

Comparative Evaluation of Rapid Diagnostic Test and Elisa Technique in Screening Donors for HIV and Syphilis in Some Blood Banks in Bayelsa State, Nigeria

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Abstract

Blood transfusion is an important component of health care; hence, the screening of blood donors for transfusion-transmissible infections. This study compared rapid diagnostic methods with ELISA assay in the screening of blood donors for Human Immunodeficiency Virus and syphilis in some selected blood banks in Bayelsa State, Nigeria. A cross-sectional study was conducted among 160 prospective blood donors of the Federal Medical Center, Yenagoa and Niger Delta University Teaching Hospital. Blood samples were taken from participants and examined by serological methods and ELISA. SPSS version 25 was used to analyse the data and chi-square test was used to determine associations at a significance level of $p \leq 0.05$. For HIV, the routine serological method detected 12 reactive samples whereas 22 reactive samples were detected by ELISA. 148 and 138 samples respectively were found to be non-reactive for HIV. The difference was not statistically significant ($\chi^2 = 1.645$, $df = 1$, $p = 0.201$). For syphilis 6 samples were reactive by routine method as compared to 20 by ELISA with no statistically significant difference ($\chi^2 = 3.915$, $df = 1$, $p = 0.079$). The sensitivity of the routine serological method was 68.75% for HIV and 58.82% for syphilis, with ELISA as the comparator. The results indicate that some of the ELISA positive specimens were not detected by the routine serological methods tested. The study emphasises the significance of sensitive and validated screening methods and suitable testing algorithms in blood banks to mitigate the risks of undetected HIV and syphilis infections in donated blood.

Key words; Blood donors, HIV, Syphilis, Rapid diagnostic test, ELISA, Transfusion transmissible infections, blood screening.

Introduction

Blood is tissue which is made up of cellular and fluid components which transports oxygen and nutrients to the cells and carries away carbon dioxide and other waste products. The fluid components are made up of plasma and the cell component which are the red blood cells,

white blood cells and platelet. The total blood volume in humans differs with sex, age body type, weight, and other factors, but is nearly about 60 milliliters per kilogram of body weight of an average figure for adults (Schwartz and Conley, 2020; Obeagu, et al., 2024). Blood transfusion saves millions of lives every year and is an integral part of modern health care. According to the World Health Organization (WHO), more than 5 million people die annually due to violence and injury and 536 000 women die during pregnancy or childbirth and blood transfusion would have prevented most deaths (Cheraghali, 2011; Yadav, et al., 2024).

