



HAL
open science

HIV rapid tests Immunological internal control can be misleading

Vincent Guiraud, Valentine Gauthier, Hadjer Lazga, Isabelle Leroy, Agnès Gautheret Dejean

► **To cite this version:**

Vincent Guiraud, Valentine Gauthier, Hadjer Lazga, Isabelle Leroy, Agnès Gautheret Dejean. HIV rapid tests Immunological internal control can be misleading. *Annales Pharmaceutiques Françaises*, 2024, 10.1016/j.pharma.2024.05.009 . hal-04597556

HAL Id: hal-04597556

<https://hal.science/hal-04597556>

Submitted on 3 Jun 2024

HAL is a multi-disciplinary open access archive for the deposit and dissemination of scientific research documents, whether they are published or not. The documents may come from teaching and research institutions in France or abroad, or from public or private research centers.

L'archive ouverte pluridisciplinaire **HAL**, est destinée au dépôt et à la diffusion de documents scientifiques de niveau recherche, publiés ou non, émanant des établissements d'enseignement et de recherche français ou étrangers, des laboratoires publics ou privés.

Titre (EN)

HIV rapid tests Immunological internal control can be misleading

Titre (FR)

Les contrôles internes immunologiques des tests rapides peuvent être faussement rassurants

Vincent Guiraud^{1a}, Valentine Gauthier^{1a}, Hadjer Lazga¹, Isabelle Leroy¹, Agnès Gautheret-Dejean^{1,2*}

¹ AP-HP, Hôpitaux Universitaires La Pitié Salpêtrière-Charles Foix, Service de Virologie, F-75013 Paris, France

² Université Paris cité, INSERM UMR-S 1139 Physiopathologie et pharmacotoxicologie placentaire humaine : microbiote pré & post-natal, F-75006 Paris, France

^a These authors contributed equally to this work

* Corresponding author: agnes.gautheret@aphp.fr

Corresponding author:

Pr Agnès Gautheret-Dejean

Hôpital Universitaire La Pitié Salpêtrière, Service de Virologie

83 Bd de l'Hôpital, 75013 Paris, France

Tel: +33 1 42177401 / Fax: +33 1 42177411

E-mail: agnes.gautheret@aphp.fr

Titre : Les contrôles internes immunologiques des tests rapides peuvent être faussement rassurants

Keywords : VIH, test rapide d'orientation diagnostique, contrôle interne, contrôle immunologique, test invalide, autotest

Points essentiels :

- Le contrôle interne (CI) de 13 tests rapides VIH a été testé avec eau, PBS et sérum VIH+
- Neuf des 13 tests rapides avaient un CI positif avec du PBS ou de l'eau
- Autotest VIH, Geenius, INSTI et MULTISURE étaient invalides en l'absence de sérum
- Le CI d'Autotest VIH, Geenius et INSTI peut alerter sur un volume insuffisant de sérum
- Le CI immunologique du MULTISURE ne peut alerter sur un volume de sérum insuffisant

Résumé :

Objectif : Déterminer si les contrôles internes (CI), notamment immunologiques, des tests rapides VIH peuvent permettre d'alerter sur une quantité insuffisante d'échantillon.

Matériels et méthodes : Nous avons évalués les tests Autotest VIH® (Autotest) (AAZ-LMB), INSTI™ HIV-1/HIV-2 Antibody Test (INSTI) (Biolytical), MULTISURE® HIV Rapid Test (MULTISURE) (MP Diagnostics), Biosynex® HIVTOP (Biosynex), Exacto HIVTOP® (Biosynex), Exacto® TEST HIV PRO (Biosynex), Genie™ Fast HIV 1/2 (Bio-Rad), Geenius™ HIV 1/2 Confirmatory Assay (Geenius) (Bio-Rad), VIKIA® HIV 1/2 (bioMérieux), FIRST RESPONSE® Test VIH 1-2. O CARTE (Premier Medical Corporation), Hexagon HIV (Human), Determine™ HIV EARLY DETECT (Abbott) et ONE STEP Anti-HIV 1&2 (InTec PRODUCTS) à l'aide d'eau distillée, de PBS et de sérum de personne vivant avec le VIH. Pour les tests invalides avec PBS ou eau, des dilutions de sérum positif pour le VIH ont été réalisées pour déterminer si les tests permettaient d'alerter correctement sur une hémodilution ou une quantité insuffisante d'échantillon.

