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1 **Rapid tests should be used with caution for HIV-1 primary infection screening**

2

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20

21 *Keywords:* rapid test, HIV-1, primary infection, seroconversion, screening, sensitivity

22

23

24 **ABSTRACT:**

25 Rapid tests allow outpatient, low cost, reliable, screening for chronic HIV infection. However,
26 data regarding their sensitivity on primary infection remain scarce. The objective of this study
27 was to assess sensitivity of nine HIV rapid tests for primary HIV-1 infection screening.
28 Seventy-five serum samples from patients during HIV-1 primary infection were included.
29 Primary infection was diagnosed by a positive 4th generation ELISA and HIV-1 RNA
30 positivity confirmed by Western blot patterns associated with HIV-1 primary infection. Early
31 seroconversion was defined as the absence of antibodies on HIV-1 Western blot associated
32 with HIV-1 RNA and p24-antigen positivity. An identical sensitivity (95% CI) of 76.7%
33 (65.2-84.2%) was observed for HIV 1/2 STAT-PAK[®] Assay (STAT-PAK), INSTI[™] HIV-
34 1/HIV-2 antibody Test (INSTI), SURE CHECK[®] HIV 1/2 (SURE CHECK) and
35 MULTISURE HIV rapid test (MULTISURE) with visual reading. Sensitivity was 74.7%
36 (63.8-83.1%) for MULTISURE (automatic result), 77.0% (66.3-85.1%) for FIRST
37 RESPONSE[®] Test VIH 1-2.O CARTE (FIRST RESPONSE), 83.8% (73.8-90.5%) for VIKIA
38 HIV1/2[®] (VIKIA), 88.0% (78.7-93.6%) for Genie[™] Fast HIV 1/2 (Genie Fast), 88.6% (79.0-
39 94.1%) for Hexagon HIV (Hexagon), and 92.8% (83.6-96.3%) for Exacto[®] TEST HIV Pro
40 (Exacto). However, rapid tests performed poorly for the early seroconversion subgroup
41 (n=14), with sensitivities ranging from 7% (1.3-31.5) for STAT-PAK, INSTI, SURE
42 CHECK, MULTISURE (automatic reading), to 29% (12-55%) for FIRST RESPONSE, 31%
43 (13-58%) for VIKIA, 43% (21-67%) for Hexagon and 57.1% (32.6-78.6%) for Exacto and
44 Genie Fast. Overall, despite significant discrepancies in sensitivity, HIV rapid tests should be
45 used with caution in the context of a suspected primary infection.

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47

48

49 **Introduction**

50 In 2021, more than 38 million people were living with HIV worldwide [1]. With the aim
51 to end the AIDS epidemic as a public health threat, UNAIDS defined new global 95-95-95
52 targets for 2025 which corresponds to 95% of people living with HIV knowing their status,
53 95% of them receiving antiretroviral treatment, and among them 95% with viral suppression
54 [2]. To achieve these objectives, diagnosis is essential. Among barriers to HIV screening are
55 costs, need to present to a medical setting, fear of stigma or delays in test result receipt [3–6].
56 Rapid tests address most of those points and are reliable for chronic HIV infection diagnosis
57 [7–10]. However, their sensitivity to detect HIV-1 primary infection exhibits discrepant
58 results [10–14]. This point remains a major concern given that patients are around 26 times
59 more contaminant at this stage of the infection, originating a significant part of HIV
60 contaminations [15–19]. However, to date only a small proportion of patients is diagnosed at
61 an early stage [20].

62 The objective of this study was to determine the sensitivity of nine HIV rapid tests for
63 HIV-1 primary infection screening.