Blood transfusion: The transfer of blood or blood products from the donor to the recipient. Blood transfusion is performed as a lifesaving manoeuvres to replace blood cells or blood products lost through bleeding or through the depression of bone marrow (Cheraghali, 2011; Brown and Brown, 2023). Also, a Blood transfusion is the intravenous infusion of blood products into a person's circulatory system. Transfusions are used for a variety of medical conditions to replace lost components of the blood (NHLBI, 2019; Brown et al., 2025). It is one of the most common procedures performed on patients in the hospital and it is associated with a great deal of risk. Hence health care providers need to know the safety standard in donation of blood for transfusion (Sahu, Hemlata and Verma, 2014; Keyser et al., 20205). Blood transfusion services are an integral part of health care delivery system. Most secondary and tertiary hospitals in Sub-Saharan Africa operate suboptimal and inefficient blood banking services. Most of the countries in Sub-Saharan Africa have national blood policies, but blood transfusion services are still inadequate and inefficient (Federal Ministry of Health Nigeria, 2006). The National Blood policy in Nigeria recommends that blood should be collected from regular voluntary non-remunerated donors and screened for HIV, Hepatitis B, Hepatitis C and Syphilis. It also requires that records be kept in a consistent and specified manner, while maintaining confidentiality. In most cases, there is far more demand for blood than there is supply. In Nigeria, about 500,000 units of blood are collected annually from the needed 1.5 million units of blood (Federal Ministry of Health Nigeria, 2018). Pre-donation screening of blood donors for Transfusion Transmissible Infections (TTI) is the practice by which a prospective donor is tested for the presence of one or more of the TTI agents by a single rapid or quick method and donation is deferred if the test is reactive for any of the TTI markers. The normal procedure everywhere is to give a standard questionnaire and to measure the donor's haemoglobin and weight. If the donor is found fit on selection criteria, he is bled and asked to leave after a period of rest. The donor units are separated into different components and stored. Samples of corresponding donated units are tested using a third generation Enzyme Linked Immunoabsorbent Assay (ELISA) batch analyser. All those non-reactive for viral markers are appropriately labelled and used for transfusion. Those reactive for any of the TTIs are appropriately discarded including their respective components (Shittu et al., 2014) Blood is needed if someone needs to replace blood lost after a major operation or a serious injury. and also, when there is bleeding in the digestive tract due to an ulcer or other conditions. It is also done when one has an illness like leukaemia or kidney disease that causes anaemia (decreased red blood cells) in cancer treatments like radiation or chemotherapy and also if a patient has a blood disorder or severe liver problems (Webster et al., 2019). Serology, i.e. antibody-based diagnostics, has been the gold standard of diagnostics in transfusion medicine. The impact of molecular diagnostics in transfusion medicine is growing rapidly today. Molecular diagnostics can improve tissue typing (HLA typing), improve the safety of blood products (NAT testing for infectious diseases) and enable blood group typing in difficult situations (after transfusion of blood products or prenatal non-invasive RhD typing). (Henk et al., 2009).

Rapid/simple assays are generally not recommended for blood screening, since they are designed for immediate and rapid testing of small numbers of samples, mainly for diagnostic purposes (WHO, 2011, Ryu et al., 2018, Vo, 2019). The purpose of blood screening is to identify markers of infection so as to prevent the release of infected blood and blood components for clinical use (WHO, 2011). As the day goes by, science too is evolving. The history of blood transfusion was dated as far back as the 17th century. Blood transfusion started with the transfusion of blood from animal to man and later from man to man. It was done first by the oral routes i.e. by mouth before intravenously (Ajmani and Ajmani, 2020). Today the successes of blood transfusion have greatly improved so that transfusion reactions and the transmission of TTIs has been greatly reduced; thanks to modern blood banking procedures. Despite this feat, emerging new diseases and window periods of disease detection is still a threat that can lead to the transmission of TTIs. It is therefore important to compare and evaluate the pre donation tests carried out on blood donors using very sensitive ELISA techniques that is not routinely used to see whether or not these TTIs are not actually being transmitted viz a viz the effectiveness of these routine/strip screening methods. The aim of this study is to evaluate and compare pre- donation tests (HIV and Syphilis) using strip and ELISA technique in blood for transfusion centres in Bayelsa state and To compare results from both methods.

Methodology

Study area

This study was carried out in two locations; the Federal Medical Centre (FMCY) and Niger Delta University Teaching Hospital (NDUTH) all in Yenagoa Local Govt Area of Bayelsa state. Yenagoa is Located in the mangrove forest south-south Nigeria. It lies on latitude 4°55'29" north, longitude 6° 15' 51" east, latitude 4.92472° north, longitude 6.26417° east. According to 2006 census, it has population of 352,285 persons. This was projected to be 470,800 persons in 2016. The land mass is 10,773 sq. km. The climate of the area is tropical, with a mean daily temperature of 31°C. It is the traditional home of the Ijaw people. English is the official language but Epie/Atisa is the major local language spoken in the state capital (Post office with maps, 2014).

Study design

A Cross sectional study design was used for the study

Ethical approval

Ethical approval was obtained from the ethical committees of Bayelsa state ministry of Health and Federal Medical Centre, Yenagoa. Due permission was taken from the officers in charge of the various health facilities.

