Comparative Analysis of Rapid Test and Enzyme Linked Immunosorbent Assay for Screening of Blood Donors for Hepatitis B Surface Antigen Seropositivity

Article *in* West African Journal of Medicine · January 2021

CITATIONS
2

READS
88

3 authors, including:

Foluke Atinuke Fasola
College of Medicine, University of Ibadan / University College Hospital Ibadan, Nig…
67 PUBLICATIONS **492** CITATIONS
SEE PROFILE

Adeola Fowotade
National Postgraduate Medical College of Nigeria
8 PUBLICATIONS **48** CITATIONS
SEE PROFILE

WEST AFRICAN JOURNAL OF MEDICINE

ISSN 0189 – 160X

Volume 38 Number 1 January, 2021

ORIGINAL ARTICLES

CASE REPORT

COLLEGE NEWS

See full Table of Contents in English (Page 1A) and French (Page 1B)

PUBLISHED BY
THE WEST AFRICAN COLLEGE OF PHYSICIANS
AND
THE WEST AFRICAN COLLEGE OF SURGEONS

www.wajmed.org

WEST AFRICAN JOURNAL OF MEDICINE

ORIGINAL ARTICLE

Comparative Analysis of Rapid Test and Enzyme Linked Immunosorbent Assay for Screening of Blood Donors for Hepatitis B Surface Antigen Seropositivity

Analyse Comparative du Test Rapide et du test Immuno-Enzymatique Pour le Dépistage de la Séropositivité de l'Antigène de Surface de l'Hépatite B Chez les Donneurs de Sang

A. S. Adeleke[†], F. A. Fasola*[‡], A. Fowotade[§]

ABSTRACT

BACKGROUND: **The Hepatitis B surface Antigen (HBsAg) is the most utilized indicator marker of hepatitis B infection. This study assesses the accuracy of the two most common screening assays used to detect HBsAg among blood donors.**

MATERIALS AND METHODS: **A total of 350 eligible blood donors were screened for HBsAg using both Bio-Check HBsAg Rapid screening kit (BioCheck Inc, South San Francisco, USA) and a fourth-generation Enzyme-Linked Immunoassays (ELISA) kit, MonolisaTM HBs Ag Ultra (Bio-Rad Laboratories, Marnes-la-Coquette-France). Questionnaires were used to inquire about risk factors for HBV infection among blood donors. The calculation of sensitivity, specificity, negative predictive and positive predictive values were carried out by comparing the performance of the rapid kit with ELISA test as the reference standard.**

RESULTS: **The prevalence of HBV infection using Rapid Diagnostic Test (RDT) was 5.7% but was 14.6% by ELISA. Using ELISA as a reference, the sensitivity and specificity of RDT were 31.4% and 98.7% respectively. The positive predictive value and negative predictive value for RDT were 80.0% and 89.4% respectively. Overall non-compliance with transfusion-transmitted infection (TTI) risk-related deferral criteria was 38%.**

CONCLUSION: **The low sensitivity of RDT kits precludes its continuous use in high HBV endemic regions where many donors fail to disclose full and truthful information about their risk for TTI. It is suggested that blood banks should complement the use of RDT with a more sensitive assay such as ELISA. 2021; 38(1): 19–23.**

Keywords: **HBsAg, Blood transfusion, rapid kit, ELISA, blood donors.**

RÉSUMÉ

CONTEXTE: L'antigène de surface de l'hépatite B (HBsAg) est le marqueur indicateur de l'infection par l'hépatite B le plus utilisé. Cette étude évalue la précision des deux tests de dépistage les plus courants utilisés pour détecter l'HBsAg chez les donneurs de sang.