64

65 **Methods**

66 *Sample collection*

67 Seventy-five samples (74 serums and one plasma) from consecutive patients at the stage of
68 HIV-1 primary infection were included at Pitié Salpêtrière Hospital (Paris, France). HIV
69 diagnosis was performed in accordance with French legislation [21], following the routine
70 algorithm. HIV screening performed using the laboratory-based enzyme immunoassay
71 Liaison XL Murex HIV Ag/Ab (DiaSorin, Antony, France) and a confirmatory assay was
72 performed using the New Lav Blot I (Bio-Rad laboratories, Marnes-la-Coquette, France)
73 Western blot. Diagnosis of primary HIV infection was based on Western blot pattern

74 according to the WHO guidelines [22], associated with a positive HIV-1 viral load, using
75 Cobas® AmpliPrep/Cobas TaqMan® HIV-1 Test, v2.0 (Roche Diagnostics, Mannheim
76 Germany). Early seroconversion was defined as the absence of antibodies on the HIV-1
77 Western blot associated with both HIV-1 RNA (assessed on Cobas® AmpliPrep/Cobas
78 TaqMan® HIV-1 Test, v2.0) and p24 antigen positivity, assessed on VIDAS HIV p24 II
79 (bioMérieux, France). Samples were stored at -20°C before use.

80

81 *Sample processing*

82 Samples were prospectively analyzed within the same freezing defrosting cycle with all the
83 nine HIV rapid tests: INSTI™ HIV-1/HIV-2 Antibody Test (INSTI) (Biolytical, Canada),
84 MULTISURE HIV Rapid Test (MULTISURE) (MP Diagnostics Asia Pacific Pte. CE Ltd),
85 SURE CHECK® HIV1/2 (SURE CHECK) (Chembio Diagnostics, Medford, USA), HIV 1/2
86 STAT-PAK® Assay (STAT-PAK) (Chembio Diagnostics, Medford, USA), Exacto® TEST
87 HIV PRO (Exacto) (Biosynex, Illkirch-Graffenstaden, France), Genie™ Fast HIV 1/2 (Genie)
88 (Bio-Rad laboratories, Marnes-la Coquette, France), VIKIA® HIV 1/2 (VIKIA) (bioMérieux,
89 Marcy l'Etoile, France), FIRST RESPONSE® Test VIH 1-2.O CARTE (FIRST RESPONSE)
90 (Premier Medical Corporation, Sarigam, India) and Hexagon HIV (Hexagon) (Human,
91 Wiesbaden, Germany). For MULTISURE, visual and automation readings were performed.
92 For Hexagon, FIRST RESPONSE and VIKIA, 71, 74 and 74 of the 75 samples were tested,
93 respectively, due to an insufficient sample quantity. Assays are described Table 1. Each assay
94 was performed and interpreted according to the manufacturers' recommendations by two
95 independent operators. Samples with invalid results according to the manufacturers'
96 recommendations were controlled once.

97

98 *Statistical analysis*

99 Statistical analyses were conducted using R version 4.2.1 [23]. Test comparisons were
100 done using Chi-squared test. Statistical tests were two sided with a significance assigned at a
101 p value < 0.05 . Confidence intervals were calculated using Wilson's score bound [24].
102 Finally, we determined that with an assumed 90% sensitivity, a sample size of 75 samples
103 would be enough to estimate our results with around 5% accuracy [25].

104

105 *Ethics*

106 This study complies with Good Clinical Practices and ethical principles of the Helsinki
107 declaration. All data were anonymized before analysis. Patients were systematically notified
108 of any supplementary biological analyses on frozen samples, initially collected as part of
109 routine clinical practice.

110

111 **Results**

112 Sensitivity varied widely for the 75 samples tested (Table 2). A sensitivity (95% CI) of 76.7%
113 (65.2-84.2%) was observed for STAT-PAK, INSTI, SURE CHECK and MULTISURE
114 (visual reading). Sensitivity was 74.7% (63.8-83.1%) for MULTISURE (automatic result),
115 77.0% (66.3-85.1%) for FIRST RESPONSE, 83.8% (73.8-90.5%) for VIKIA, 88.0% (78.7-
116 93.6%) Genie Fast, 88.6% (79.0-94.1%) for Hexagon, and 92.8% (83.6-96.3%) for Exacto
117 (Table 2). As a consequence, using Chi-squared tests, Exacto and Hexagon performed
118 statistically better than STAT-PAK, INSTI, SURE CHECK and MULTISURE (both
119 readings), while Genie Fast was better than MULTISURE automatic reading only (Table 3).