Résultats : Parmi les 13 tests, 4 étaient invalides en l'absence de sérum : Autotest, Geenius, INSTI et MULTISURE. Autotest et INSTI ont correctement identifié les échantillons dilués, avec un résultat positif pour le VIH une dilution en deçà du CI. Pour Geenius, le CI et la ligne de test étaient positifs jusqu'à la même dilution. Le CI du MULTISURE ayant été positif pour des dilutions 1000 fois supérieure à la bande test, il ne peut alerter en cas de quantité d'échantillon insuffisante.

Title: HIV rapid tests immunological internal control can be misleading

Keywords: HIV, rapid test, internal control, immunologic control, invalid test, self-testing

Highlights

- Internal controls (IC) of 13 HIV rapid tests were tested with water, PBS and positive serum samples
- Nine out of 13 HIV rapid tests had a positive IC using PBS or distilled water
- Autotest VIH, Geenius, INSTI and MULTISURE were invalid if tested without human serum sample
- Autotest VIH, Geenius and INSTI IC may alert for insufficient sample quantity
- MULTISURE, despite a protein A based IC cannot alert for insufficient sample quantity

Abstract (EN)

Objective: To assess whether internal controls (IC) of HIV rapid tests (HRT) and a rapid confirmatory assay (Geenius) were designed to solely prevent procedural missteps or whether they can also alert for insufficient sample quantity.

Material and methods: Thirteen tests were evaluated using distilled water, phosphate buffered saline, and HIV-1 positive serum samples : Autotest VIH[®] (Autotest) (AAZ-LMB), INSTI[™] HIV-1/HIV-2 Antibody Test (INSTI) (Biolytical), MULTISURE[®] HIV Rapid Test (MULTISURE) (MP Diagnostics Asia Pacific Pte. CE Ltd), Biosynex[®] HIVTOP (Biosynex), Exacto HIVTOP[®] (Biosynex), Exacto[®] TEST HIV PRO (Biosynex), Genie[™] Fast HIV 1/2 (Bio-Rad laboratories), Geenius[™] HIV 1/2 Confirmatory Assay (Geenius) (Bio-Rad laboratories), VIKIA[®] HIV 1/2 (bioMérieux), FIRST RESPONSE[®] Test VIH 1-2.O CARTE (Premier Medical Corporation), Hexagon HIV (Human), Determine[™] HIV EARLY DETECT (Determine) (Abbott), and ONE STEP Anti-HIV 1&2 (InTec PRODUCTS, Xiamen, Fujian P. R. China).

Results: Among the 13 tests, 4 were invalid when tested without human serum sample: Autotest, Geenius, INSTI and MULTISURE. The Autotest and INSTI accurately labelled diluted samples, with a Test line positive at least one dilution below the IC. Geenius test line and IC were positive up to the same dilution with automated reading. However, MULTISURE IC was positive up to 1000-fold dilution higher than its test line, making it unsuitable to alert for low sample quantity.

Introduction

As HIV rapid tests (HRT) represent a cost-effective, user-friendly strategy for HIV-infection screening they are considered as a critical components of the United Nations' 95-95-95 targets to end the HIV epidemic by 2025 [1]. They present as single-use immunochromatographic or immunofiltration assay which provides an indication of HIV status with high sensitivity and specificity, usually within an hour [2–8]. Accordingly, they are widely used outpatient testing, especially in communities with a high HIV prevalence [3,9,10], in the event of viral exposure of healthcare workers, or after a high risk behavior [11,12]. Moreover, some HRT based on immunochromatographic technology can be reliable to differentiate between HIV-1 and HIV-2 [13], and one the Geenius assay, is approved for HIV-1 and HIV-2 confirmation and differentiation.