MATÉRIAUX ET MÉTHODES: Au total, 350 donneurs de sang admissibles ont été soumis à un test de dépistage de l'HBsAg à l'aide du kit de dépistage rapide de l'HBsAg Bio-Check (BioCheck Inc, South San Francisco, États-Unis) et d'un kit d'immuno-essais enzymatiques (ELISA) de quatrième génération, MonolisaTM HBs Ag Ultra (Bio-Rad Laboratories, Marnes-la-Coquette-France). Des questionnaires ont été utilisés pour s'enquérir des facteurs de risque d'infection par le VHB chez les donneurs de sang. Le calcul de la sensibilité, de la spécificité, des valeurs prédictives négatives et positives a été effectué en comparant les performances du kit rapide avec le test ELISA comme standard de référence.

RÉSULTATS: La prévalence de l'infection par le VHB en utilisant le test de diagnostic rapide (TDR) était de 5,7 %, mais elle était de 14,6 % en utilisant le test ELISA. En utilisant ELISA comme référence, la sensibilité et la spécificité du RDT étaient respectivement de 31,4 % et 98,7 %. La valeur prédictive positive et la valeur prédictive négative du TDR étaient respectivement de 80,0 % et 89,4 %. La non-conformité globale aux critères d'exclusion liés au risque d'infection transmise par transfusion (ITT) était de 38 %.

CONCLUSION: La faible sensibilité des kits de TDR empêche leur utilisation continue dans les régions à forte endémicité du VHB, où de nombreux donneurs ne divulguent pas d'informations complètes et véridiques sur leur risque d'ITT. Il est suggéré que les banques de sang complètent l'utilisation du TDR par un test plus sensible tel que l'ELISA. **WAJM 2021; 38(1): 19–23.**

Mots-clés: HBsAg, transfusion sanguine, kit rapide, ELISA, donneurs de sang.

Departments of [†]Biomedical Laboratory Science, College of Medicine, University of Ibadan, Ibadan, Nigeria; [‡]Haematology, College of Medicine, University of Ibadan, University College Hospital, Ibadan, Nigeria; [§]Medical Microbiology & Parasitology, College of Medicine, University of Ibadan, University College Hospital, Ibadan, Nigeria.

***Correspondence:* Dr Foluke A. Fasola,** Department of Haematology, University College Hospital, Ibadan, Nigeria. Postal Code: 200. E-mail: folukefasola@yahoo.com, fafasola@comui.edu.ng Phone number: +234 8033375785

Abbreviations: ELISA, Enzyme-Linked Immunoassays; **HBsAg,** Hepatitis B surface Antigen; **RDT,** Rapid Diagnostic Test; **TTI,** Transfusion-Transmitted Infection.

INTRODUCTION

Hepatitis B virus is a viral infection that primarily affects the liver, causing both acute and subsequently chronic disease of the liver.[1] Hepatitis B surface antigen (HBsAg) has been the major component of the virus used for laboratory testing to identify active infection by HBV. The hepatitis B surface antigen (HBsAg) is detected in the blood during the early phase of acute HBV infection. In the acute liver disease, the HBsAg is gradually cleared and disappears from the patients' blood stream as the patient clears the virus from the body and recovers from the acute liver injury. For patients who recover, there is a loss of HBsAg seropositivity. Patients who fail to mount an adequate immune response to combat the infection, end up living with the disease their entire life-time, thus resulting in chronic hepatitis B virus infection. Chronic hepatitis B infection is associated with liver-related morbidity and mortality and characterized by the persistence of HBsAg.

An estimated 257 million people are living with hepatitis B virus infection with about 50 million chronic carriers resident in Africa.[2] The sero-positivity rate for HBsAg among blood donors in Nigeria ranges between 8 and 22%.[3,4] The identification of HBV carrier status among blood donors is critical to eliminating the transmission of HBV through blood transfusion. Several test methods are used to detect HBsAg in the blood of infected individuals. These include using rapid diagnostic tests (RDTs) and the laboratory-based immunoassays.[5] Routine screening for HBsAg is typically through rapid test and or enzyme-linked immunoassays (ELISA) test in Nigeria.

