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# A Comparison of Two HIV Antibody ELISAs with a Combined Antigen-Antibody ELISA for the Occurrence of False Results in a Hospital-Based Blood Bank In north-Central Nigeria: Implications on Blood Safety and Availability

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***Authors' contributions***

*This work was carried out in collaboration between all authors. Author JAO designed the study, performed the statistical analysis and wrote the first draft of the manuscript. Authors JOE, SSG and EOA managed the analyses and literature searches. All authors read and approved the final manuscript.*

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## ABSTRACT

**Background:** Global targets of providing safe blood available universally by 2020 as well as that seeking to eliminate HIV transmission by 2030 has compelled many hospital-based blood banks to employ relevant strategies in their transfusion practice towards realizing these targets.
**Aim:** To assess two HIV antibody ELISA tests (Determine™ HIV- 1/2 and Dia Pro HIV 1/2/0 ELISA)

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deployed for blood safety and availability amongst blood donors at a hospital-based blood bank in north-central Nigeria for the occurrence of false test results.

**Materials and Methods:** This cross-sectional study was carried out at the hospital-based blood bank of Jos University Teaching Hospital (JUTH) between May and August 2008. The sera of four hundred and forty blood donors were serially tested with two HIV antibody ELISAs Determine™ HIV-1/2 and Dia Pro HIV 1/2/0 ELISA and then comparatively tested with Genscreen ®PLUS HIV Ag- Ab ELISA (a combined HIV antigen-antibody ELISA. The proportion of false negative (FN), false positive (FP), negative predictive value (NPV) and positive predictive value (PPV) of test results were determined using prism pad statistical package version 5 with $p<0.05$ taken as the level of statistical significance.

**Results:** False negative (FN) tests results were recorded as 60.98% and 46.34% for Determine ™ HIV 1/2/0 and Dia Pro HIV 1/2/0 respectively related to the sensitivities (39.02% and 53.65%) and specificities (100% and 99.50%) of Determine ™ HIV 1/2/0 and Dia Pro HIV 1/2/0 respectively. The proportion of FP test results were found to be 0 and 0.50 percent for Determine ™ HIV 1/2/0 and Dia Pro HIV 1/2/0. The positive predictive value (PPV) was 100% and 91.67% while the negative predictive value (NPV) was 94.1% and 95.4% for Determine ™ HIV 1/2/0 and Dia Pro HIV 1/2/0 respectively.

**Conclusion:** The high FN and low NPV obtained with the two HIV antibody ELISAs suggest their unsafety if deployed for TTI screening in our blood bank. The low FP and relatively higher PPV, on the other hand, suggest low deferral rate for Determine ™ HIV 1/2/0 but not necessarily so for Dia Pro HIV 1/2/0. The contentious deployment of these antibody tests would compromise initiatives necessary in developing blood safety and availability in order to achieve the global targets.

**Recommendation:** Hospital-based blood banks in our setting should be supported to deploy only the combined HIV antigen-antibody ELISA for all blood donors and donations in order to ensure blood safety and availability pending the implementation of nucleic acid amplification testing (NAAT).

*Keywords: HIV antibody ELISA; combined HIV Ag-Ab ELISA; false positive; false negative; transfusion-transmissible-HIV; Nigeria.*

## 1. INTRODUCTION

Blood donor unit or pre-donation testing to intersect human immunodeficiency virus (HIV) infection in blood transfusion practice is now a global strategy that deploy different test assays either as Enzyme-Linked Immuno-sorbent Assay (ELISA) or non-ELISA- based techniques. These tests target specific parts of the virus-like; the gene sequence, gene products or measures the hosts' antibodies. These tests have undergone contentious quality improvement from the first generation through to fourth generation and most recently, there has been the introduction of HIV Nucleic acid amplification testing (NAAT) in resource endowed settings (RES) which has helped in narrowing the diagnostic window and in reducing the risk of transfusion-transmissible HIV (TTI- HIV) by over 50 percent [1,2]. In resource-limited settings (RLS) high expense, technical demands and logistic challenges associated with NAAT has restricted the application of this technology in all countries. Therefore, HIV antibody-based tests either as Rapid Diagnostic Tests (HIV-RDT) or manual plate Enzyme Immunoassays (EIA) are the traditional methods utilized in securing blood donations from TT-HIV.