Since HRT can be performed by untrained people, numerous studies have reported a non-negligible number of invalid or misinterpreted results, up to 23% [10,14,15]. Among causes of invalid results are insufficient blood sampling, buffer spillage or procedural missteps [10,16,17]. Built-in internal controls (IC) are mainly made to address procedural missteps, and, for protein A based IC, alert for insufficient blood volume, as protein A binds to IgG from the patient's sample (whole blood, serum or plasma). This last point is advertised to act as a safety net to prevent false-negative results due to insufficient sample quantity, recognized as the leading cause of such erroneous result [10,18]. However, most manufacturers don't disclose the operating mechanism of their IC, and so far no study has addressed if protein A based IC can accurately alert for inadequate blood sampling.

The objective of this study was to characterize these built-in internal controls, and to verify their ability to alert for inadequate sample quantities in assays that use protein A based IC.

Methods

Twelve HRT and one rapid confirmatory assay were evaluated using distilled water, phosphate buffered saline (PBS), and two serum samples from chronically HIV-1 infected patients. Serums were screened using Architect HIV Ag/Ab combo (Abbott, Rungis, France) with New LAV Blot I (Bio-Rad laboratories, Marnes-la-Coquette, France) as the confirmatory assay, selected for their anti-HIV-1 levels, and assessed using the surrogate marker S/CO (ratio) of the Architect. Ratio was 42.26 for low-HIV antibody patient and 1090.55 for high-HIV antibody patient.

Assays evaluated were Autotest VIH® (Autotest) (AAZ-LMB, Boulogne-Billancourt et Viatrix, Lyon, France), INSTI™ HIV-1/HIV-2 Antibody Test (INSTI) (Biolytical, Canada), MULTISURE® HIV Rapid Test (MULTISURE) (MP Diagnostics Asia Pacific Pte. CE Ltd), Biosynex® HIVTOP (bHIV-TOP) (Biosynex, Illkirch-Graffenstaden, France), Exacto HIVTOP® (eHIV TOP) (Biosynex, Illkirch-Graffenstaden, France), Exacto® TEST HIV PRO (Exacto) (Biosynex, Illkirch-Graffenstaden, France), Genie™ Fast HIV 1/2 (Genie fast) (Bio-Rad laboratories, Marnes-la Coquette, France), Geenius™ HIV 1/2 Confirmatory Assay (Geenius) (Bio-Rad laboratories, Marnes-la Coquette, France), VIKIA® HIV 1/2 (VIKIA) (bioMérieux, Marcy l'Etoile, France), FIRST RESPONSE® Test VIH 1-2.O CARTE (FIRST RESPONSE) (Premier Medical Corporation, Sarigam, India), Hexagon HIV (Hexagon) (Human, Wiesbaden, Germany), Determine™ HIV EARLY DETECT (Determine) (Abbott), and ONE STEP Anti-HIV 1&2 (ONE STEP) (InTec PRODUCTS, Xiamen, Fujian P. R. China). Test characteristics are reported in Table 1. Each assay was performed and interpreted according to the manufacturers' recommendations by two independent operators. As the use of an automatic reader is advised by its manufacturer for the Geenius™ HIV 1/2 Confirmatory Assay, visual and automatic readings were performed.

Finally, if IC was negative upon PBS or sterile water testing, kits were further tested using HIV-positive serum diluted in PBS to determine which would exhibit a negative result first: the IC or the test line. Dilutions were: 1:2, 1:5, 1:10, 1:50, 1:100, 1:1,000, 1:10,000, 1:100,000, and 1:1,000,000.

Results

As expected, all assays were reactive and had a positive IC if used with the two patient serum samples. Among the 13 assays tested, 9 had a reactive IC band upon testing with sterile water or PBS: bHIVTOP, eHIVTOP, Determine, Exacto, FIRST RESPONSE, Genie fast, Hexagon, Vikia and ONE STEP (figure 1).