Study subjects and enrollment

The study subjects were all potential blood donors in the facilities. All gender and ages were considered. A total of one hundred and sixty (160). subjects participated in the study

Sample collection

Five (5) mls of venous blood was collected from each subject and put into a EDTA container. Part of it was separated by centrifugation to obtain plasma.

Syphilis

Strip method

Principle (iCARE method)

The Test is a colloidal gold enhanced immunoassay for the determination of Syphilis in human whole blood, serum or plasma. Goat anti-Syphilis antibody is immobilized in the test region on nitrocellulose membrane. During the assay specimen is allowed to react with the coloured conjugate (antibody-colloidal gold conjugate); the mixture then migrates chromatographically on the membrane by the capillary action. A Syphilis positive specimen produces a distinct colour band in the test region, formed by the specific antibody-Syphilis-coloured conjugate complex. Absence of this coloured band in the test region suggests a negative result.

ELISA technique (My BioSource)

Principle of assay

The microtiter plate provided in this kit has been pre-coated with SyphilisAb. Samples are then added to the appropriate microtiter plate wells with a Horseradish Peroxidase (HRP)-conjugated SyphilisAb and incubated. Then substrate solutions are added to each well. Only those wells that contain Syphilis and enzyme-conjugated SyphilisAb will exhibit a change in color. The enzyme-substrate reaction is terminated by the addition of a sulphuric acid solution and the color change is measured spectrophotometrically at a wavelength of 450 nm $\pm$ 2 nm.

HIV Test

Strip methods

(a) Determine

Determine™ HIV-1/2 Ag/Ab Combo is an in vitro, visually read, qualitative immunoassay for the simultaneous detection of Human Immunodeficiency Virus Type 1 (HIV-1) p24 antigen (Ag) and antibodies (Ab) to HIV Type 1 and Type 2 (HIV-1 and HIV-2) in human serum, plasma, capillary (fingerstick) whole blood or venipuncture (venous) whole blood.

(b)STAT-PAK; from Chembio Diagnostic Systems inc

Principle of test

The Chembio HIV 1/2 STAT-PAK™ Assay uses a unique combination of a specific antibody binding protein conjugated to colloidal gold dye particles and HIV-1/2 antigens bound to the solid phase membrane. Venous or capillary (fingerstick) whole blood, serum or plasma is added to the SAMPLE (S) well of the test device, followed by the addition of Running Buffer. The Buffer helps the antibodies bind to the antigen and allows the specimen and test reagents to flow laterally. The specimen/buffer mixture moves by capillary action along the test strip and rehydrates the conjugate. The antibodies, if present, bind to the antibody binding protein conjugated to colloidal gold. In a reactive sample, the dye conjugated-immune complex migrates on the nitrocellulose membrane and gets captured by the antigens immobilized in the TEST (T) area resulting in a pink/purple line. There is no pink/purple line in the TEST (T) area in the absence of HIV-1 and HIV-2 antibodies. The sample still migrates along the membrane and a pink/purple line appears in the CONTROL (C) area with immunoglobulin G antigens. This procedural control is employed to demonstrate that the specimen and reagents have been applied correctly and have migrated across the device.

(a) Uni-Gold

Principle of test

Uni-Gold™ Recombigen® HIV is a rapid immunoassay for the detection of antibodies to HIV-1 in human whole blood (venipuncture and fingerstick). The Uni-Gold™ Recombigen® HIV contains proteins which represent areas of the HIV virus. If the sample contains antibodies to HIV-1 they will bind to these proteins and a colour reagent and this complex

will bind to the proteins in the test forming a visible pink/red band in the test region of the device next to the word 'Test'. The control line should always have a pink/red band in the control region of the device to indicate the test device is functioning properly.

The device has a pink/red band in the test region that shows a reactive result. A non-reactive result is when there are no detectable levels of antibodies to HIV-1 in the specimen and therefore no visually detectable band in the test region of the device.

