healthy blood donors participated in this study.

### Sample Size Determination.

The sample size was obtained by calculation using the Fisher formula as described by Araoye, [8]. The formula is $n = z^2p\ (1\text{-}p)/d^2$, where n= required sample size, z= confidence level 95% (Standard value of 1.96). P= estimated prevalence of 4.1% as reported in Nigeria by Nwannadi et al [9]. d= margin of error at 5% (standard value is 0.05). Sample size calculation performed obtained 60 blood donors. Finally, the sample size of 365 blood

donors were recruited and enrolled in the study. From these 365 blood donors, a total of 53 anti-HCV positive and 36 negative samples (89 samples) were obtained and used as the reference panel.

**Ethical Considerations and Inclusion Criteria**

Ethical clearance was obtained from the ethical committee of University of Abuja Teaching Hospital Gwagwalada, Abuja with Protocol number: UATH/HREC/PR/2017/012/122 and approval number UATH/HREC/PR/2017/012/008. Informed consent was obtained from all participants before they were enrolled as subjects for this study. All donors who gave their informed consent were included as participants in this study. Also, blood donors that declined were excluded.

**Specimen Collection and Processing**

Ten millilitres of blood was collected by vein-puncture from each participant and dispensed into plain and EDTA tubes in 5ml aliquots. The samples in plain tubes were allowed to clot and thereafter centrifuged to separate the sera and plasma. These were stored at -20ºC until testing was performed.

**Preparation of Evaluation panel**

Hepatitis C virus antibodies testing were performed on the 365 sera using RecombiLISA HCV Ab ELISA kit (CTK Biotech, USA) with lot number: E1209Q3B01. Positive ELISA samples were subjected to qPCR using GenXpert molecular diagnostic systems (Cepheid, France) with reagent lot ID:13203. Known positive samples (ELISA and PCR positive) and negative samples were obtained for the determination of the sensitivity, specificity, positive predictive values (PPV) and negative predictive values (NPV) of the 3 RDTs (Aria, LabAcon and GLOBAL) to be evaluated. The standard operating procedures for ELISA and PCR were strictly followed.

**Anti-HCV Rapid Diagnostic Test Kits for Evaluation**

The three anti-HCV RDTs evaluated include; Aria HCV Ab plus rapid test kit, Lot number: FO515Q15C00 (CTK Biotech Inc., USA), LabAcon HCV rapid test kit with lot number: HCV19060006 (Biotest, Co. Ltd, Hangzhou, China) and GLOBAL rapid test kit with lot number: HCV17110020 (Global Diagnostics, USA). The kits were stored at room temperature as recommended by the manufacturers. All are in vitro, qualitative, immune-chromatographic, single-use, disposable chamber tests that provide visual results within 20 minutes for anti-HCV detection.

**Evaluation Procedures**

The RDTs testing were performed as per the manufacturers' instruction manuals using the known positive (n=53) and negative (n=36) panel. The procedure for testing and interpretation of the results was similar for all assays. An assay was interpreted as negative if a control line was present (regardless of intensity) with no corresponding test line. The appearance of a control line and a test line indicated a positive result. A missing or broken control line indicated an invalid result regardless of the presence of a test line.

**Calculation of Sensitivity, Specificity, PPV and NPV of Kits evaluated**

The sensitivity, specificity, positive predictive values (PPV) and negative predictive values (NPV) of the RDTs were calculated by using the formula given in (Table 1) as described by Niyibizi et al [10].

**Table 1:** Formulas that were used in data analysis

| Parameters | Formulas |
|---|---|
| Sensitivity | **Sensitivity**= (true positive/ (true positive+ false negative) x 100 |
| Specificity | **Specificity**= (true negative/ (false positive + true negative) x 100 |
| Negative predictive values (NPV) | **NPV**= (true negative/(true negative + false negative) x 100 |
| Positive predictive values (PPV) | **PPV= (**true positive/(true positive + false positive) x 100 |

**Panel Characterization**
The positivity and negativity of ELISA using PCR showed that out of 365 samples tested by HCV ELISA, 55 (15.1%) were positive. Out of the 55 samples analyzed for assessments of test positivity rate, 100% of the samples were anti-HCV positive by ELISA while HCV RNA was detected in 53 (96.4%) samples by RT-PCR. There was no statistically significant difference in the positivity detection rate of both assays (p=0.155). Out of the 39 samples analyzed for assessments of test negativity rate, 36 (92.3%) of the samples were anti-HCV negative by ELISA while 3 (7.67%) was positive. There was no significant difference in the negativity detection rate of both assays (p=0.195) (Table 2).