To further explore whether protein A based IC would accurately alert from insufficient blood sampling, serial dilutions were performed using 2 patients, the first with a high anti-HIV titer, and the second with a low anti-HIV titer (Figure 2). Autotest and INSTI performed well, with a reactive Test line at least one dilution higher compared to the IC line. Geenius confirmed the presence of HIV-1 up to a dilution of 1:100 for the Test line, with reactive IC in both samples for the same dilution with automatic reading, but with a weak IC band up to 1:10 000 with visual reading. Surprisingly, while MULTISURE HIV-1 Test line showed positivity up to 1:10 and 1:100 dilutions for the low and high titer sera respectively, but the IC was positive at a staggering dilution of 1:100,000. Therefore, the MULTISURE IC is not reliable to address insufficient blood sampling. Photographs of all HRT with the use of water, PBS and positive serum sample are provided in figure 1.

Discussion

Overall, 70% (9/13) of the HRT IC evaluated solely prevent procedural missteps, since they returned a valid result upon testing with either water or PBS. : Only the HIV Autotest, Geenius, INSTI and MULTISURE kits provided invalid results in the absence of human serum due to a protein A coating in their IC. However, they differed in their ability to detect insufficient sample loading. Autotest and INSTI accurately labelled diluted samples, with a Test line positive at least one dilution below the IC. Geenius test line and IC were positive up to the same dilution with automated reading, but a weak IC line was detectable

up to 1:10 000. According to the manufacturer, these assays should be interpreted as invalid since a faint IC band is not acceptable. However, as IC intensity is a subjective measure, the use of the automatic reader for the Geenius assay should be advised to enable correct identification of over-diluted / insufficient samples. Finally, this result should be interpreted in light with previous studies that have established that the automatic reader has an ability to diagnose HIV-1 and classify HIV-1/HIV-2 with an accuracy that rivals or surpasses visual assessment methods [19–21]. Lastly, the use of the Geenius specific reader allows a reliable traceability. As a consequence, we advise the use of this test in combination with its reader. MULTISURE IC, finally, was unable to address for insufficient or diluted blood sample, with IC line reactive up to 1:10000.

As a conclusion, although the use of protein A is advertised to avoid false-negative results due to low sample quantity, this method does not always improve the reliability of the test.

Fundings

This work received no specific funding

Declaration of Competing Interests

The authors declare that they have no competing financial interests or personal relationships that could have influenced the work reported in this paper.

Acknowledgments

The authors thank the laboratories for providing free kits for this study. Laboratories that gave HIV detection kits had no part on study design, data collection, data analyses, data interpretation nor manuscript writing. The authors thank ADEBIOPHARM ER28 association for the financial participation to this study.

Ethics

In accordance with the French legislation, this study was registered to the French authorities under the number 20240202103446 by the Data Protection Officer of the Pitié-Salpêtrière Hospital using the MR-004 referral methodology of the “Commission Nationale de l’Informatique et des Libertés”. Patients were systematically notified of any supplementary biological analyses on frozen samples, initially collected as part of routine clinical practice.