Blood banks with limited laboratory capacity depend on the rapid screening test to determine the HBV status and eligibility of donors even though this method is generally not recommended for blood screeningý.[6] The analytical performance of the assays vary, therefore, a sensitivity which is required in blood transfusion screening for viral markers is also not the same for all kits used for screening. An evaluation of the HBsAg positive rate of the blood donors who had passed the rapid test in our blood bank using ELISA kit reported a prevalence of 8.5%. Scheiblauer *et al* evaluated 17 different diagnostic reagent sets available in Europe and found that detection limits varied from 5 to 10-fold between the most sensitive and least sensitive assays, depending on the serotype of HBsAg tested.[7] The performance levels of available HBsAg qualitative assays is critical to mitigating the transmission of HBV through blood transfusion. Therefore, this study aims to assess the accuracy of the two most common assays used to detect HBsAg among blood donors in our hospital to influence the existing guidelines on hepatitis screening of blood donors.

SUBJECTS, MATERIALS AND METHODS

This study was a cross-sectional study conducted at the blood bank of a tertiary institution in Nigeria that recruits an average of 650 blood donors in a month. The blood donors are usually replacement donors with a few voluntary donors. The routine procedure for donor selection criteria of the blood bank includes health talk by a nurse counsellor and counselling of donors who test positive to any of the TTIs, verbal administration of a set of questions to identify those who are high-risk blood donors and the use of copper sulphate test to detect anaemia in the donors. The screening algorithm involves the use of rapid test followed by ELISA tests to detect the presence of HBV, Hepatitis C virus (HCV), Human immunodeficiency virus (HIV) and syphilis among the donors. The inclusion criteria for this study were individuals whose age ranged from 18–65 years, weighed ≥ 50kg, passed the questionnaire stage of the selection criteria and passed the CuSO4 test. Individuals with tattoos (exclusive of tribal marks obtained from infancy) were eliminated from the study as well as from donating blood by the transfusion service. Ethical approval was obtained from the UI/UCH ethics committee, University College Hospital, Ibadan (UI/EC/19/0204). Consent of willingness to participate in the study was obtained from all participants included in the study. At the point of initial donor screening by rapid test, questionnaires were administered to inquire about the presence of risk factors for HBV infection among the blood donors. Blood samples were collected at the blood bank from 350 blood donors. All the 350 blood donors' samples were tested with both rapid test and ELISA test. The serum from the blood sample was separated into 2 aliquots. One of the aliquots of the serum was tested for HBsAg using BioCheck HBsAg Rapid screening kit (BioCheck Inc, South San Francisco, USA). The second aliquots were tested using a fourth-generation ELISA kit, Monolisa™ HBs Ag Ultra (Bio-Rad Laboratories, Marnes -la-Coquette-France). All the specimens were processed as per instructions in the kit insert.

Statistical Analysis

The statistical package for social sciences (SPSS), IBM SPSS Statistics for Windows, Version 24.0. Armonk, NY: IBM Corp. was used for statistical analysis. The calculation of sensitivity, specificity, negative predictive and positive predictive values of the rapid kit were carried out with the ELISA test as the reference standard. ELISA is one of the recommended and preferred screening techniques for blood banking, therefore the use as reference test.[6] Sensitivity was calculated as true positives/(true positives + false negatives) × 100; specificity as true negatives/ (true negatives + false positives) × 100; negative predictive value as true negatives/ (true negatives + false negatives) × 100 and positive predictive value as true positives/ (true positives +false positives) × 100.

RESULTS

All the blood donors that came to the blood bank during the period of study were replacement donors. The mean age of the blood donors was 32.25 ± 8.47 years. The socio-demographic characteristics of the blood donors showed that 86.9% were male and those with tertiary education constituted 61.7% (Table 1). Assessing the risk factors for HBV infection, 4.6% had previously been diagnosed and managed for STD. Also, few (3.7%) of the participants had ever used a recreational drug and 4% had received HBV vaccine (Table 2). Seventeen percent (17%) had been asked to do test for Hepatitis B virus for an

earlier health problem, this was weakly significant (p=0.063). The degree of failure to disclose full and truthful information is termed noncompliance. Overall non-compliance with transfusion-transmitted infection (TTI) risk-related deferral criteria was 38%. Previous history of jaundice was the only risk factor that was significantly associated with seropositivity for HBsAg using ELISA test (p=0.010) (Table 2).