**Table 2:** Percentage Agreement between ELISA and PCR Positivity and Negativity Rates

| Test Kits Used | Total Samples Tested | No. Positive (%) | No. Negative (%) | Chi-Square (p-value) |
|---|---|---|---|---|
| ELISA POSITIVE | 55 | 55 (100) | 0 (0.0) | *Reference* |
| PCR | 55 | 53 (96.36) | 2 (3.64) | *2.02 (0.155)* |
| ELISA NEGATIVE | 39 | 3 (7.67) | 36 (92.3) | *3.08 (0.195)* |

***Statistically Significant (p<0.05)***

**Statistical Analysis**
Data obtained from this study were analyzed by Statistical Package for Social Science (IBM, New York, USA) version 26. Descriptive statistics which include percentages were used to describe the frequency of categorical variables. The relationship between variables was tested using chi-square. One-tailed and two-tailed chi-square test was used to compare the performance characteristics of 3 RDTs evaluated. A value of P<0.05 was considered statistically significant.

## RESULTS

### Performance Characteristics of Anti-HCV Rapid Diagnostic Test Kits

By using ELISA as gold standard and reference test, the Sensitivity, Specificity, Positive Predictive Values and Negative Predictive Values of Aria ®, LabACON ® and Global ®were (83.02%, 64.86%, 77.20%, 71.88%), (81.25%, 86.11%, 88.64%, 68.88%) and (75.0%, 86.11%, 88.88%, 70.45%), respectively. The test performance characteristics of the 3 RDTs significantly varied with the performance of the gold standard (p<0.0001) (Table 3). The sensitivity and specificity of the 3 RDTs evaluated were compared and presented in Table 4. Aria ® had the highest sensitivity and NPV. Conversely, LabACON and GLOBAL had the highest Specificity and PPV. There was a statistical significant difference in the specificity (p<0.0001) and PPV (p=0.023) of the 3 RDTs. However, there was no significant difference in the sensitivity (p=0.343) and NPV (p=0.827) of the 3 RDTs (Table 4).

**Table 3:** Sensitivity, Specificity, PPV, and NPV of the 3 RDTs in Comparison to ELISA

| TEST Kits/Format Used | Sensitivity (%) | Specificity (%) | PPV (%) | NPV (%) |
|---|---|---|---|---|
| ELISA | 100 | 100 | 100 | 100 |
| ARIA | 83.02 | 64.86 | 77.2 | 71.88 |
| LabAcon | 81.25 | 86.11 | 88.64 | 68.88 |
| GLOBAL | 75.0 | 86.11 | 88.88 | 70.45 |
| Chi-square | *26.67* | *31* | *26.5* | *37.7* |
| (p-value) | *(<0.0001)** | *(<0.0001)** | *(<0.0001)** | *(<0.0001)** |

***Statistically Significant (p<0.05)***

**Table 4:** Comparison of the sensitivity, specificity, PPV, and NPV of the 3 RDTs

| Test Kits Used | Sensitivity (%) | Specificity (%) | PPV (%) | NPV (%) |
|---|---|---|---|---|
| ARIA® | 83.02% | 64.86% | 77.20% | 71.88% |
| LabACON® | 81.25% | 86.11% | 88.64% | 68.88% |
| GLOBAL® | 75.0% | 86.11% | 88.88% | 70.45% |
| Chi-square (p-value) | *2.14 (0.343)* | *17.72 (<0.0001)** | *7.53 (0.023)** | *0.381 (0.827)* |

***Statistically Significant (p<0.05)***

By using HCV ELISA as a reference test, the Sensitivity, Specificity, Positive Predictive Value and Negative Predictive Value of Aria ® was (83.02%, 64.86%, 77.20%, 71.88%) respectively. The test performance of Aria ® was significantly lower than the performance of ELISA (p<0.05). However, there was no significant difference between the Sensitivity of Aria® and ELISA performance (p=0.188) (Table 5). By using HCV ELISA as reference test, the Sensitivity, Specificity, Positive Predictive Value and Negative Predictive Value of LabACON ® was (81.25%, 86.11%, 88.64%, 68.88%) respectively, The test performance of LabACON ® was significantly lower than the performance of ELISA (p<0.05) (Table 6).