References

- [1] Frescura L, Godfrey-Faussett P, Feizzadeh A. A, El-Sadr W, Syarif O, Ghys PD, et al. Achieving the 95 95 95 targets for all: A pathway to ending AIDS. *PLoS ONE* 2022;17:e0272405. <https://doi.org/10.1371/journal.pone.0272405>.
- [2] Alexander TS. Human Immunodeficiency Virus Diagnostic Testing: 30 Years of Evolution. *Clin Vaccine Immunol* 2016;23:249–53. <https://doi.org/10.1128/CVI.00053-16>.
- [3] Dovel K, Shaba F, Oforjebe OA, Balakasi K, Nyirenda M, Phiri K, et al. Effect of facility-based HIV self-testing on uptake of testing among outpatients in Malawi: a cluster-randomised trial. *The Lancet Global Health* 2020;8:e276–87. [https://doi.org/10.1016/S2214-109X\(19\)30534-0](https://doi.org/10.1016/S2214-109X(19)30534-0).
- [4] Kendrick SR, Kroc KA, Withum D, Rydman RJ, Branson BM, Weinstein RA. Outcomes of Offering Rapid Point-of-Care HIV Testing in A Sexually Transmitted Disease Clinic: *JAIDS* 2005;38:142–6. <https://doi.org/10.1097/00126334-200502010-00004>.
- [5] Muñoz-Chimeno M, Valencia J, Rodriguez-Recio A, Cuevas G, Garcia-Lugo A, Manzano S, et al. HCV, HIV AND HBV rapid test diagnosis in non-clinical outreach settings can be as accurate as conventional laboratory tests. *Sci Rep* 2023;13:7554. <https://doi.org/10.1038/s41598-023-33925-2>.
- [6] Njouom R, Ngono L, Mekinda-Gometi DD, Ndé CK, Sadeuh-Mba SA, Vernet M-A, et al. Evaluation of the performances of twelve rapid diagnostic tests for diagnosis of HIV infection in Yaounde, Cameroon. *J Virol Methods* 2017;243:158–63. <https://doi.org/10.1016/j.jviromet.2017.02.008>.
- [7] Fisher DG, Hess KL, Reynolds GL, Alonzo TA, Huckabay LM, Van Otterloo L, et al. Comparisons of New HIV Rapid Test Kit Performance. *AIDS Behav* 2019;23:313–7. <https://doi.org/10.1007/s10461-018-2204-4>.
- [8] Mourez T, Lemée V, Delbos V, Delaugerre C, Alessandri-Gradt E, Etienne M, et al. HIV rapid screening tests and self-tests: Be aware of differences in performance and cautious of vendors. *EBioMedicine* 2018;37:382–91. <https://doi.org/10.1016/j.ebiom.2018.10.012>.
- [9] Burgos-Soto J, Ben Farhat J, Alley I, Ojuka P, Mulogo E, Kise-Sete T, et al. HIV epidemic and cascade of care in 12 east African rural fishing communities: results from a population-based survey in Uganda. *BMC Public Health* 2020;20:970. <https://doi.org/10.1186/s12889-020-09121-6>.
- [10] Phongphiew P, Songtaweasin WN, Paiboon N, Phiphatkhunarnon P, Srimuan P, Sowapruj T, et al. Acceptability of blood-based HIV self-testing among adolescents aged 15–19 years at risk of HIV acquisition in Bangkok. *Int J STD AIDS* 2021;32:927–32. <https://doi.org/10.1177/09564624211003742>.
- [11] Packer M. Critical Reanalysis of the Mechanisms Underlying the Cardiorenal Benefits of SGLT2 Inhibitors and Reaffirmation of the Nutrient Deprivation Signaling/Autophagy Hypothesis. *Circulation* 2022;146:1383–405. <https://doi.org/10.1161/CIRCULATIONAHA.122.061732>.
- [12] Attou M-A, Morand-Joubert L. Fiabilité du test rapide d'orientation diagnostique de l'infection à VIH : expérience au laboratoire de virologie de l'hôpital Saint-Antoine (Paris). *Immuno-analyse & Biologie Spécialisée* 2011;26:23–6. <https://doi.org/10.1016/j.immbio.2010.10.001>.
- [13] Guiraud V, Bocobza J, Desmonet M, Damond F, Plantier J-C, Moreau G, et al. Are Confirmatory Assays Reliable for HIV-1/HIV-2 Infection Differentiation? A Multicenter Study. *J Clin Microbiol* 2023:e00619-23. <https://doi.org/10.1128/jcm.00619-23>.
- [14] Andersson S, da Silva Z, Norrgren H, Dias F, Biberfeld G. Field evaluation of alternative testing strategies for diagnosis and differentiation of HIV-1 and HIV-2 infections in an HIV-1 and HIV-2-prevalent area: *AIDS* 1997;11:1815–22. <https://doi.org/10.1097/00002030-199715000-00005>.
- [15] Bwana P, Ochieng' L, Mwau M. Performance and usability evaluation of the INSTI HIV self-test in Kenya for qualitative detection of antibodies to HIV. *PLoS ONE* 2018;13:e0202491. <https://doi.org/10.1371/journal.pone.0202491>.
- [16] De La Fuente L, Rosales-Statkus ME, Hoyos J, Pulido J, Santos S, Bravo MJ, et al. Are Participants in a Street-Based HIV Testing Program Able to Perform Their Own Rapid Test and Interpret the Results? *PLoS ONE* 2012;7:e46555. <https://doi.org/10.1371/journal.pone.0046555>.