The prevalence of HBV infection using RDT was 5.7% while the prevalence of HBV infection using ELISA was 14.6%. The diagnostic performance of the rapid test against the ELISA test is as shown in table 3. Of the 350 blood donors, 330 (94.3%) were negative for HBsAg with RDT, while 299 (85.4%) were negative using ELISA. RDT reported that 68.6% of the blood donors who were seropositive for HBsAg by ELISA were negative. ELISA reported as seronegative 20% of the blood donors that were seropositive by RDT. Using ELISA as reference, the sensitivity and specificity of RDT were 31.4% and 98.7% respectively. The positive predictive value and negative predictive value for RDT were 80.0% and 89.4% respectively.

Table 1: Socio-demographic Characteristics of Blood Donors

Socio-demographic Factors	N=350	%
Sex		
Male	304	86.9
Female	46	13.1
Total	350	100.0
Age group (years)		
18-27	108	30.9
28-37	142	40.6
≥38	100	28.6
Total	350	100.1
Marital status		
Married	207	59.1
Single	142	40.6
Widow	1	0.3
Total	350	100.0
Occupation		
Vocational	69	19.7
Unskilled	26	7.4
Skilled	165	47.1
Professional	90	25.7
Total	350	99.9

Table 2: Effect of Risk Factors for HBV on the Seropositivity for HBsAg by ELISA Test

Variables	Negative n (%)	Positive n (%)	χ^2	p-value
Previous knowledge of Hepatitis				
No	230(84.2)	43(15.8)	1.387	0.239
Yes	69(89.6)	8(10.4)		
Sexually active				
No	55(84.6)	10(15.4)	0.042	0.837
Yes	244(85.6)	41(14.4)		
Multiple sex partners				
No	270(85.7)	45(14.3)	0.207	0.649
Yes	29(82.9)	6(17.1)		
History of STD				
No	285(85.3)	49(14.7)	0.058	0.810
Yes	14(87.5)	2(12.5)		
History of tattoo/scarification mark				
No	265(86.0)	43(14.0)	0.768	0.381
Yes	34(81.0)	8(19.0)		
Ever used recreational drug before sex				
No	290(86.1)	47(13.9)	2.846	0.092
Yes	9(69.2)	4(30.8)		
Use of Shared sharp objects				
No	186(85.7)	31(14.3)	0.037	0.847
Yes	113(85.0)	20(15.0)		
Ever been transfused with blood				
No	274(84.6)	50(15.4)	2.595	0.107
Yes	25(96.2)	1(3.8)		
Had jaundice in the last one year				
No	298(85.9)	49(14.1)	6.597	0.010*
Yes	1(33.3)	2(66.7)		
Ever had blood tested for HBV				
No	244(83.8)	47(16.2)	3.461	0.063
Yes	55(93.2)	4(6.8)		
History of HBV vaccination				
No	285(84.8)	51(15.2)	2.487	0.115
Yes	14(100.0)	0(0.0)		

*, *Significant.*

Table 3: Diagnostic Performance of the Rapid Test (RDT) and Enzyme Immunoassay Tests (ELISA)

		ELISA		Total
	Test Results	Positive	Negative	
RDT	Positive	16 (TP)	4(FP)	20
	Negative	35(FN)	296 (TN)	331
Total		**51**	**299**	**350**

Fischer's exact test p=0.000;
TP, True positive; TN, True negative; FN, False negative; FP, False positive