ELISA technique

Reagents from My BioSource (China) was also employed to check for HIV P24 antigen
Procedure

All materials and prepared reagents are equilibrated to room temperature prior to use.

1. All reagents working standards and samples were prepared as described in previous sections.
 2. Remove excess microplate strips from plate frame, return to foil pouch with desiccant pack, reseal and return to 4°C storage.
- 3.50 µL of each sample or standard was added to the respective wells.
Then, 4.50 µL of the Antibody Cocktail was added to each well.
4. The plate was sealed and incubated at room temperature on a plate shaker at 400 rpm for 1 hour.
 5. Wash each well 3 x 350 µL 1X Wash Buffer PT. Wash by removing or decanting from wells and adding 350 µL 1X Wash Buffer PT to each well. It is essential to remove all liquid at each step for good performance. After the last wash, invert the plate and blot against clean paper towels to remove excess liquid.
 6. The plate was placed in the dark on a plate shaker set to 400 rpm and incubated for 10 minutes, and 100 µL of TMB Development Solution was added to each well. The optimal time for incubation may vary from 5 to 20 minutes due to the variability of environmental conditions in the laboratory. Note: Addition of Stop Solution will change colour from blue to yellow and increase signal intensity approximately 3X. Do not proceed to the next step until the high concentration of the standard has reached a blue colour of O.D.600 equal to 1.0. This is done to avoid saturation of the signal.
 7. To each well, add 100 µL of Stop Solution. Place on plate shaker and shake plate for 1 minute to mix. Measure the OD at 450 nm. This is a read from the end point.

Statistical analysis

Data is here presented in tables. Inferential statistics (chi square) was used to test the association between variables. Analysis was done using Statistical Product for Service Solution software (Version 25 for windows, SPSS Inc, Chicago, USA). A p value of $P \leq 0.05$ was considered significant. Sensitivity of the Serological test's methods were also calculated using the following formular (with ELISA technique as the gold standard);

Sensitivity (S) = $TP / (TP + FN) \times 100$

Where; TP = True Positive and FN = False Negative

Results

Table 1 Blood groups, Sex and Age distribution of study subjects in blood banks.

There were 154 male and 6 female blood donors. The table reveals that 130 out of the 154 males donated blood were of blood group O. Twenty of them were blood group B and 4 blood group A. There was no male donor for blood group AB. Also, the table shows that 114 of the blood were Rh positive and 4 Rh negative. In the age brackets, 19 – 30yrs donated 122 pints, 31 – 40, 28 and 41 – 50 had 4 pints of blood donated. Out of the 6 pints donated by females, 4 were blood group O, 1 blood group A and the other 1 blood group B. All 6 pints

were Rh positive. In the age brackets, 19 – 30yrs donated 3 pints, 31 – 40, 2 and 41 – 50 had 1 pint of blood donated. (Table 1).

Table 1 Blood groups, Sex and Age distribution of study subjects in FMCY and NDUTH blood banks.

Sex			Age bracket		Total					Total
Male		19 – 30	31 – 40	41 – 50		Female	19 – 30	31 – 40	41 – 50	
ABO	A	4	0	0	4		1	0	0	1
	B	16	4	0	20		0	1	0	1
	O	112	24	4	130		2	1	1	4
	AB	0	0	0	0		0	0	0	0
Total		122	28	4	148		3	2	1	6
Rh	Pos	118	28	4	144		3	2	1	6
	Neg	4	0	0	4		0	0	0	0
Total		122	28	4	154		3	2	1	6

Table 2 Comparison of Serological and ELISA test results for HIV FMCY and NDUTH blood bank.

The results of the comparison between routine and ELISA screening of HIV among blood donors in FMCY and NDUTH blood bank gives a chi square value of $X^2 = 1.645$ and a p value of $P = 0.3050$ (Table 4.2).