- [17] for the eSTAMP Study Group, MacGowan RJ, Chavez PR, Gravens L, Wesolowski LG, Sharma A, et al. Pilot Evaluation of the Ability of Men Who Have Sex with Men to Self-Administer Rapid HIV Tests, Prepare Dried Blood Spot Cards, and Interpret Test Results, Atlanta, Georgia, 2013. *AIDS Behav* 2018;22:117–26. <https://doi.org/10.1007/s10461-017-1932-1>.
- [18] Figueroa C, Johnson C, Ford N, Sands A, Dalal S, Meurant R, et al. Reliability of HIV rapid diagnostic tests for self-testing compared with testing by health-care workers: a systematic review and meta-analysis. *The Lancet HIV* 2018;5:e277–90. [https://doi.org/10.1016/S2352-3018\(18\)30044-4](https://doi.org/10.1016/S2352-3018(18)30044-4).
- [19] Kosack CS, Page A, Beelaert G, Benson T, Savane A, Ng'ang'a A, et al. Towards more accurate HIV testing in sub-Saharan Africa: a multi-site evaluation of HIV RDTs and risk factors for false positives. *JIAS* 2017;20:21345. <https://doi.org/10.7448/IAS.20.1.21345>.
- [20] Luo W, Sullivan V, Smith T, Peters PJ, Gay C, Westheimer E, et al. Performance evaluation of the Bio-Rad Geenius HIV 1/2 supplemental assay. *J Clin Virol* 2019;111:24–8. <https://doi.org/10.1016/j.jcv.2018.12.006>.
- [21] Herssens N, Beelaert G, Fransen K. Discriminatory capacity between HIV-1 and HIV-2 of the new rapid confirmation assay Geenius. *J Virol Methods* 2014;208:11–5. <https://doi.org/10.1016/j.jviromet.2014.07.025>.

Table 1: Detailed characteristics of HIV rapid tests evaluated

Commercial kit name	Manufacturer/ Distributor	Marking / Approval	Use	Ag/Ab used	Technology / time of reading	Matrix volume used (µL)
Autotest VIH [®]	AAZ-LMB (FR) / AAZ-LMB and Viatrix (FR)	CE / WHO ^p / FDA ^p	Screening	gp120 ^a , gp41 ^a and gp36 ^a	IC / 15-20 min	S, P: 2.5 WBI: one drop
Biosynex [®] HIVTOP	BioSynex (FR) / BioSynex (FR)	CE	Screening	gp41 ^a , gp36	IC / 10 min	S, P: 25 WBI: 50
Determine [™] HIV EARLY DETECT	Abbott (US) / Abbott (US)	CE / WHO	Screening	gp41 ^a , gp36 ^a , /p24	IC / 20-40 min	S, P: 50
Exacto HIVTOP [®]	NA / All Diag (FR) – BioSynex (FR)	CE	Screening	gp41 ^a , gp36 / V1 vs V2	IC / 10 min	S, P: 25
Exacto [®] TEST HIV PRO	BioSynex (FR) /BioSynex (FR)	CE	Screening	gp41 ^a , gp36 ^a	IC / 10-20 min	S, P, WBI: 5
FIRST RESPONSE [®] Test VIH 1-2.O Card test	Premier Medical Corporation Ltd. (US) / Nephrotek (FR)	CE / WHO	Screening	gp41 ^a , p24 ^a , gp36 ^a / V1 vs V2	IC / 15 min	S, P: 10 WBI: 20
Genie [™] Fast HIV 1/2	BioRad (US) / BioRad (US)	CE	Screening	gp120 ^a , gp41 ^a and gp36 ^a	IC / 10-30 min	S, P, WBI: 80
Geenius [™] HIV 1/2 Confirmatory Assay	BioRad (US) / BioRad (US)	CE / WHO / FDA	Confirmation	p31, gp160, p24, gp41, gp36, gp140 / V1 vs V2	IC / 15-30 min	S, P: 5
Hexagon HIV	Human (Gr) / Servibio (FR)	CE	Screening	gp41 ^a , p24 ^a , gp36 ^a	IC / 5-20 min	S, P: 10 WBI: 20
INSTI [™] HIV-1/HIV-2 Antibody Test	bioLytical (C) / Nephrotek (FR)	CE / FDA / WHO	Screening	gp41 ^a , gp36 ^a	IF / immediate	S, P, WBI: 50
MULTISURE [®] HIV Rapid Test	MP Biomedicals Asia Pacific Pte. Ltd. (Sg) / Nephrotek (FR)	CE	Screening	gp120 ^a , gp41 ^a , p24 ^a , gp36 ^a / V1 vs V2	IC / 20-25 min	S, P: 25 WBI: 20
VIKIA [®] HIV 1/2	bioMérieux [®] (FR) /bioMérieux [®] (FR)	CE / WHO	Screening	gp41 ^b , gp36 ^b	IC / 30 min	S, P, WBI: 75
ONE STEP Anti-HIV 1&2	InTec PRODUCTS (PRC) / Prodiag (HOLLAND)	CE / WHO	Screening	gp120 ^a , gp41 ^a , gp36 ^b	IC / 15-20 min	S,P,WBI : 30