DISCUSSION

Screening of blood donors is one of the most effective ways of reducing the prevalence of HBV infection. The high endemicity of HBV chronic carriage prevalence of ≥8% in Sub-Saharan Africa is a big threat to blood transfusion safety particularly if the selection criteria to determine donor eligibility are not stringently enforced. This study showed that there is a disparity between the ability of the rapid test and the ability of the ELISA to identify those who have HBV infection among the donors. This is consistent with studies carried out in places with different levels of endemicity for HBV.[5] The prevalence of HBV among our blood donors using RDT was similar to an earlier report from another institution in Nigeria.[8] The RDT assay showed that 68.6% of the blood donors that were sero-positive for HBsAg by ELISA were negative, this value is considerably higher than 9% reported from another study using a different RDT kit.[9] The sensitivity of 31.4% for RDT suggests that RDT could only correctly identify 31.4% of the participants with the disease. This is consistent with the poor overall sensitivity in an assessment of the accuracy of TTI screening in Africa using both RDTs and ELISAs on an external quality assessment panel for HBsAg detection.[10] This sensitivity is lower than that of 78% reported in a study carried out in Gabon that has similar hepatitis B seroprevalence with Nigeria.[11] This may be due to differences in the type of kit used as evidenced by variable sensitivities observed for a consi-derate number of testing laboratories in Africa.[12] The rapid screening test may have a lower detection threshold than the immuno-assays hence it could not detect the smallest amounts of HBsAg in low-level carriers. A study reported the sensitivity for strong HBsAg as 93·8% and intermediate HBsAg as 51·5% suggesting that the sensitivity of the kit may be influenced by the concentration of HBsAg in the sample. The research assessed the sensitivity of rapid tests for the detection of HBsAg compared to enzyme immunoassays by evaluating the samples based on the strength of positivity (strong and intermediately positive samples).[13] The HBsAg concen-tration in our donors was likely lower than the detection level of the RDT kit thereby reducing the ability of the rapid kit to detect the infection. HBsAg mutants or specific genotypes have been attributed to falses-negative RDT results.[14]

Despite the relatively high sensi-tivity, specificity and accuracy quoted on the insert of the RDT kits, high false negatives of RDT reported by other authors and supported by this study are of serious concern.[15,16] Despite the advantages of the RDT kits which include being cheap, thus making it to fit into the budget of many blood banks in sub-Saharan Africa and the conduct of the test also does not require electricity, special training or equipment before use. The suitability and efficiency in the high endemic regions are questionable, therefore, the existing policy of screening of blood donors with rapid kits should be revisited. For blood banks that cannot afford to further complement the use of RDT with ELISA, the use of 2 different RDT tests that use different methods and have been validated for high sensitivity and should be encouraged. The continual use of a single test policy should strongly be discouraged in high endemic regions. The specificity of 94.5% in an earlier study is consistent with 98.7% in our study.[10] There is a high probability that a person who tests negative does not have the disease and also a high probability that a person who tests positive has the disease. Surpris-ingly, RDT reported that 20% of donors that were negative with ELISA were positive. This could be a false-positive result. Although one of the flaws of RDT is that it is operator dependent but this information should not be discarded. One of the limitations of this study is the inability to further investigate the 20% to rule out false-positive results. The presence of HBV mutants with epitopes that are not recognized by the anti-HBs assay reagents in the capture phase and the conjugates is also a possibility.[17] The suspicion that some samples could have false positive status particularly samples that were positive by rapid test but negative by ELISA could be resolved by a HBsAg Neutralization test or a nucleic acid test (NAT) for HBV deoxyribo-nucleic acid (DNA).