According to the world health organization (WHO), donated blood should be screened for HIV using a highly sensitive and specific anti-HIV-1 anti-HIV-2 immunoassay or a combined HIV antigen-antibody immunoassay (EIA/CLIA) that is capable of detecting subtypes specific to the country or region and in its absence, a highly sensitive and specific anti-HIV-1 anti-HIV-2 rapid assay could be used in laboratories with small throughput, remote areas or emergency situations [3]. To this effect, NAAT is desirable but not compulsory globally and other acceptable testing methodologies are often deployed in different regions of the world depending on hospital policies or national recommendations. The principal target in hospital-based HIV testing of blood donors or donations is to "screen in" seronegative blood units or donations that may be utilized for transfusion and to "screen out" seropositive donors or donations considered unsafe. Seropositive donors are often referred to a treatment centre wherever it exists for diagnosis, treatment or follow up while seropositive donations or blood units are discarded with implicating financial and man-hour losses or wastages to the hospital or blood bank unit. Quintessentially, HIV antibody assays deployed for blood safety and availability

programmes are ideally expected to be extremely sensitive and able to detect all known HIV subtypes tested without having to record false negative results and be absolutely specific to minimize false positive tests [4]. Discrepancies in the performance of test assays usually arise from the proportion of false positive and false negative test results which bear implications to patients, practitioners and governments.

A false negative test result is observed where a potential blood donor or donation is identified as being HIV sero-negative when in fact such donor or donation has the infection when tested on a gold standard test or method. On the other hand, a false positive test result is observed where a potential blood donor or donation is screened as being HIV sero-positive when indeed such donor or donated unit does not have the infection as tested with by a gold standard test or method. In reality, all tests when measured against standards show varying sensitivity, specificity, positive and negative predictive values and no single test has both 100% sensitivity and 100% specificity nor 100% positive and 100% negative predictive values [5]. It is therefore advised on careful and appropriate selection of HIV tests in different settings because even the best method for HIV screening is capable of producing false positive and false negative test results [6].

In many resource-limited settings (RLS) in Africa, the organization of hospital-based transfusion service is peculiar; hospitals are generally “stand alone” entities relying on their lean financial budgets to run the reputably high-cost services associated with blood transfusion. Their responsibilities revolve around all key aspects of blood transfusion including; donor recruitment, blood collection, screening for transfusion transmissible infections, processing into components and products as well as cross-matching and clinical utilization for transfusion in individual centres or hospitals. Besides these, they are burdened with donor assessment and counselling in an unprofessional manner paving way for paucity of truly voluntary, altruistic and non-remunerated blood donors that will assure safety and availability of blood in this setting [7].

As the target of ensuring safe and available blood by 2020 [8] and that eliminating HIV transmission by 2030 [9] gets closer, the global community is making remarkable innovations. For instance, while a recent comparative assessment of safety in blood donations has questioned the economy of deploying NAAT in screening the high quality blood donations and blood units in developed countries of Europe and America, it justified its utilization in RLS [1]. Relatedly, in order to scale up safety and availability of blood, there are revised recommendations for determining eligibility of donors of human tissues, cells and those who have received human derived clotting factors [10]. Similarly, a recent review of blood donor deferral periods for men who have sex with men (MSM) from an earlier recommendation of lifetime deferral to 12 months since the last sexual contact with another man is under consideration [11,12]. Even at that, further downward review is being sought from 12 months to approximately 2-3 weeks and to accept donations without deferral from low-risk MSM who meet specific behavior-based criteria and their blood screened with NAAT [10]. Furthermore, there are evolving reentry criteria being put in place to reduce the number of blood donors permanently deferred because of certain factors associated with a positive NAAT result. [13,14]. All these measures are aimed at improving safety and availability of blood donations and donor units. In African countries blood safety and availability initiatives can achieve desired outcomes through proactive evidence-based practices. This underscores the relevance in evaluating HIV screening tests in the population of intending use before widespread application as advocated [15].

This study therefore, sought to assess the occurrence of false test results obtained with two HIV antibody ELISAs at a hospital-based blood bank in north central Nigeria and to determine its attendant implications on blood safety and availability in this setting.

