Sensitivity of HIV Rapid Diagnostic Test Kits in Detecting HIV-2 in HIV Care and Support Centres in Ghana

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Research

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Abstract

Background

Among Human Immunodeficiency Virus (HIV) infected people in Ghana, the prevalence of HIV-2 is low compared with HIV-1. There is a paucity of reliable data on HIV-2 prevalence in Ghana which may justify targeted routine HIV-2 testing for all people for whom HIV-1 testing is required. Prevention and treatment of AIDS depends on accurate laboratory diagnosis of HIV infection. HIV Rapid diagnostic Test (RDT) kits are the preferred preliminary screening assay type in many resource-constrained countries. The study sought to determine whether the RDT kits used in screening for HIV positive patients are missing capturing HIV-2 in the patients.

Methods

Venous blood was aseptically collected from 100 HIV-1 infected patients reporting to the Fevers Unit of the Korle-Bu Teaching Hospital for antiretroviral therapy. Using Plasma the HIV 1 status was reassessed with Oraquick® Advance Rapid HIV-1/2 kit, First Response HIV-1-2 RDT kit and Multisure MP Diagnostics, the RDTs in use at the care and support centre.

Results

Of the 100 patients previously determined as HIV-1 positive at the HIV Care and Support Centre, 88 tested positive for HIV-1, 10 tested positive for HIV-1 & 2, 2 tested negative and no patient tested positive for HIV-2 using First Response RDT kit and Multisure RDT kit, and OraQuick kit which gave qualitative results of 98 positives and 2 negatives. The twelve (12) samples with different study results from the known, prior to the study(10 HIV 1& 2 and 2 negative), were subjected to confirmatory test at the Noguchi Memorial Institute for Medical Research (NMIMR) with INNO-LIA HIV Score kit, a standard confirmatory protocol.

When INNO-LIA HIV Score kit was used as confirmatory test for the 12 samples, 9 tested positive for HIV-1, one patient tested negative and two patients tested positive for HIV-2.

Conclusion

All the rapid diagnostic test kits in use missed classifying the two samples correctly as HIV-2 infection.

Introduction

Diagnosing Human Immuno-Deficiency Virus (HIV) infection at the early stages is very important in HIV/AIDS disease surveillance. A rapid diagnostic test (RDT) is a medical diagnostic test kit that is quick and easy to perform [1]. Rapid (point-of-care) tests can be conducted away from specialized laboratory facilities and give results in less than 15 minutes [2]. Although RDT kits have the lowest detection ability, they remain the preferred assay for HIV testing in many countries [3]. The performance of HIV RDT kits differ with brand(s), therefore, are used in combination to give accurate diagnosis [4]. HIV testing is a critical step that helps to control HIV prevalence and incidence in a population (Harries et al., 2010). HIV positive cases were initially diagnosed negative due to poor RDT sensitivity [5]. Other conducted studies in sub-Saharan Africa revealed
that 3% of individuals undergoing HIV testing are at a risk of receiving false negative results and advised a follow-up post transfusion HIV testing for blood recipients to monitor sero-conversion [6].

Owusu-ofori et al. proposed that Ghana complement serologic rapid test with Nucleic Acid Test (NAT) in pre-donation screening of blood donors. Nevertheless, NAT comes with a lot of technical and economic limitation [7]. This leaves the country in equipoise since studies on the affordable HIV RDT kits are reporting varying sensitivity and specificity with test specimen types [8].

Several rapid tests have been developed in various countries, and most of them have not been extensively evaluated. A lot of attempts have been made to determine how sensitive the HIV RDTs are to the viruses, however, its sensitivity to the less common virus, HIV-2, has received little attention [9].

This study was designed to compare the sensitivities of First Response HIV-1-2, OraQuick Advance (OraSure/Launch), and Multisure MP Diagnostics to HIV-2 to help in accurate diagnosis and proper administration of therapy to patients.

It has been determined that persons infected with HIV-2 have a longer asymptomatic phase, higher CD4 cell counts, lower viral RNA levels, and slower progression to AIDS than HIV-1 infection [10]. Though HIV-2 has a higher mutation rate, it does not have a selective advantage over HIV-1[10]. Once persons with HIV-2 infection have progressed to clinical AIDS, the manifestations are similar to those of persons with AIDS from HIV-1 infection [11].