120 We performed an exploratory analysis on the 14 samples from an early seroconversion stage,
121 defined as the absence of antibody on HIV-1 Western blot associated with HIV-1 RNA and
122 p24 antigen positivity (stage 2 and 3 Fiebig) [26]. All HIV rapid tests performed poorly

123 (Table 2), with sensitivities ranging from 7% (1-31%) for MULTISURE (automatic reading),
124 INSTI, STAT-PAK and SURE-CHECK to 57% (33-79%) for Exacto and Genie Fast.
125 Of note, three samples had a negative HIV-antibody signal (S/CO <1) with Liaison XL. The
126 first, with a 0.515 S/CO signal was non-reactive for all rapid tests, the second, with a 0.661
127 S/CO signal had a trace for Exacto and Multisure. The last, with a 0.973 S/CO value had a
128 trace for Exacto and Genie. These few results might imply that lack of sensitivity during early
129 seroconversion stage could result directly from a lack of HIV antibody, although much more
130 samples would be needed to address this point. As expected, Liaison XL p24 S/CO signal was
131 highly positive for the three samples.

132 Finally, one sample tested invalid with Genie was negative upon retesting, and one invalid
133 sample with VIKIA returned positive upon retesting.

134

135 **Discussion**

136 This study highlighted significant sensitivity discrepancies between 9 rapid tests to screen
137 for HIV-1 primary infection, ranging from 74.7% for the MULTISURE (automatic reading)
138 to 92.8% for Exacto. This study also highlighted a significant concern regarding the early
139 seroconversion subgroup, since sensitivity was at most 57% only. Although these results
140 applied to a much lower number of samples due to the very stringent criteria applied, they
141 raised concerns regarding rapid tests diagnostic windows. Consequently, the use of rapid tests
142 might be discouraged in a context of a suspected HIV-1 primary infection, and an ELISA test
143 should be favored instead.

144 To the best of our knowledge, sensitivities of MULTISURE, Exacto, SURE CHECK,
145 FIRST RESPONSE, Genie Fast and STAT-PAK were only studied on chronically HIV-
146 infected people [3,9,10,14,27–31]. A previous study assessed INSTI sensitivity during HIV-1
147 primary infection, with values within the ranges observed in this study: 69% (54-81%) [32].

148 VIKIA sensitivity during HIV-1 primary infection was estimated as 75% (35%–97%) and
149 91% (73-98%) on 7 serum and 23 plasma samples, respectively [33,34], and Hexagon 90%
150 (60-98%) on a panel of 10 serum samples of seroconversion [35].

151 This study has some limitations. First, the 2 investigators were unblinded. This may have
152 slightly overestimated our results, although sensitivity between automatic and visual results
153 for MULTISURE was roughly the same. Second, as the study was performed on thawed sera,
154 results may show some discrepancies with fresh whole blood that is usually used for
155 outpatients screening. Third, most of the samples were originated from HIV-1 group M
156 subtype B (43%) or CRF02_AG (20%) infected patients, which reflected European
157 epidemiology [36]. As a consequence, these results might be taken with caution depending on
158 local epidemiology [37]. Moreover, our results are based on 75 samples only. However all our
159 samples originated from seroconversion samples, while those from commercial
160 seroconversion panels include a non-negligible number of pre-HIV infection and post-
161 seroconversion samples [32]. Fifth, as HIV-1 primary infection was determined by 4th
162 generation ELISA and HIV-1 Western blot patterns and early seroconversion by both HIV-1
163 RNA and p24-antigen positivity, we were unable to give precise insights on the time between
164 contamination and HIV screening, and stage I Fiebig (HIV-RNA positivity only) could not be
165 identified.

166

167

168 **Conclusions**

169 This study highlighted important discrepancy in sensitivity of rapid tests for HIV-1 primary
170 infection, and a lack of sensitivity for the early seroconversion period. As a consequence,
171 rapid tests should be used with an extreme caution in the context of a suspected primary
172 infection.