The Sensitivity, Specificity, Positive Predictive Value and Negative Predictive Value of Global ® rapid test was (75.00%, 86.11%, 88.88%, and 70.45%) respectively compared with a reference panel. The performance characteristics of Global ® was significantly lower than the performance of ELISA (p<0.05) except there was no significant difference between the Positive Predictive Value of Global ® and that of ELISA (p=0.061) (Table 7).

**Table 5:** Sensitivity, Specificity, Positive Predictive Values and Negative Predictive Values of the ARIA RDT in Comparison to Reference Panel

| Test Kits Used | Sensitivity (%) | Specificity (%) | PPV (%) | NPV (%) |
|---|---|---|---|---|
| Gold Standard | 100 | 100 | 100 | 100 |
| ARIA ® | 83.02 | 64.86 | 77.20 | 71.88 |
| Chi-square (p-value) | *7.32 (0.188)* | *27.98 (<0.001)** | *15.38 (0.001)** | *13.48 (0.002)** |

***Statistically Significant (p<0.05)***

**Table 6:** Sensitivity, Specificity, Positive Predictive Values and Negative Predictive Values of the LabAcon RDT in Comparison to Reference Panel

| Test Kits Used | Sensitivity (%) | Specificity (%) | PPV (%) | NPV (%) |
|---|---|---|---|---|
| **Gold Standard** | 100 | 100 | 100 | 100 |
| LabAcon® | 81.25 | 86.11 | 88.64 | 68.88 |
| Chi-square (p-value) | *9.23 (0.0024)** | *4.69 (0.03)** | *3.51 (0.061)* | *16.77 (<0.0001)** |

***Statistically Significant (p<0.05)***

**Table 7:** Comparing the Sensitivity, Specificity, PPV and NPV of GLOBAL RDT Kit with a Gold Standard

| Test Kits Used | Sensitivity (%) | Specificity (%) | PPV (%) | NPV (%) |
|---|---|---|---|---|
| **Gold Standard** | 100 | 100 | 100 | 100 |
| GLOBAL | 75.0 | 86.11 | 88.88 | 70.45 |
| Chi-square (p-value) | *15.61 (0.001)** | *4.69 (0.03)** | *3.51 (0.061)* | *16.77 (<0.0001)** |

***Statistically Significant (p<0.05)***

## DISCUSSION

The study evaluated the performance characteristics of 3 anti-HCV rapid test kits using a well-characterized serum panel of known positive and negative samples confirmed by HCV ELISA and PCR. The 3 RDTs assessed included Aria, LabAcon and GLOBAL. The study observed that the 3 anti-HCV rapid test kits had varied performance characteristics. In addition there are 2 major observations from this study; there was no statistically significant difference between the positivity and negativity of ELISA and PCR in the detection of HCV antibodies. The study observed high false positive and false negative with the rapid kits evaluated which translate to low sensitivity and specificity. The sensitivity and specificity

of the 3 rapid tests kits determined varied with the acclaimed sensitivity (98.7%, 99.1% and 98.7% for Aria. LabAcon and GLOBAL respectively) and sspecificity (99.6%, 99.5% and 99.1% for Aria, LabAcon and GLOBAL respectively) recorded by kit manufacturers. The values recorded by producers of these kits were higher than the values obtained from the study. This variation could be a result of the panel they used in the evaluation of their products, as most kit producers use seroconversion sera for evaluation. Besides, manufacturers of test kits may give high sensitivity and specificity to attract buyers to their products. The accuracy of rapid tests as claimed by the manufacturers is normally based on seroconversion test panels which do not necessarily reflect the antibody spectrum in the population studied. This is the reason for kit evaluation and validation. This result showed that none of these rapid test kits has comparable sensitivity and specificity to ELISA that had sensitivity of 100% and specificity of 100%, showing the superiority of HCV ELISA over the 3 RDTs evaluated. The sensitivity and specificity of the 3 RDTs evaluated showed that Aria ® had the highest sensitivity and NPV. Conversely, LabACON and GLOBAL had the highest Specificity and PPV. There was a significant difference in the specificity ($p<0.0001$) and PPV ($p=0.023$) of the 3 RDTs. However, there was no significant difference in the sensitivity ($p=0.343$) and NPV ($p=0.827$) of the 3 RDTs. None of the 3 rapid test kits has good sensitivity and specificity compared to the referential panel. The implications of this finding is some patients or blood donors may test negative using these rapid test kits but they are positive for HCV antibodies. This will result in the transfusion of the infected blood units to recipients leading to infection and invariably translate to high prevalence of HCV infection in the community.