Testing of HIV can be done by a health care provider using a Rapid Diagnostic Test kit. A rapid diagnostic test (RDT) is a medical diagnostic test kit that is quick and easy to perform [1]. RDTs are suitable for preliminary or emergency medical screening and for use in medical facilities with limited resources [12]. Rapid (point-of-care) tests can be conducted away from specialized laboratory facilities and give results in not more than 15 minutes [13]. Rapid tests were first developed in the early 1990s for use in developing countries (where specialized laboratory facilities may not be available) [14]. An advantage of this test type is that it is a very rapid test procedure, with results available in as little as 15 minutes [2].

Although RDT kits have the lowest detection ability, they remain the preferred assay for HIV testing in many countries [3]. The performance of HIV RDT kits differ with brand(s), therefore, are used in combination to give accurate diagnosis [4]. More often than not, First Response HIV-1-2 kit is often used as a single test kit in national HIV prevention and control programs [15]. A study by Ly et al., linked the practice of single RDT kit use (for screening test samples) to high HIV infection rates. In that study, single RDT kit detected 85% of infections that were detectable by standard Enzyme Linked Immuno-Sorbent Assay (ELISA). In other words, 15% HIV infected individuals were not detected when a single RDT kit was used to screen the population [16]. It was recorded in Cape Town, South Africa during a study that, 1100 HIV positive cases were initially diagnosed negative due to poor RDT sensitivity [5]. Other conducted studies in sub-Saharan Africa revealed that 3% of individuals undergoing HIV testing are at a risk of receiving false negative results and advised a follow-up post-transfusion HIV testing for blood recipients to monitor sero-conversion [6].

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Several rapid tests have been developed in various countries, and most of them have not been extensively evaluated. A lot of attempts have been made to determine how sensitive the HIV RDTs are to the viruses, however, it is sensitivity to the less common serotype of the virus, that is HIV-2, has received little attention.

A number of test kits that are widely used in other countries are First Response HIV-1/2, Oraquick Advance Rapid HIV-1/2, Multisure MP Diagnostics, Determine HIV 1/2 (Alere), Determine HIV 1/2 Ag/Ab Com, INSTI HIV-1/HIV-2 Rapid Antibody Test (Pasante/BioLytical Laboratories) (Alere), Core HIV 1&2 (Core Diagnostics), Immunoflow HIV1-HIV 2 (Core Diagnostics), Vikia HIV 1/2 (bioMerieux), Rapidan anti-HIV1/2 (Turklab).

Various studies have reported on HIV-1 & 2 globally and also pointed out that HIV-2 is prevalent in West African countries such as Ghana. The need to determine sensitivity in the detection of HIV-1 or 2 is crucial since most clinical settings in Ghana depend only on HIV RDTs in the preliminary diagnosis of HIV prior to initiation of antiretroviral therapy (ART), due to resource constraints. Specifically, in the HIV Support and Care Centres in Ghana, First Response HIV-1/2 and Oraquick Advance Rapid HIV-1/2 are used in the detection of HIV infection prior to the initiation of ART without a higher level of confirmatory testing as provided by the Inno-Lia Test kit [20]. Some patients showing symptoms of immunosuppression could be as a result of HIV-2 or both types; and hence may not be detected by the commonly used RDT kits. This could affect diagnosis of the patient by giving false negative results.

Also, treatments for both HIV-1&2 differ, but since there is the prevalence of HIV-1 as compared to HIV-2, some patients who test positive may be treated as HIV-1 patients though they may be HIV-2, this can also affect the proper treatment of the infection.

Rapid test kits for testing for HIV-1&2 may not be able to accurately determine whether the infecting virus is Type 1 or Type 2 or both. This goes a long way to affect the treatment therapies since it differs with each virus and also gives the likelihood of reporting false negatives. Some patients suffering from HIV-2, unknowingly may find themselves taking drugs from the First Line Art regimen (20) that work for HIV-1, which may lead to suboptimal response from HIV-2 infected persons. This study was designed to determine whether HIV-2 was being accurately diagnosed using the RDTs available in the health sector of Ghana - First Response HIV-1-2, OraQuick Advance (OraSure/Launch), and Multisure MP Diagnostics – in order to address the issue of misclassification of the HIV infection so as to improve diagnosis and treatment of the patients. The study also sought to determine the prevalence of HIV-2 among the study population and to assess the level of sensitivity and specificity of the of the RDTs in use at the study site and other HIV Care and Support Centres in Ghana.