173

174

175 **Declaration of Competing Interests**

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

178

179 **Author contributions**

180 Vincent Guiraud acquisition and analyses of data, writing-original draft preparation,
181 submission of the final manuscript, Quentin Beaulieu supervision, samples testing, validation,
182 Antoine Fauchois analyses of data, Pascale Jean-Charles samples testing, Marie-Capucine
183 Costes samples testing, Bruno Le Labousse samples testing, Agnès Gautheret-Dejean
184 conceptualization, methodology, validation writing-reviewing and editing.

185

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188

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193 Biomedicals Nephrotek/Premier Medical corporation for providing free kits for this study.
194 Laboratories that gave HIV detection kits had no part on study design, data collection, data
195 analyses, data interpretation, manuscript writing nor submission to publication.

196

197

198

199 **Data Availability Statement**

200 The data that support the findings are available as supplementary table 1 for HIV rapid tests,

201 Liaison XL S/CO values and Western blot results.

202 **References**

203 1. UNAIDS data 2022. In Geneva, Switzerland: World Health Organization; 2022. Available from:
204 https://www.unaids.org/sites/default/files/media_asset/data-book-2022_en.pdf

205 2. Frescura L, Godfrey-Faussett P, Feizzadeh A. A, El-Sadr W, Syarif O, Ghys PD, et al. Achieving the
206 95 95 95 targets for all: A pathway to ending AIDS. Ambrose Z, editor. PLoS ONE. 2022 Aug
207 4;17(8):e0272405.

208 3. Kendrick SR, Kroc KA, Withum D, Rydman RJ, Branson BM, Weinstein RA. Outcomes of Offering
209 Rapid Point-of-Care HIV Testing in A Sexually Transmitted Disease Clinic: JAIDS Journal of
210 Acquired Immune Deficiency Syndromes. 2005 Feb;38(2):142–6.

211 4. Kobrak P, Remien RH, Myers JE, Salcuni P, Edelstein Z, Tsoi B, et al. Motivations and Barriers to
212 Routine HIV Testing Among Men Who Have Sex with Men in New York City. AIDS Behav. 2022
213 Nov;26(11):3563–75.

214 5. Laprise C, Bolster-Foucault C. Understanding barriers and facilitators to HIV testing in Canada
215 from 2009–2019: A systematic mixed studies review. CCDR. 2021 Mar 4;47(2):105–25.

216 6. the Adolescent Medicine Trials Network for HIV/AIDS Interventions, Gamarel KE, Nelson KM,
217 Stephenson R, Santiago Rivera OJ, Chiaramonte D, et al. Anticipated HIV Stigma and Delays in
218 Regular HIV Testing Behaviors Among Sexually-Active Young Gay, Bisexual, and Other Men Who
219 Have Sex with Men and Transgender Women. AIDS Behav. 2018 Feb;22(2):522–30.

220 7. Fisher DG, Hess KL, Reynolds GL, Alonzo TA, Huckabay LM, Van Otterloo L, et al. Comparisons of
221 New HIV Rapid Test Kit Performance. AIDS Behav. 2019 Feb;23(2):313–7.

222 8. O’Connell RJ, Agan BK, Anderson SA, Malia JA, Michael NL. Sensitivity of the Multispot HIV-
223 1/HIV-2 Rapid Test Using Samples from Human Immunodeficiency Virus Type 1-Positive
224 Individuals with Various Levels of Exposure to Highly Active Antiretroviral Therapy. J Clin
225 Microbiol. 2006 May;44(5):1831–3.

226 9. Tan WS, Chow EPF, Fairley CK, Chen MY, Bradshaw CS, Read TRH. Sensitivity of HIV rapid tests
227 compared with fourth-generation enzyme immunoassays or HIV RNA tests. AIDS. 2016 Jul
228 31;30(12):1951–60.