The results of previous studies on HCV rapid test kit evaluation showed good performance of OraQuick HCV kit over Biorapid and Axiom as reported by Kosack and Nick [11]. In another evaluation study by Ghamdan et al [12], the rapid test kits evaluated had good performance. In the evaluation of five rapid diagnostic tests for the detection of anti-HCV done in India, Mane et al [13] reported that Alere Truline, SD Bioline and OraQuick RDTs had sensitivity and specificity in accordance with acceptable standard in India. The acceptable standard for rapid test to be used for testing patients' samples in India is kits should have a minimum 95% sensitivity and specificity Mane et al [13]. Also, Smith et al [14] in their study on evaluation of 3 RDTs concluded that false rapid assay results were associated with HIV seropositivity. This shows that rapid test kits performance is dependent on the make-up of the kit and on the samples being tested.

This present study is the first on the evaluation of Aria, LabAcon and GLOBAL HCV rapid test kits in Nigeria. The reason for this variation in RDTs sensitivity and specificity obtained could be due to kit potency as these test kits were purchased from dealers and marketers and storage cannot be guaranteed. Rapid kits potency could be affected by poor storage [7]. It could also be due to inadequate coating of the antigen, nature of antigens used and genetic heterogeneity of the virus [15, 16]. In this study, we observed high false-negative results with the rapid diagnostic kit compared to ELISA. The results obtained from ELISA testing for HCV showed that ELISA format is more sensitive than rapid test kit [5]. The result of this study corroborates the finding of Bjoerkvoll et al [17]. In their cross-sectional epidemiological study, they

compared the accuracy of rapid test immunochromatographic kits in the detection of HBsAg, anti-HBc and anti-HCV against ELISA, in two populations of 1200 potential blood donors in rural Cambodia and Vietnam. For HBsAg specifically, they found the rapid test kits to be high in specificity (99.8–99.9 %) but lower in sensitivity (86.5 %). They also found a difference in its sensitivity between both countries. In Cambodia, the sensitivity was 93.5 % and in Vietnam 81.8 %. The test sensitivity observed was significantly lower than that claimed by the manufacturer: 86.5% for HBsAg, 86.6% for anti-HBc, and 76.4% for anti-HCV. The low sensitivity of the actual rapid tests for HBsAg, anti-HBc and anti-HCV make them useless for blood donor screening in rural Southeast Asia. Rapid tests may be useful screening tools in blood transfusion services in low-resource settings, but tests should be carefully validated locally before being used for screening purposes since test performance varies by location. Other reasons for low sensitivity of rapid test kits could be due to prozone effect and the genetic makeup of the kit. The prozone effect may explain why some true positive result turned negative with the rapid test [20]. Cross reacting antibodies may also disturb the test result. There may be errors due to genotype variations that may influence test [18]. Hepatitis C virus is an extremely variable virus with six different genotypes and more than 70 subtypes [14]. HCV genotype 1 is dominant in Nigeria and most West African countries [19] compared to type 6 in Southeast Asia and China where this kit evaluated were manufactured. The low sensitivity observed can be related to deficient detection of genotypes and/or subtype with the test kit.

## CONCLUSION

In summary, the sensitivities and specificities of the 3 rapid test kits evaluated for detecting anti-HCV were low and false negative and false positive rates were too high to make the test feasible for blood donor screening in Nigeria. There are large variations in test performance comparing the 3 rapid test kits validated. It is hereby recommended that rapid test for anti-HCV should be carefully validated locally before being used for blood donor screening and only test kit with comparable performance characteristics with ELISA should be used for screening blood donors and testing patients' samples in Nigeria.

## LIMITATIONS OF THE STUDY

The small number of positive (n=53) and negative (n=36) panels used to evaluate the 3 rapid diagnostic test kits could affect the outcome of the validation. The reason for this is because of insufficient sample volume particularly for HCV negative samples and lack of finance as the study is not funded by any donor agency. Also, the 3 rapid test kits evaluated were not obtained from the manufacturers but were purchased from dealers and suppliers of the products. Possibly, the storage temperature might have affected the potency of the kits.

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## Data Availability

The data used to support the findings of this study are included in the article. The raw data of this study will be made available on reasonable request.