Materials And Methods

Study Design and Participants

This was a cross-sectional study that involved HIV infected patients from March 2018 to May 2018 who were on treatment based on their earlier diagnosis as HIV positive. The study was carried out on samples obtained
from HIV infected individuals reporting to the Fever's Clinic at the Korle-Bu Teaching Hospital in Accra, Ghana. The patients who consented to participate in the study were known HIV positive males and females between the ages of sixteen (16) and sixty-eight (68) years.

**Sample Collection & Processing**

Venous blood was aseptically collected from 100 HIV-infected patients. Patient selection and sampling were randomly done after explanation of the study and obtaining written consent from the patients at the study site. Three (3) mls of whole blood was taken from the antecubital vein of each participant and dispensed into EDTA- treated tubes and labelled. The whole blood sample from each participant was centrifuged at 3000 rpm for 10 minutes to obtain plasma which was transferred into micropipette tubes with a pipette. The Micropipettes tubes were labelled with participant’s identification number to match that on the EDTA tubes.

**Laboratory Analysis**

Each plasma sample was tested on all the rapid detection kit for the study- First Response HIV-1-2 RDT kit, Oraquick Advance Rapid HIV-1/2, and Multisure MP Diagnostics kit. The manufacture's instructions for preparing the reagents, carrying out the test procedure and applying the interpretation criteria were followed to arrive at the positivity or otherwise of the sample. The different test kit’s sensitivity, specificity, positive and negative predictive values achieved with each test kit were compared and recorded.

All laboratory standard operating procedures (SOPs) that ensured quality analysis were followed strictly in the processing of the serum specimens by the techniques approved by the manufacturer. Each assay included a negative and positive control. Results for First Response test kit was not read after 15 minutes, MP Diagnostics Multisure was not read after 20 minutes and OraQuick Advance was not read after 40 minutes (all according to manufacturer's instructions.

Twelve (12) samples (comprising 9 positive for HIV 1 & 2, 2 HIV negative and 1 Untypeable) from the preliminary screening using the RDTs were further tested using INNO-LIA HIV I/II Score kit (by INNOGENETICS, BELGIUM), a line immunoblot assay for confirming HIV status of samples. The manufacturer's instructions for preparing the reagents, carrying out the test procedure and applying the interpretation criteria were followed to differentiate HIV-1 from HIV-2 infections; thus the study used INNO-LIA as the gold standard assay.

**Statistical Analysis**

Data obtained from the study was entered into the data base of Microsoft Excel 2013 and imported into SPSS version 20. Inno-lia was considered as the reference standard in this study. Data thereby generated from the test kits were compared with the confirmatory assay, Inno-lia. Sensitivity and specificity of the assays were determined in order to assess the performance of the three assays on the same sample in the accurate diagnosis of HIV infections, particularly HIV-2. Positive predictive values (PPV) and negative predictive values (NPV) were also computed to buttress the results. Sensitivity was determined according to the formula {TP / (TP + FN)} x 100 where TP was true positive, and FN was false negative. Specificity was determined by {TN / (TN + FP)} x 100, where TN was true negative, and FP was false positive.

Positive predictive values were determined using the formula {TP / (TP + FP)} x 100 and negative predictive values were determined by {TN / (TN + FN)} x 100. Prevalence of HIV-2 infected patients was also determined.
The Pearsons chi-square test was used to determine associations between age and type of HIV. All tests were two sided and p-value less than 0.05 was interpreted significant.

**Ethical Issues**

Ethical clearance was sought from the Ethical Review Committee of the School of Biomedical and Allied Health Sciences of the University of Ghana, Legon.

**Results**

A total of 100 HIV infected patients comprising 62 (62%) females and 38 (38%) males (p = 0.001) were enrolled unto the study; the mean age was 45 +/-11 years for males and 42 +/-10 years for females. Majority of the participants (53%) were aged between 41–60 years, one-third (37%), were between the ages of 20-40 years, 3% were less than 20 years with 7% being over 60 years (Table 1). Pre-study data obtained for the participants from the study site database revealed that the majority, 92(92%), tested positive for HIV 1 whilst 3 participants tested positive for HIV-2 and 5 tested positive for both HIV-1&2 (Table 1). Study time analysis with the First Response rapid test kit indicated that the majority, 91(91%), of the participants tested positive for HIV-1, 7 tested positive for HIV-1&2 and 2(2%) of participants tested negative for HIV and no participant tested positive for HIV-2 alone (Table 1).