^aRecombinant antigens; ^bSynthetic peptides; ^pProfessional use; C: Canada; CE: european community; FDA: food and drug administration; FR: France; gp: glycoprotein; Gr: Germany; IC: immunochromatography; IF: immunofiltration; NA : not available; P: plasma; S: serum; Sg: Singapore; WBI: whole blood; US: United States of America; V1 vs V2: differentiation between HIV-1 and HIV-2 ; WHO: World Health Organization.

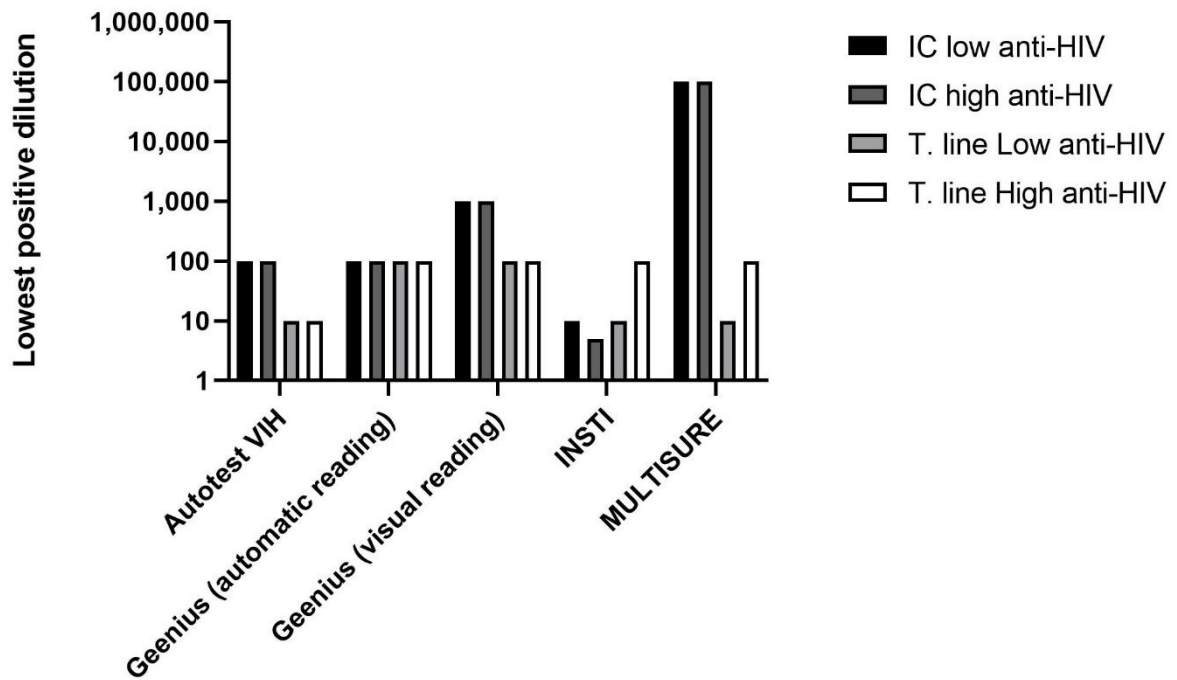









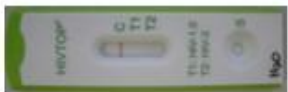

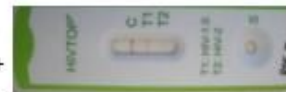



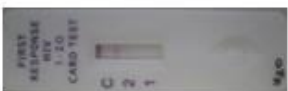


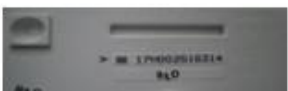
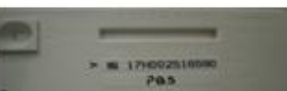
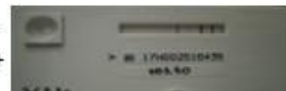



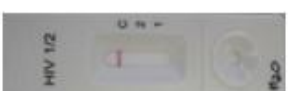
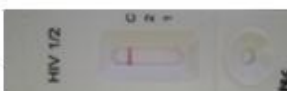
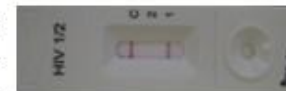


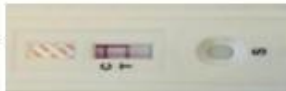











Figure 2: lowest sample dilution to provide a positive result for protein A based internal control and Test lines (low and high anti-HIV serum titers). IC: Internal control, T. line: Test line, low and high anti-HIV serum titers were assessed using S/CO values on the Architect platform.