## 2. METHODOLOGY

### 2.1 Study Design

This was a cross sectional study comparing two HIV antibody screening assays (Determine™ HIV- 1/2 and Dia Pro HIV 1/2/0 ELISA) with combined HIV antigen-antibody ELISA (GENSCREEN®PLUS HIV Ag-Ab ELISA) for false negative and false positive test results.

### 2.2 Study Site

This was the blood bank unit of Jos University Teaching Hospital (JUTH), in north Central Nigeria.

Jos is the capital city of Plateau State located in north central Nigeria along Latitude 9°53'N and Longitude 8°55'E. It is located on an altitude of 1300 metres above sea level and is surrounded by high plains with elevations of between 600 and 900 meters. The city is endowed with pleasant geographical features including highlands, captivating rock formations and savanna vegetation. The weather is mild all year round with temperatures about 4°C lower than coastal cities and an average rainfall of 1300 mm [16]. Given these features, a cosmopolitan population comprising people from different parts of Nigeria and beyond live in this city with majority of whom are civil servants traders, peasant traders and few factory workers.

Jos University Teaching Hospital offers tertiary health care for the inhabitants of Plateau State and serve as a referral centre for the neighboring states of Nassarawa, Benue, Bauchi, Taraba and Kaduna as well as the Federal Capital Territory.

## 2.3 Study Population

The study population was blood donors of both sexes aged between 18 and 55 years who presented to the blood bank unit of JUTH between May and August 2008, met the pre donation criteria of donating blood in Nigeria [17] and gave a written informed consented to participate in the study were included. Those who failed to give their consent and those who did not fulfil the pre-donation criteria were excluded.

## 2.4 Sample Size

The sample size was determined using the formulae; "$n=Z^2pq/d^2$" where n= minimum sample size; Z= standard normal deviate of 1.96 (from Z table) corresponding to 95% confidence level; p= best estimate of sero prevalence of HIV by combined antigen antibody assay. In the absence of documented reports from previous studies in our environment, "p" was estimated as 50%; q=1-p; d=absolute precision (5% or 0.05). The calculated n=384 was extended to 440 to accommodate for the HIV antibody ELISA plate and controls.

## 2.5 Survey Procedure

Four hundred and forty (440) blood donors completed a validated questionnaire administered by trained research assistants. The major contents of the questionnaire were; donors' bio-data and their relevant characteristics; motivation and type of donation, assessment of high risk practices and risk of post donation complications.

## 2.6 Sample Collection, Processing and Testing

Ten (10) milliliters of venous blood was collected from ante-cubital vein of all the blood donors using a large bore needle to avoid haemolysis and under aseptic conditions. Haemostasis was secured and the collected blood emptied into a clean evacuated tube without an anticoagulant. The process of serum extraction and storage was carried out using standard methods [18,19]. The serum collected was screened for HIV antibodies using Determine™ HIV 1/2 manufactured by Abbott Japan Co. Ltd, Minato-Ku, Tokyo-Japan and thereafter, tested with Dia Pro HIV 1/2/0 EIA and Genscreen®Plus HIV Ag-Ab ELISA manufactured by diagnostic Bioprobes Sx/Italy and BIO-RAD laboratories, 3 Bd Raymond Poincaré, Marnes La Couquette-France respectively. All reagents were sourced from commercial vendors within the country and a cold chain was maintained in the transport, delivery and storage of the reagents until its eventual utilization for testing. All procedures were carried out following the manufacturers' recommendations strictly

## 2.7 Statistical Analysis

The combined HIV antigen-antibody ELISA Genscreen®Plus HIV Ag-Ab ELISA reported to have similar in performances with NAAT(2) was used to validate the two HIV antibody testing methods for False-Negative (FN), false positive (FP), negative predictive value (NPV) and positive predictive value. (PPV) this was done using the Graph Pad Prism 5 Statistical Package. A p-value ≤ 0.05 was taken as level of statistical significance for interpretation of data using Fishers Exact Test.

## 2.8 Ethical Consideration

Ethical standards were strictly adhered to. All blood donors participating in the study gave an informed written consent and a letter conveying ethical approval for the study was obtained from the ethical committee of JUTH.

## 3. RESULTS

A total of 440 blood donors aged between 18 and 55 years who participated in the study reported the following false test results and other related characteristics as indicated in the Tables 1,2 and 3.