Using Multisure rapid test kit in the study, 96(96%) of the participants tested positive for HIV-1 and 3(3%) tested positive for HIV-1&2. One patient was untypeable and no one tested positive for HIV-2 alone. Oraquick, a qualitative RDT showed 98(98%) of the patients tested positive and 2 (2%) tested negative for HIV (Table 1).

The sensitivity of the HIV Rapid Test kits in use for detecting HIV-2 was assessed using the INNO-LIA HIV I/II Score kit. There was concordance in the results between the Pre-Study database results and the Study-Time results for 88 samples captured as HIV-1 positive. Therefore, the 12 HIV positive samples whose Study-Time results deferred from the Pre-study-Time database results were assessed via the INNO-LIA HIV I/II Score kit. Out of these 12 samples, 1 sample tested negative for HIV, nine (9) were positive for HIV-1 and two (2) tested positive for HIV-2. There was none positive for HIV-1&2 dual infection (Table 1).

The samples that tested positive for HIV using Oralquick tested positive with Innolia; of the two samples (Samples 33 and 75) which tested negative for HIV by Oralquick, only Sample 33 was determined as negative by Innolia. Though Sample 75 was determined as negative by both First Response and Oralquick, it was determined as positive for HIV-1 by Innolia.

The 33rd Sample was determined as Untypeable with Multisure but tested negative with Inno-lia. (Table 1).

In determining the Sensitivity and Specificity of the assay methods used, the study established that the First Response RDT had 11.1% sensitivity for HIV-1, 0% sensitivity for HIV-2 and 0% sensitivity for HIV-1&2. Specificity could not be determined with regards to both HIV-1 and HIV-2. HIV-1&2 on the other hand had a specificity of 41.7%. Positive predictive value (PPV) was 100%, 0%, 0% for HIV-1, HIV-2 and HIV-1&2 respectively. Negative predictive value (NPV) on the other hand was 11.1%, 83.3% and 100% respectively (Table 2).
Multisure recorded a sensitivity of 88% for HIV-1, 0% for HIV-2 and 0% for HIV-1&2. Specificity could not also be determined for HIV-1 and HIV-2 with Multisure but HIV-1&2 had a specificity of 75%. PPV for Multisure was 100%, 0% and 0% for HIV-1, HIV-2 and HIV-1&2 respectively. NPV was 75%, 83.3% and 100% for HIV-1, HIV-2 and HIV-1&2 respectively. Sensitivity of the assay with OraQuick gave a sensitivity of 90.9%, specificity of 100%, PPV of 100% and NPV of 50%. Table 2 summarizes the sensitivity and specificity of the assays in the study.

Discussion

A reliable estimation of the sensitivity of HIV Rapid Test kits has difficulties due to discrepancies that are peculiar to the different viral antigens used as a diagnostic marker by different kit manufacturers.

Inno-lia possessed five (5) HIV-1 antigens, namely the envelope transmembrane (TM) glycoprotein (gp) 41, an additional env antigen (gp120) as well as core antigens p31 (integrase), p17 (gag protein) and p24 (capsid). Multisure possessed three (3) HIV-1 antigens namely env antigen (gp120), envelope transmembrane (TM) glycoprotein (gp) 41 and gp24. First Response on the other hand, had only two (2) HIV-1 antigens namely gp41 and p24. Inno-lia had a sensitivity of 100% while that of First Response was 11.1% which is significantly different. This resulted in as much as 88.9% disparity in the diagnosis of HIV-1 between First Response and Inno-lia. This is not surprising since the confirmatory test, Inno-lia, has more antigenic surfaces, and the HIV-1 antibodies can bind more as compared to First response.

Generally, First Response recorded a PPV of 100% in this study for HIV-1. This means that, all the HIV-1 cases that were detected with First Response actually had the infection from HIV-1. The NPV for HIV-1 with First Response was 11.1% which explains that, only 11.1% of patients who did not test positive for HIV-1 were actually free of HIV-1 viral infection.