A standard pre-donation risk assessment requires that a donor self-declares or self-completes a question-naire before donation followed by a confi-dential interview with a medical counsesllor.[18] The study shows that the oral administration of questionnaires for risk-behaviour evaluation by our institution may not be adequate to provide the required privacy for blood donors to divulge certain intimate questions which can be put into writing. This is evidenced by high-risk blood donors attesting to these risk factors on the administration of the questionnaire. Multiple and complex factors were found associated with non-compliance, varying from deliberate (e.g., test seeking, social discomfort, disagreement with deferral criteria and misunderstanding of the pre-donation screening purpose since donations are tested further) to genuine (e.g., misinterpretation of questions, failure of recall and erroneous no-risk belief associated with temporally remote exposure) non-disclosure.[18] These reasons for evading the questions cannot be ruled out among the blood donors. While an overall non-compliance with transfusion-transmitted infection (TTI) risk-related deferral criteria rate of 38% was observed amongst our donors, an estimated rate of 1.65 and 13% in general donor populations, irrespective of blood screening results, has been reported in Australian and Hong Kong blood donors.[18] Studies have reported percent-ages as high as 25% among donors who tested positive for viral infection.[18] Ten percent (10%) of the blood donors confessed to having multiple sexual partners and 4.6% had previously been treated for the sexually transmitted disease. Half of those who confessed to the use of recreation drugs were positive for HBV. There is an urgent need to start to use a typed questionnaire, that can provide confidentiality. Donor education could also increase the compliance with TTI risk-related deferral criteria. There was no significant association between HBV infection and the risk factors enumerated in the study except for those with jaundice (p=0.010). This calls into question the degree to which both the rapid kit and ELISA HBsAg assays could detect HBV infection among our patients.

This study also reported that 100% of those that have been vaccinated were negative; this is suggestive of the effectiveness of the vaccine and heart-warming that vaccination could stem the endemicity of HBV among blood donors. However just 4% of the donors were vaccinated. Donor education is one of the factors that determine the effectiveness of donor self-deferral, this is not reflected in the donors even though more than half of the donors had tertiary education. The high dependence on family replacement donors and high level of compromise at the questionnaire stage leaves a lot of loopholes for the high prevalence of HBV infection. While there is an urgent need to have a written questionnaire administered to our replacement donors, the need for an efficient laboratory screening test cannot be over-emphasized.

ACKNOWLEDGEMENT

We would like to thank the members of staff of the blood bank who provided the enabling environment for the collection of data and also the blood donors who participated in the study.

Statement of Ethics

Ethical approval was granted by the UI/UCH ethics committee, University College Hospital, Ibadan (UI/EC/19/0204).

Disclosure Statement

The authors declare no conflict of interest.

Funding Sources

We received no funding for this work.

Author Contributions

F. A. Fasola and A. S. Adeleke conceptualized the study. A. S. Adeleke participated in the design of the study, laboratory analysis, data analysis and interpretation and wrote the first draft of the manuscript. F. A. Fasola participated in the design of the study, data analysis and interpretation, managed the literature search and wrote the first draft of the smanuscript. A. Fowotade participated in the design of study and laboratory analysis. All authors reviewed the manuscript for substantial content.

Financial Support

Nil.