List of approved HIV Rapid tests kits	Test results		
	Water	PBS	HIV-1 positive serum
Autotest VIH®	IC - T - 	IC - T - 	IC + T + 
Biosynex® HIVTOP	IC + T1 - T2 - 	IC + T1 - T2 - 	IC + T1 + T2 - 
Determine™ HIV EARLY DETECT	IC + Tag - Tab - 	IC + Tag - Tab - 	IC + Tag + Tab + 
Exacto HIVTOP®	IC + T1 - T2 - 	IC + T1 - T2 - 	IC + T1 + T2 - 
Exacto® TEST HIV PRO	IC + T - 	IC + T - 	IC + T + 
FIRST RESPONSE® HIV 1-2.O Card Test	IC + T1 - T2 - 	IC + T1 - T2 - 	IC + T1 + T2 - 
Geenius™ HIV 1/2 Confirmatory Assay	IC - T1 - T2 - 	IC - T1 - T2 - 	IC + T1 + T2 - 
Genie™ Fast HIV 1/2	IC + T - 	IC + T - 	IC + T + 
Hexagon HIV	IC + T1 - T2 - 	IC + T1 - T2 - 	IC + T1 - T2 - 
One Step Anti-HIV 1&2	IC + T - 	IC + T - 	IC + T + 
INSTI™ HIV-1/HIV-2 Antibody Test	IC - T - 	IC - T - 	IC + T + 
MULTISURE® HIV Rapid Test	IC - T1 - T2 - 	IC - T1 - T2 - 	IC + T1 + T2 - 
VIKIA® HIV 1/2	IC + T - 	IC + T - 	IC + T + 

+ : presence of a colored band/spot; - : no apparent band/spot; IC: internal control; PBS: Phosphate Buffered Saline; T: Test; T1: Test for HIV-1; T2: Test for HIV-2; T_{ab}: Test for antibodies to HIV; T_{ag}: Test for p24 antigen.