## 4. DISCUSSION

This study has found 60.98% and 46.34% false negative (FN) tests results and 0 and 0.50 percent false positive (FP) test results recorded for Determine $^{TM}$ HIV 1/2/0 and Dia Pro HIV 1/2/0 respectively. These findings reflect the sensitivities of 39.02% and 53.65% and specificities 100% and 99.50% of Determine $^{TM}$ HIV 1/2/0 and Dia Pro HIV 1/2/0 respectively. (Tables 1, 2 and 3) The finding in this with particular reference to Determine HIV RDT is different from that reported by Mbaya [20] whose evaluation of Determine RDT reported low FP and FN rates, high sensitivity and specificity of 100% and 99.6% respectively thereby meeting an acceptable clinical performance which is;a sensitivity of $\geq$ 99% for RDT and 100% for EIAs and clinical specificity of $\geq$ 98% for both RDT and EIAs [19]. In this regard, while Mbaya's assessment qualifies these assays for safety, our findings in this study indicate that, the two HIV test assays deployed for blood safety and availability seem inadequate. The statistically significant relationship ($p< 0.001$) in our study also suggest that these two assays are inefficient

**Table 1. HIV antibody (Determine $^{TM}$ HIV 1/2/0) versus Genscreen ®PLUS HIV Ag-Ab ELISA among blood donors**

| | Genscreen ®PLUS HIV Ag-Ab positive | Genscreen ®PLUS HIV Ag-Ab negative | Total |
|---|---|---|---|
| Determine $^{TM}$ positive | 16 | 0 | 16 |
| Determine $^{TM}$ negative | 25 | 399 | 424 |
| Total | 41 | 399 | 440 |

**Table 2. HIV antibody (Dia Pro HIV 1/2/0) versus Genscreen ®PLUS HIV Ag-Ab ELISA among blood donors**

| | Genscreen ®PLUS HIV Ag-Ab positive | Genscreen ®PLUS HIV Ag-Ab negative | Total |
|---|---|---|---|
| Dia Pro HIV 1/2/0 positive | 22 | 2 | 24 |
| Dia Pro HIV 1/2/0 negative | 19 | 397 | 416 |
| Total | 41 | 399 | 440 |

**Table 3. False negative, false positive and some laboratory considerations of Determine $^{TM}$ HIV 1/2/0 and HIV Dia Pro HIV 1/2/0 HIV-antibody assays in comparison with Genscreen ®PLUS HIV Ag-Ab ELISA among blood donors**

| Parameter | Determine $^{TM}$ HIV 1/2/0 vs Genscreen ®PLUS HIV Ag-Ab ELISA | HIV Dia Pro HIV 1/2/0 vs Genscreen ®PLUS HIV Ag-Ab ELISA |
|---|---|---|
| Total number of blood donors | 440 | 440 |
| True positive | 16 | 22 |
| False positive | 0 | 2 |
| True negative | 399 | 397 |
| False negative | 25 | 19 |
| Sensitivity | 39.02% | 53.65% |
| Specificity | 100% | 99.50% |
| Proportion of false negative | 60.98% | 46.34% |
| Proportion of false positive | 0 | 0.50% |
| Positive predictive value | 100% | 91.67% |
| Negative predictive value | 94.1% | 95.4% |
| P<0.05 | < 0.0001 | < 0.0001 |
| Statistical Significance | Yes | Yes |

in preventing TT-HIV infections. While FN test results are expected to be low among a low risk group like blood donors who are usually selected through a rigid pre donation screening procedures and other quality measures usually deployed to defer those with identifiable risks, it is mind bulging that our findings in this study are on a contrary. However, other studies in some parts of Africa have reported related trends. In Ethiopia, Dessie et al, [21] reported a high proportion of FN and a low sensitivity of the RDT while in Ghana, the residual risk of TT-HIV in blood donation despite TTI screening was reported and necessitating recommendation for urgent intervention by internal and external quality control bodies to guarantee transfusion safety [22]. Relatedly, in Abidjan- Cote d'Ivoire, Saravit et al estimated that about 6-12% of the total infected blood units at their NBTS were due to FN test results obtained with screening [23]. Growing concerns for FN testing has brought forth suggestions on the application of probabilities table for false-negative HIV test results in the pre- and post-test HIV counselling. It opined that, the probability of a false-negative result is 0.01 at 80 days' post-exposure for third-generation tests and at 42 days for fourth-generation tests [24]. False-negative test results may occur in the pre-seroconversion phase during primary HIV infection or associated with genetic variability, delayed or absent immune response in the very early or advanced stages of infection and laboratory reporting errors and problems inherent to the assay with respect to its formant and design [4]. Besides FN HIV antibody test results have been reported in patients on antiretroviral therapy.