REFERENCES

1. Clements JC, Coghlan B, Creati M, Locarnini S, Tedder RS, Torresi J. Global control of hepatitis B virus: does treatment-induced antigenic change affect immunization? *Bulletin of the World Health Organisation.* 2010; **88:** 66–73. doi: 10.2471/BLT.08.065722
2. Hepatitis B – World Health Organisation. Available at: https://www.who.int › news-room › fact-sheets › detail › hepatitis-b. Accessed 01 Dec 2019.
3. Berinyuy BE, Alawode RA, Mohammed AB, Babalola BS, Mustapha A. Oshevire RM, *et al.* Prevalence of Hepatitis B Virus in Nigeria: Review Update. *Annal Pub Health & Epidemiol.* 2019; **1:** APHE.MS.ID.000501.
4. Fasola FA, Fadimu PA and Akpan VO. A seven-year Review of the Seroprevalence of Transfusion Transmitted Infections in a Hospital-based Blood Bank in Ibadan Nigeria. *Clin Med Res.* 2017; **6:** 1–8.
5. Amini, A, Varsaneux O, Kelly H, Tang W, Chen W, Boeras DI, *et al.* Diagnostic accuracy of tests to detect hepatitis B surface antigen: a systematic review of the literature and meta-analysis. *BMC Infect Dis* 2017; **17:** 698.
6. World Health Organisation. (2009). Screening donated blood for transfusion-transmissible infections: recommendations. World Health Organisation. Available at: https://apps.who.int/iris/handle/10665/44202)). Accessed on: 01 December 2019.
7. Scheiblauer H, Soboll H, Nick S. Evaluation of 17 CE-marked HBsAg assays with respect to clinical sensitivity, analytical sensitivity, and hepatitis B virus mutant detection. *J Med Virol* 2006; **78:** S66–S70.
8. Salawu L, Murainah HA. Pre-donation screening of intending blood donors for antibodies to infectious agents in a Nigerian tertiary health institution: A pilot study. *Afri J Med Med Sci.* 2006; **35:** 453–456.
9. Erhabor O, Kwaifa IK, Bayawa AM, Isaac ZI, Dorcas I, Sani I. Comparison of ELISA and Rapid Screening Techniques for the Detection of HBsAg among Blood Donors in Usmanu Danfodiyo University Teaching Hospital Sokoto, North-Western Nigeria. *J Blood Lymph.* 2014; **4:** 124.
10. Laperche S. Francophone African Group for Research in Blood T. Multinational assessment of blood-borne virus testing and transfusion safety on the African continent. *Transfusion*. 2013; **53:** 816–826.
11. Eko Mba JM, Bisseye C, Mombo LE, Ntsame Ndong JM, Mbina Ekayeng SC, Bengone C, *et al.* Assessment of rapid diagnostic tests and fourth-generation Enzyme-Linked Immunosorbent Assays in the screening of Human Immunodeficiency and Hepatitis B virus infections among first-time blood donors in Libreville (Gabon). *J Clin Lab Anal.* 2019; **33:** e22824.
12. Bloch EM, Shah A, Kaidarova Z, Laperche S, Lefrere JJ, van Hasseltet J, *et al.* A pilot external quality assurance study of transfusion screening for HIV, HCV and HBsAg in 12 African countries. *Vox Sang*. 2014; **107:** 333–342.
13. Prugger C, Laperche S, Murphy EL, Bloch EM, Kaidaova Z, Tafflet M, *et al.* Screening for transfusion transmissible infections using rapid diagnostic tests in Africa: a potential hazard to blood safety? *Vox Sang.* 2016; **110:** 196–198.
14. Njai HF, Shimakawa Y, Sanneh B, Ferguson L, Ndow G, Mendy M, *et al.* Validation of rapid point-of-care (POC) tests for detection of hepatitis B surface antigen in field and laboratory settings in the Gambia, Western Africa. *J Clin Microbiol*. 2015; **53:** 1156–1163.
15. Adeyemi AA, Omolade OA, Raheem-Ademola RR. Immunochromatographic Testing Method for Hepatitis B, C in Blood Donors. 2013; *J Antivir Antiretrovir.* S3.
16. Khan JK, Lone DS, Hameed A, Munim R, Bhatti M, Khattak AA, *et al.* Evaluation of the Performance Of Two Rapid Immunochromatographic Test for Detection of Hepatitis B Surface Antigen and Anti HCV Antibodies Using Elisa Tested Samples. *Annals of KEMU* 2010; **16:** 84–87.
17. Ly TD, Servant-Delmas A, Bagot S, Gonzalo S, Férey MP, Ebel A, *et al.* Sensitivities of four new commercial hepatitis B virus surface antigen (HBsAg) assays in detection of HBsAg mutant forms. *J Clin Microbiol*. 2006; **44:** 2321–2326. doi: 10.1128/JCM.00121-06.
18. Candotti D. Laperche S. Hepatitis B Virus Blood Screening: Need for Reappraisal of Blood Safety Measures? *Front Med*. 2018; **5:** 29.