229 10. Mourez T, Lemée V, Delbos V, Delaugerre C, Alessandri-Gradt E, Etienne M, et al. HIV rapid
230 screening tests and self-tests: Be aware of differences in performance and cautious of vendors.
231 EBioMedicine. 2018 Nov;37:382–91.

232 11. Duong YT, Mavengere Y, Patel H, Moore C, Manjengwa J, Sibandze D, et al. Poor Performance
233 of the Determine HIV-1/2 Ag/Ab Combo Fourth-Generation Rapid Test for Detection of Acute

- 234 Infections in a National Household Survey in Swaziland. Caliendo AM, editor. *J Clin Microbiol*.
235 2014 Oct;52(10):3743–8.
- 236 12. Faraoni S, Rocchetti A, Gotta F, Ruggiero T, Orofino G, Bonora S, et al. Evaluation of a rapid
237 antigen and antibody combination test in acute HIV infection. *Journal of Clinical Virology*. 2013
238 May;57(1):84–7.
- 239 13. Patel P, Bennett B, Sullivan T, Parker MM, Heffelfinger JD, Sullivan PS. Rapid HIV screening:
240 Missed opportunities for HIV diagnosis and prevention. *Journal of Clinical Virology*. 2012
241 May;54(1):42–7.
- 242 14. Lewis JM, Macpherson P, Adams ER, Ochodo E, Sands A, Taegtmeier M. Field accuracy of
243 fourth-generation rapid diagnostic tests for acute HIV-1: a systematic review. *AIDS*. 2015 Nov
244 28;29(18):2465–71.
- 245 15. Pilcher CD, Tien HC, Eron, Jr. JJ, Vernazza PL, Leu S, Stewart PW, et al. Brief but Efficient: Acute
246 HIV Infection and the Sexual Transmission of HIV. *J INFECT DIS*. 2004 May 15;189(10):1785–92.
- 247 16. Yerly S, Vora S, Rizzardi P, Chave JP, Vernazza PL, Flepp M, et al. Acute HIV infection: impact on
248 the spread of HIV and transmission of drug resistance: *AIDS*. 2001 Nov;15(17):2287–92.
- 249 17. Verhofstede C, Mortier V, Dauwe K, Callens S, Deblonde J, Dessilly G, et al. Exploring HIV-1
250 Transmission Dynamics by Combining Phylogenetic Analysis and Infection Timing. *Viruses*. 2019
251 Nov 26;11(12):1096.
- 252 18. Kroon EDMB, Phanuphak N, Shattock AJ, Fletcher JLK, Pinyakorn S, Chomchey N, et al. Acute
253 HIV infection detection and immediate treatment estimated to reduce transmission by 89%
254 among men who have sex with men in Bangkok. *Journal of the International AIDS Society*.
255 2017;20(1):21708.
- 256 19. Hollingsworth TD, Anderson RM, Fraser C. HIV-1 Transmission, by Stage of Infection. *J INFECT
257 DIS*. 2008 Sep;198(5):687–93.
- 258 20. Santé Publique France. Bulletin de santé publique VIH-IST. Décembre 2022. 28/11/2022
259 [Internet]. 2022 Dec; Available from: [https://www.santepubliquefrance.fr/maladies-et-
260 traumatismes/infections-sexuellement-transmissibles/vih-sida/documents/bulletin-
261 national/bulletin-de-sante-publique-vih-ist.-decembre-2022](https://www.santepubliquefrance.fr/maladies-et-traumatismes/infections-sexuellement-transmissibles/vih-sida/documents/bulletin-national/bulletin-de-sante-publique-vih-ist.-decembre-2022)
- 262 21. Arrêté du 28 mai 2010 fixant les conditions de réalisation du diagnostic biologique de l'infection
263 à virus de l'immunodéficience humaine (VIH 1 et 2) et les conditions de réalisation du test
264 rapide d'orientation diagnostique dans les situations d'urgence [Internet]. 2010 [cited 2023 Oct
265 20]. Available from: <https://www.legifrance.gouv.fr/loda/id/JORFTEXT000022320859>
- 266 22. AIDS: proposed WHO criteria for interpreting western blot assays for HIV-1, HIV-2, and HTLV-
267 I/HTLV-II. *Bull World Health Organ*. 1991;69(1):127–9, 131–3.
- 268 23. R Core Team. R: A Language and Environment for Statistical Computing.
- 269 24. Brown LD, Cai TT, DasGupta A. Interval Estimation for a Binomial Proportion. *Statist Sci*
270 [Internet]. 2001 May 1 [cited 2023 Jun 14];16(2). Available from:
271 [https://projecteuclid.org/journals/statistical-science/volume-16/issue-2/Interval-Estimation-
272 for-a-Binomial-Proportion/10.1214/ss/1009213286.full](https://projecteuclid.org/journals/statistical-science/volume-16/issue-2/Interval-Estimation-for-a-Binomial-Proportion/10.1214/ss/1009213286.full)