With regards to FP test results, Rahman et al. [25] also reported a low FP test result for RDT amongst the Pakistan population similar to that reported in our study. A Ghanaian multicenter study, on the other hand reported the mean FP as 11.1% and in one of the centres, a value as high as 28.0% was reported [26]. Some workers have opined that, HIV RDTs may use a restricted target antigen range making them more susceptible than other immunoassays like western blot and line immune assay (LIA) to produce high FP test result [27,28]. Other factors responsible for FP test results have been reported including; difference in constituent reagents, antigens, testing formants and personal operator errors, cross reactivity of HIV-1 and Hepatitis B virus, vaccination for influenza flu and the presence of HLA antibodies amongst others [25]. Generally, a successful elimination of FP test results in hospital-based blood bank is desired in order to avoid inappropriate deferral of blood donors, encourage wastages and losses associated with discard of false positive blood units and other costs in acquiring this scarce commodity-blood. Besides these, such blood donors may develop apathy and lose confidence in the services offered in that health facility, develop psychosocial problems at the time of donation which may result in shortage of blood supply especially if less common blood groups like Rhesus Negative are involved and deplete the blood donor pool for the hospital [25].

This study also found a negative predictive value (NPV) of 94.1% and 95.4% as well as a positive predictive value (PPV) of 100% and 91.67% for Determine $^{TM}$ HIV 1/2/0 and Dia Pro HIV 1/2/0 respectively. Many workers have reported varying PPV for different commercially available HIV assays in different populations [29,30]. A Negative predictive value (NPV) is the proportion of blood donors who test negative and who actually does not have the disease by comparison with the gold standard while a positive predictive value is the proportion of blood donors who test positive and who actually have the disease in comparison with the gold standard.

A high NPV > 99% indicates a very high chance that, a negative result obtained with the assay is truly HIV-uninfected and this is the expectation for a screening test deployed in blood donation screening. The findings of a low NPV < 99% in our study, suggest that, they are inadequate screening assays in our population. The high PPV of Determine suggest it would correctly identify all HIV positive blood donors or donated units with the infection further reiterating its usefulness in diagnosis and surveillance studies or initiatives. On the other hand, Dia Pro with a lower PPV is capable of deferring or allowing wastages of about 83/1000 blood donations arising from positive testing which in our population with paucity of voluntary blood donation < 10/1000 and resources generally scarce is significant. Its deployment may be counterproductive for an effective management of hospital-based blood bank service and may impact negatively on blood donor recruitment, nurturing and retention efforts needed to guarantee safe and available blood supplies in line with set targets.

Finally, since screening for TTIs require all attributes of laboratory quality, our comparative

findings of FP, FN, NPV and PPV rates obtained with these two HIV-antibody tests show low quality if deployed in our hospital-based blood bank. While this could be improved by deploying further test algorithms it carries an enormous financial, economic and logistic burden on the already "constrained" hospital-based blood bank in our setting.

## 5. CONCLUSION

The two HIV antibody ELISAs (Determine $^{TM}$ HIV 1/2/0 and Dia Pro HIV 1/2/0 ) demonstrate low performance with respect to the proportion of FN test results when compared with the combined Ag-Ab ELISA and could potentially compromise the quality of blood sourced in this setting. The proportion of FP seen with the DiaPro HIV ELISA would encourage wastages and wrongful discard of blood units or disqualification of blood donors.

## 6. RECOMMENDATIONS

Hospital-based blood banks should be supported to deploy only the combined HIV antigen-antibody ELISA for all blood donors and donations pending the implementation of NAAT in hospitals.

## CONSENT

As per international standard or university standard, patient's written consent has been collected and preserved by the authors.

## ETHICAL APPROVAL

As per international standard or university standard, written approval of Ethics committee has been collected and preserved by the authors.

## COMPETING INTERESTS

Authors have declared that no competing interests exist.

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