Table 2 Comparison of Serological and ELISA test results for HIV FMCY and NDUTH blood banks

Parameter	Routine	ELISA	X^2 , df	P value	Comment
Non-reactive	148	138	1.645, 1	0.3050	Not significant
Reactive	12	22			

Table 3 Comparison of Serological and ELISA test results for Syphilis in FMCY and NDUTH blood banks.

The results of the comparison between serological and ELISA screening of Syphilis among blood donors in FMCY and NDUTH blood banks gives a chi square value of $X^2 = 3.915$ and a p value of $P = 0.079$ (table 3).

Table 3 Comparison of Serological and ELISA test results for Syphilis in FMCY and NDUTH blood banks

Parameter	Routine	ELISA	X ² , df	P value	Comment
Non-reactive	154	140	3.915, 1	0.0790	Not significant
Reactive	6	20			

Table 4 is the Sensitivity test result of HIV for Serological method. The calculation gives an Serological sensitivity of 68.75% of the ELISA technique.

Table 4 Sensitivity test of HIV for Serological method

	Disease	No disease
+	TP = 22	FP = 0
-	FN = 10	TN = 138

$$S = 22 / 22 + 10 \times 100 = 22 / 32 \times 100 = 68.75\%$$

Table 5 is the Sensitivity test result of Syphilis for Serological method. The calculation gives a Serological sensitivity of 58.80% of the ELISA technique.

Table 5 Sensitivity test of Syphilis for Serological methods

	Disease	No disease
+	TP = 20	FP = 0
-	FN = 14	TN = 140

$$S = 20 / 20 + 14 \times 100 = 20 / 34 \times 100 = 58.80\%$$

Discussion

This discussion is based on the titled ‘Comparative Evaluation of Rapid Diagnostic test and ELISA Technique in Screening Donors for HIV and Syphilis in some Blood Banks in Bayelsa State’ The research found that there were more male blood donors than females. This might be due to popular believes that females cannot donate blood due to their monthly flow (Javadzadeh, 2007). This is consistent with the reports of Anyanwu-Yeiyia et al., (2015) and Ugwu et al., (2018) in their works in south-west and south-east respectively.

This research work found out that there were no female blood donors all through the period of the research in FMCY. This is in contrast to the findings of Anyanwu-Yeiyia et al., (2015) and Ugwu et al., (2018) in Nigeria and Misje et al., (2010) in Norway where females participate not only as Family donors but Voluntary non-remunerated blood donors. The same findings were seen in Madrona et al., (2012) in their research work in Spain. A one and half year retrospective study on similar subject matter at the university College hospital

Ibadan states that out of 8,619 donors, 90.1% and 9.9% were male and female respectively (Anyanwu-Yeiyi et al., 2015). The age group of 19 – 30 was also seen to be the most active probably because of their young age. The table (Table 1) also shows that about 90% of donated blood is of ABO blood group O. This might not be too good since giving group specific blood is the best way to reduce complications from blood transfusions (Yazer et al., 2023) The results of HIV test using serological and ELISA techniques in FMCY and NDUTH blood banks were compared and the comparison did not yield a significant p-value ($P=0.3050$). It tells us then that there is no significant association in HIV test result using serological or ELISA technique.

However, this present study assessed the diagnostic performance of a serological method for the detection of HIV and syphilis using ELISA as a comparator method. Sensitivity is the ability of a diagnostic test to identify correctly those that really have the disease. The results of the study showed that the serological method sensitivity for HIV was 68.75% with correct identification of 22 out of 32 ELISA positive specimens while 10 specimens were missed and reported as false negatives. The serological method for syphilis had a lower sensitivity (58.82%) in identifying 20 of 34 ELISA-positive specimens, while 14 specimens were falsely classified as negative. These results suggest that serological method was better than syphilis method in the study population for HIV.