- 273 25. Motulsky H, Citta M, Citta-Vanthsche M. *Biostatistique: une approche intuitive*. 3e éd.
274 Louvain-la-Neuve: De Boeck supérieur; 2019.
- 275 26. Fiebig EW, Wright DJ, Rawal BD, Garrett PE, Schumacher RT, Peddada L, et al. Dynamics of HIV
276 viremia and antibody seroconversion in plasma donors: implications for diagnosis and staging
277 of primary HIV infection. *AIDS*. 2003 Sep;17(13):1871–9.
- 278 27. Boadu R, Darko G, Nortey P, Akweongo P, Sarfo B. Assessing the sensitivity and specificity of
279 First Response HIV-1-2 test kit with whole blood and serum samples: a cross-sectional study.
280 *AIDS Res Ther*. 2016 Dec;13(1):9.
- 281 28. Kim HN, Hur M, Kim H, Moon HW, Yun YM, Oh EJ, et al. Evaluation of the MULTISURE HIV Rapid
282 Test in a Korean population with low human immunodeficiency virus prevalence. *Clinical
283 Chemistry and Laboratory Medicine (CCLM)*. 2019 Jul 26;57(8):e189–91.
- 284 29. Jaspard M, Le Moal G, Saberan-Roncato M, Plainchamp D, Langlois A, Camps P, et al. Finger-
285 Stick Whole Blood HIV-1/-2 Home-Use Tests Are More Sensitive than Oral Fluid-Based In-Home
286 HIV Tests. Abrams WR, editor. *PLoS ONE*. 2014 Jun 27;9(6):e101148.
- 287 30. Manak MM, Njoku OS, Shutt A, Malia J, Jagodzinski LL, Milazzo M, et al. Evaluation of
288 Performance of Two Rapid Tests for Detection of HIV-1 and -2 in High- and Low-Prevalence
289 Populations in Nigeria. Tang YW, editor. *J Clin Microbiol*. 2015 Nov;53(11):3501–6.
- 290 31. Dagnra AY, Dossim S, Salou M, Nyasenu T, Ali-Edje K, Ouro-Médéli A, et al. Evaluation of 9 rapid
291 diagnostic tests for screening HIV infection, in Lomé, Togo. *Médecine et Maladies Infectieuses*.
292 2014 Dec;44(11–12):525–9.
- 293 32. Adams S, Luo W, Wesolowski L, Cohen SE, Peters PJ, Owen SM, et al. Performance evaluation of
294 the point-of-care INSTI™ HIV-1/2 antibody test in early and established HIV infections. *Journal
295 of Clinical Virology*. 2017 Jun;91:90–4.
- 296 33. Delaugerre C, Antoni G, Mahjoub N, Pialoux G, Cua E, Pasquet A, et al. Assessment of HIV
297 Screening Tests for Pre-Exposure Prophylaxis Programs. *The Journal of Infectious Diseases*
298 [Internet]. 2017 Jun 27 [cited 2022 Dec 29]; Available from:
299 <https://academic.oup.com/jid/article-lookup/doi/10.1093/infdis/jix297>
- 300 34. Gomes C, Azevedo-Pereira JM. The performance of the VIKIA® HIV1/2 rapid test—Evaluation of
301 the reliability and sensitivity. *Journal of Virological Methods*. 2011 May;173(2):353–6.
- 302 35. Ferreira OC, Ferreira C, Riedel M, Widolin MRV, Barbosa-Júnior A. Evaluation of rapid tests for
303 anti-HIV detection in Brazil. *AIDS*. 2005 Oct;19(Suppl 4):S70–5.
- 304 36. Bbosa N, Kaleebu P, Ssemwanga D. HIV subtype diversity worldwide. *Current Opinion in HIV
305 and AIDS*. 2019 May;14(3):153–60.
- 306 37. Biyang YVS, Parkouda S, Bivigou-Mboumba B, Iroungou BA, Ondeme AM, Bisseye C. Evaluation
307 of HIV-1 rapid diagnostic tests in the context of viral genetic diversity in Libreville (Gabon). *Pan
308 Afr Med J*. 2022;42:194.
- 309