## Conflicting interests

No conflict of interest

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**REFERENCES**

1. Anasaldi F, Buzzone B, Salmosa S, Rola NG, Durando P, Gasparini R, Kandi G. Different seroprevalence and molecular Epidemiology pattern of Hepatitis C virus infection in Italy. J. Med. Virol. 2005; 76: 327-332.

2. Raja NS, Janjua KA. Epidemiology of hepatitis C virus infection in Pakistan. J. Microbiol. Immune Infect. 2008; 41: 4-8.

3. Chukwurah EF, Ogbodo SO, Obi GO. Seroprevalence of Hepatitis C virus (HCV) infection among donors in southern Eastern states of Nigeria. Bio med. Res. 2005; 16 (2): 133-135.

4. Villar LM, Cruz HM, Barbosa JR, Bezerra CS, Portilho MM, Scalioni LP. Update on Hepatitis B and C diagnosis. World J. Virol. 2015; 4 (4): 323-342.

5. Levinson, W. Review of Medical Microbiology and Immunology. 13th Ed. McGraw Lange Medical Book, USA.2014; Pages 331- 341.

6. Shivkumar S, Peeling R, Jafari Y, Joseph L, Pai NP. Accuracy of Rapid and Point of care screening tests for Hepatitis C: A Systematic Review. Inter Med. 2012; 157: 558-566.

7. Constantine NT, Saville RD, Dax EM. Retroviral Testing and Quality Assurance Essential for Laboratory Diagnosis. 1st Ed. A non-profit supported through an educational grant from MedMira Laboratories. 2005; Pages 133-151.

8. Araoye MO. Subject Selection. In: Research Methodology with statistics for health and social sciences. 2nd Ed. Nathadex Ilorin, Kwara State, Nigeria. 2004; Pages 115-121.

9. Nwannadi IA, Alao O, Shoaga L. Hepatitis C among Blood donor in a Teaching Hospital in North Central Nigeria. J. Dental Med. Sci. 2014; 13 (1): 20-23.

10. Niyibizi JB, Gatera EK. Diagnostic Performance between Histidine-Rich Protein (HRP-2), a rapid Malaria Diagnostic Test and microscopic-based staining techniques for the diagnosis of Malaria. J. Trop. Med. Vol. 2020; https:/doi.org/10:1155/2020/5410263.

11. Kosack CS, Nick S. Evaluation of two rapid screening assays for the detection of HCV in a resource-constrained setting. Trop. Med. Inter. Health. 2016; 21 (5); 603-609.

12. Ghamdan AL, Talish M, A-EL B, Mona HH., Zainab H. Effectiveness of three types of a rapid test for the detection of HCV antibodies among blood donors in Alexandria Egypt. J. Virolog. Methods. 2013; 189 (2): 687.

13. Mane A, Sacks J, Sharma S, Singh H et al. Evaluation of five rapid diagnostic tests for detection of antibodies to hepatitis C Virus (HCV): A step towards scale-up of HCV screening efforts in India. PLoS ONE. 2019; 14(1): e0210556.

14. Smith BD, Drobenine J, Jewett A, Branson BM, Garfein BS, Teshaie SK, Weinbaum CM. Evaluation of Three Rapid Screening Assay for detection of antibodies to hepatitis C Virus. The J. Infect. Dis. 2011; 204: 825-831.

15. Yokosuka O, Arai M. Molecular Biology of Hepatitis B Virus: Effect of Nucleotide substituting on the Surface of Hepatitis B. Med. Molecular Morphol. 2006; 39: 113-120.

16. Torane VP, Shastri JS. Comparison of ELISA and rapid screening tests for diagnosis of HIV, Hepatitis B and HCV among healthy blood donors in a Tertiary Care Hospital in Mumbai. Indian J. Med. Microbiol. 2008; 26: 284-285.

17. Bjoerkvoll B, Viet L, Ol HS, Lan NT, Sothy S, Hoel H, Gutteberg T, Husebekk A, Larsen S, Husum H. Screening test accuracy among potential blood donors of HBsAg, anti-HBc and anti-HCV to detect hepatitis B and C virus infection in rural Cambodia and Vietnam. Southeast Asian J. Trop. Med. and Pub. Health. 2010; 41 (5): 1127–1135.

18. Pujol FH, Rodrigez I, Devesa M, Rangel-Aldo R, Liprandi F. A double sandwich monoclonal enzyme immunoassay. Immunoassay. 1993; 14:21-31.

19. Messina JP, Humphreys I, Flazman A. Global distribution and prevalence of hepatition C virus genetypes. Hepatol. 2015; 61:77-87.