The 68.75% sensitivity obtained for HIV means that the serological method detected about two-thirds of the specimens positive by ELISA. Serological testing is still an important method for HIV diagnosis because of its simplicity, relatively low cost and applicability for decentralised testing. Sensitivity achieved in the present study is much lower than that reported for most validated contemporary HIV diagnostic assays. A systematic review and meta-analysis of 35 commercially available HIV serologic assays and nearly 30,000 specimens. Bhatta et al. (2022) reported pooled sensitivities and specificities of at least 98%, but there was considerable heterogeneity among the assays they evaluated. Similarly, a systematic review of HIV in-vitro diagnostic assays evaluated through the WHO prequalification program showed generally high diagnostic performance among appropriately evaluated assays (Banerjee et al., 2022).

The relatively low HIV sensitivity observed in the present study may therefore be attributable to the characteristics of the particular serological method or kit employed. Diagnostic sensitivity can be affected by antigen composition, assay format, threshold for antibody detection, characteristics of the specimen, reagent stability, and testing procedures. Bhatta et al. (2022) pointed out that there is a large heterogeneity amongst the commercially available HIV diagnostic assays and suggested that the performance of one serological product should not be generalised to all HIV serological tests.

False negative HIV results can also be explained by the window period of infection. During early HIV infection, antibody levels may not have risen to a level that can be detected by some antibody-based assays. This limitation is particularly applicable where the serological method detects predominantly antibodies rather than both HIV antibodies and p24 antigen. Previous studies of diagnostic accuracy have shown that rapid tests based on antibody detection may miss a proportion of acute HIV infections, especially compared with fourth-generation enzyme immunoassays or nucleic-acid based methods (Tan et al., 2017). This early study was performed before some of the more recent evidence was available, but the findings are still relevant to understanding why antibody-based methods can give false-negative results during early infection.

The 10 false-negative HIV results found in the present study are therefore of great clinical relevance. A false-negative HIV result can result in missed diagnosis, delay in initiation of antiretroviral therapy, and continued potential transmission of infection. The high number of false negatives indicates that the serologic method evaluated in this study is not sufficiently

sensitive to rule out HIV infection when used alone. This interpretation is particularly important as diagnostic accuracy is critical at the screening stage where the primary objective is to minimise the probability of missing infected individuals.

Many modern HIV rapid diagnostic tests perform markedly different from the findings of the current study. A systematic review and meta-analysis of HIV rapid tests based on more than 110,000 test results found an overall sensitivity of about 94.5% when comparing rapid tests to enzyme immunoassays, although performance varied by population and testing setting (Tan et al., 2017). The sensitivity of 68.75% obtained in the present study is thus significantly poorer than the performance of a well-validated HIV screening assay. This difference may be due to the particular kit used, characteristics of the study population, disease stage of the subjects, or methodologic differences between the present study and the published diagnostic accuracy studies.

The syphilis results were less favourable than the HIV results. The serological method could detect 20 out of 34 ELISA-positive syphilis specimens with a sensitivity of 58.82%. 14 specimens were false negative. So, ELISA detected 41% of syphilis-positive samples that were not detected by the serological method. The relatively low sensitivity indicates that the method may be limited in its ability to rule out syphilis infection in individuals who produce antibody responses that are detectable by ELISA.