There was however, a discrepancy of 100% between Inno-lia and First Response in the diagnosis of HIV-2, where the sensitivity of Inno-lia was 100% and that of First Response was 0%. From the manufacturer's literature, Inno-lia has an extra antigen, gp105 (INNOLIA from Innogenetics of Belgium) which First Response lacks, which equips Inno-lia in the identification of HIV-2 virus [18]. It can therefore be inferred that, HIV-2 in Ghana has the gp105 antigen. With the identification of HIV dual-infection, the routinely used rapid test kit, First Response, was able to identify seven (7) cases with PPV of 0%. PPV being the proportion of patients with a positive test who actually have the disease, implying that the positive results gotten could not be trusted. This assumption was confirmed when a zero case of dual-infection was recorded with the Inno-lia. This implies that the positive cases recorded with First Response have a high possibility of being false. This was not a surprise as the sensitivity of First response to HIV-2 was 0%.

With Multisure, similar to the results of First response, there was a disparity from Inno-lia in the diagnosis of HIV-1, but this disparity was less comparative. A 12% disparity between Inno-lia and Multisure could also be explained with the number of antigens being used by the assay to identify the viral antibodies. Multisure performed better as compared to First response in identification of HIV-1 because it had an extra antigen, gp120 which Inno-lia also has. In the identification of HIV-2, there was a disparity of 100% between Inno-lia and Multisure which is no different from that gotten from that between Inno-lia and First response. This is
because, both of them have only one antigen (gp36). However, for the diagnosis of HIV-2, Inno-lia had gp105 in addition to gp36 and a strong reactivity to either one or both, along with a core antigen, which increases the sensitivity of Inno-lia to identification of HIV-2. Same results were gotten for the identification of the HIV dual-infection by Multisure as compared to First response, with a disparity of 100%.

OraQuick on the other hand only gave qualitative results as to whether the test was positive or negative. Therefore, there was 9.1% discrepancy from Inno-lia. In these three cases, OraQuick correctly diagnosed more of the infections qualitatively as compared to the other rapid test kits. Since it is not differentiating between the various serotypes it is expected that its sensitivity should be higher.

Effectively, plasma HIV-2 antibodies in the samples missed out on the HIV-2 antigen (gp36) in both First Response and Multisure.

According to the package inserts of all the 3 rapid test kits, both the RDTs had sensitivity of 100% and specificity of > 99%. The test’s performance was, however, lower in this study, the RDTs failing to detect HIV-2. This must make a case for the introduction of Inno-Lia Kit into the workflow in confirming the detection of HIV infection in the HIV Care and Support Centres since the RDTs used are not able to detect HIV-2. This finding must be considered as a significant contribution towards the introduction of Inno-Lia as a confirmatory assay for all positive HIV tests or HIV discordant test results.

Some HIV-1 infected patients in this study were misdiagnosed as HIV-1&2 depriving them of the standard HIV-1 treatment regimen, which will have an effect on the therapeutic mechanism or might affect the patient adversely since regimen for both infections differ. HIV-2 infected patients were also misdiagnosed as HIV-1&2. It is even more dangerous to misdiagnose a potential HIV-2 infected patient as HIV-1 because this patient would be initiated with a NNRTI-based ART regimen which is not effective against HIV-2. Such patients may experience treatment failure and progressive decline in CD4 cell count despite good adherence. Such misdiagnosis could lead to mistreatment resulting in suboptimal response to the antiretroviral therapy. HIV drug resistance would be on the increase with such patients and hence the treatment failure. Such patients would have no antiretroviral options [18] unless they are switched to a Second Line drugs regimen in accordance with the national guidelines, which stipulates that HIV-2 and HIV-1&2 infections should be treated with a protease inhibitor-based ART regimen [20]. As Protease Inhibitors (PIs) are used for second-line treatment of HIV-1, the misdiagnosis compromises treatment options in cases of treatment failure.

Although MP Diagnostics Multisure had the overall best performance in terms of positivity, it misclassified HIV-2 infected patients as HIV-1&2 which could have potential adverse effect on effective treatment.

According to the Joint United Nations Programme on HIV and AIDS, test combinations should always be evaluated in the context in which they will be used before widespread implementation. This study has shown that the diagnosis of HIV-2 infection remains a problem and the spectre of misdiagnosis is still real. This study also demonstrated the need to ensure continual assessment of Rapid Diagnostic Test kits in Ghana used by various institutions in the diagnosis of infectious and non-infectious agents.
The study was limited by factors such as resources which put constraints on the sample size and the number of HIV/AIDS care centres that could have been included in the study and would have shown a wider spread problem with misclassification of HIV-2, a possible reason for the low level of detection of HIV-2 in Ghana.