The present observation is at odds with the results of recent studies evaluating syphilis diagnostic assays Angel-Müller et al. (2021) conducted a systematic review and meta-analysis of rapid point-of-care tests for active syphilis and reported a mean sensitivity and specificity of 86% and 98%, respectively, although individual assays had a wide range of sensitivities from 67% to 100%. Similarly, Chen et al. (2023) reported a pooled sensitivity of about 93% for the treponemal component of enhanced rapid diagnostic tests for syphilis, with pooled specificity of about 98%. The results suggest that the sensitivity of 58.82% obtained in the present study is much lower than the performance reported for many syphilis diagnostic tests evaluated. Partially, the low sensitivity observed for syphilis may be due to the complexity of syphilis serology. Syphilis has several clinical stages and the concentration and type of antibodies that are detectable in serum can be dependent on the stage of infection. Treponemal tests detect antibodies specific for *T. pallidum*, while non-treponemal tests detect antibodies directed against lipid antigens associated with cellular damage. Different serological tests may therefore give different results in the same patient. Recent laboratory recommendations highlight the complementary nature of treponemal and non-treponemal tests and the need for appropriate testing algorithm rather than a single serological test for syphilis diagnosis (Papp et al., 2024). This interpretation is also further supported by recent empirical evidence. An assessment of over 2300 serum specimens employed RPR, TPHA, ELISA and a modified TPHA rapid test by Lyngdoh et al. (2024) reported variations in diagnostic performance. TPHA and TP-ELISA had the highest sensitivity, and RPR had the highest specificity in their study. The authors concluded that one serological test has its limitations and recommended the use of complementary tests in an effort to improve diagnostic accuracy. These observations may explain the relatively poor sensitivity of the serological method in the present study. Likewise, Santos et al. (2024) pointed out that the performance of syphilis serological assays may vary according to the type of test, antigen used and clinical stage of infection. They showed that differences in test characteristics can influence the accuracy of diagnosis in their evaluation of commercially available treponemal and nontreponemal assays. The sensitivity of 58.82% obtained in the present study, does not necessarily mean that serological diagnosis of syphilis is inherently insensitive, but rather it may be the performance characteristics of the specific serological method studied.

A significant result from both tables is that there are no false positive results (FP=0). This shows that in the present data set, all specimens classified as negative by ELISA were also

negative by serological method. Then the apparent specificity of the serological method would be 100% for HIV and syphilis. However, this finding should be interpreted with caution as the present analysis is primarily for sensitivity, and the number and characteristics of disease-negative specimens influence the precision of specificity estimates. More importantly, the absence of false positives does not make up for the relatively high number of false negatives. In the setting of screening for infectious diseases, particularly HIV and syphilis, the clinical and public-health consequences of missing an infected person are more severe than those of an initial false-positive screening result, which can be resolved through confirmatory testing. It's worth pointing out the difference between the two infections. The serological method for HIV had a sensitivity of 68.75%, which was about 9.93 percentage points higher than that of its sensitivity for syphilis (58.82%). Thus, the method was comparatively more efficient in identifying ELISA positive HIV specimens than ELISA positive syphilis specimens. The difference may be due to the biological nature of the two infections and importantly, to the differences in the antigenic targets and immune responses detected by the assays in question. For syphilis, different treponemal and non-treponemal antigen systems can cause a significant difference in diagnostic performance (Chen et al., 2023; Lyngdoh et al., 2024). Results have practical implications for diagnostic laboratories. If the method is used in isolation, a screening method with a sensitivity of 68.75% for HIV and 58.82% for syphilis would result in a huge proportion of infected individuals being classified as negative. Thus, the performance might not be adequate for a single screening strategy. This finding for HIV highlights the need for validated high-sensitivity testing algorithms and appropriate testing of persons with suspected recent exposure or clinical indications despite an initial negative result. Regarding syphilis, the findings indicate the use of complementary treponemal and non-treponemal methods, where appropriate, instead of a single serological assay (Park et al., 2024; Lyngdoh et al., 2024).

Conclusion

To summarise, the results of this study revealed that the serological method tested in this study had moderate sensitivity for HIV (68.75%) and low sensitivity for syphilis (58.82%) compared to ELISA. The findings were lower than the sensitivities reported in some recent diagnostic accuracy studies of validated HIV and syphilis assays (Bhatta et al., 2022; Banerjee et al., 2022; Gliddon et al., 2021; Chen et al., 2023; Lyngdoh et al., 2024). The findings also underline the need to use highly sensitive, validated diagnostic assays and appropriate testing algorithms to reduce the risk of undetected HIV and syphilis infections.

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