**Conclusion**

None of the three tests kits in use at the various HIV Care Centres was able to detect HIV-2, a clear indication that the kits are not sensitive to HIV-2 infection. It can also be deduced that patients whose previous classification does not match results obtained from Inno-lia were not confirmed at the various hospitals after they were tested positive at the preliminary stage. Thus HIV-2 infection would be missed and a misleading trend (such as the 0% prevalence recorded in 2016) would be recorded by the hospitals or care centres. This study determined the Prevalence of HIV-2 in the study population to be 2%. The findings of this present study should serve as a basis for further studies including, research on more effective assay methods to be used in Ghana’s HIV care and support centres for HIV-2 and also creating room for improvement to correctly classify the type of HIV infection to help in choosing an effective ART. The findings have potential impact on the incidence and prevalence of HIV registered in the country and therefore a larger study would be useful to policy makers in the national HIV/AIDS space.

**Declarations**

**Author Contribution**

AMO conceptualized the study; HAO carried out the field work and performed the laboratory analysis with CZA, under the supervision of AMO and SA. DNA carried out the statistical analysis with AMO and HAO. All the authors contributed evenly to the intellectual content of the manuscript.

**Author statement**

All authors have carefully revised the manuscript point-by-point. None of the authors of this paper has a financial or personal relationship with other people or organizations that could inappropriately influence or bias the content of this paper.

**Declaration of Competing Interest**

None of the authors of this paper has a financial or personal relationship with other people or organizations that could inappropriately influence or bias the content of this paper.

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Tables

Table 1: Analysis of Results
| Parameter                  | Frequency | Percentage (%) |
|---------------------------|-----------|----------------|
| **Gender**                |           |                |
| Male                      | 38        | 38.0           |
| Female                    | 62        | 62.0           |
| **Age**                   |           |                |
| < 20 years                | 3         | 3.0            |
| 20 - 40 years             | 37        | 37.0           |
| 41 - 60 years             | 53        | 53.0           |
| > 60 years                | 7         | 7.0            |
| **Pre-Study Status of Study Participants** | | |
| HIV-1                     | 92        | 92.0           |
| HIV-2                     | 3         | 3.0            |
| HIV-1&2                   | 5         | 5.0            |
| **Study-Time Status of Participants** | | |
| **First Response**        |           |                |
| HIV-1                     | 91        | 91.0           |
| HIV-1&2                   | 7         | 7.0            |
| HIV-2                     | 0         | 0.0            |
| Negative                  | 2         | 2.0            |
| **Multisure**             |           |                |
| HIV-1                     | 96        | 96.0           |
| HIV-1&2                   | 3         | 3.0            |
| HIV-2                     | 0         | 0.0            |
| Untypeable                | 1         | 1.0            |
| **OraQuick**              |           |                |
| Positive                  | 98        | 98.0           |
| Negative                  | 2         | 2.0            |
| **Confirmatory Test for the 12 Discordant Results** | | |
| Innolia Typing            |           |                |
| HIV-1                     | 9         | 75             |
| HIV-2                     | 2         | 16.7           |
| HIV-1 & 2                 | 0         | 0              |
| Negative                  | 1         | 8.3            |

Table 2. Comparison of the Sensitivity and Specificity of RDTs in the Study.
| Assay          | Infection type | Positive samples | TP* | TN  | FP  | FN  | Sensitivity (%) | Specificity (%) | PPV (%) | NPV (%) |
|---------------|----------------|------------------|-----|-----|-----|-----|-----------------|-----------------|----------|---------|
| First response| HIV-1          | 9                | 3   | 3   | 0   | 6   | 11.1            | NA              | 100      | 11.1    |
|               | HIV-2          | 2                | 0   | 10  | 0   | 2   | 0               | NA              | 0        | 83.3    |
|               | HIV-1&2        | 0                | 0   | 5   | 7   | 0   | 0               | 41.7            | 0        | 100     |
| Multisure     | HIV-1          | 9                | 3   | 0   | 0   | 3   | 88              | NA              | 100      | 75.0    |
|               | HIV-2          | 2                | 0   | 3   | 0   | 2   | 0               | NA              | 0        | 83.3    |
|               | HIV-1&2        | 0                | 0   | 3   | 0   | 1   | 0               | 41.7            | 0        | 100     |
| Oraquick      |                | 11               | 10  | 1   | 0   | 1   | 90.9            | NA              | 100      | 50      |

* TP = True positive   TN = True negative   FP = False positive   FN = False negative

PPV = Positive predictive value   NPV = Negative predictive value   NA = Not applicable