Table 1. Detailed characteristics of HIV Rapid tests.

Name of the Kit	Manufacturer / distributor	Ab/Ag used	Immunoassay type / Ig class detected	Technology / time of reading	Matrix / volume used (μL)	Self-testing / Professional purpose
Exacto [®] TEST HIV PRO	BioSynex (FR)	None / Gp41 ^c and gp36 ^c	Sandwich ^d	IC / 10-20 min	S, P, WBI / 5	Self testing
Genie [™] Fast HIV 1/2	BioRad (US)	None / Gp120 ^a , gp41 ^a , gp36 ^a	Sandwich ^d	IC / 10-30 min	S, P, WBI / 80	Professional purpose
HIV 1/2 STAT-PAK [®] Assay	Chembio (US)	None / Gp41 ^a and gp36 ^a	Sandwich ^d	IC / 15 min	S, P, WBI / 5	Professional purpose
INSTI [™] HIV-1/HIV-2 Antibody Tests	Biolytical (CA)/ Nephrotek (FR)	None / Gp41 ^a and gp36 ^a	Indirect immunoassay / IgG and IgM	IF / immediate	S, P, WBI / 50	Self-testing
SURE CHECK [®] HIV 1/2	Chembio (USA)	None / Gp120 ^a , gp41 ^a , gp36 ^a	Sandwich ^d	IC / 15-20 min	S, P / 2.5, WBI / 1 drop	Self-testing
VIKIA [®] HIV 1/2	bioMérieux [®] (FR)	None / Gp41 ^b and gp36 ^b	Sandwich ^d	IC / 30 min	S, P, WBI / 75	Professional purpose
FIRST RESPONSE [®] Test VIH 1-2.0 CARTE	Premier Medical (India)	None / Gp41 ^a , p24 ^a and gp36 ^a	Sandwich ^d	IC / 15 min	S, P / 10 WBI / 20	Professional purpose
Hexagon HIV	Human (De)/ Servibio (FR)	None / Gp41 ^a , p24 ^a and gp36 ^a	Sandwich ^d	IC / 5-20 min	S, P / 10 WBI / 20	Professional purpose
MULTISURE HIV Rapid Test	MP Biomedicals (Singapour)/ Nephrotek (FR)	None / Gp120 ^a , gp41 ^a , p24 ^a and gp36 ^a	Indirect immunoassay / IgG	IC / 20-25 min	S, P / 25 WBI / 20	Professional purpose

^a Recombinant antigens.

^b Synthetic peptides.

^c Not specified

Ag, antigen; Ab, antibody; IC, immunochromatography; IF, immunofiltration; S, serum; P, plasma; WBI, whole blood; US, United States of America; FR, France; CA, Canada; De, Germany.

^d All immunoglobulin class are recognized, in particular IgG and IgM

Table 2. Sensitivity rate for HIV-1 primary infection screening.

Assay	Overall No Positive samples/ sample tested	Overall Sensitivity (95% CI)	No Positive samples/ early seroconversion subgroup samples tested	Sensitivity (95% CI), early seroconversion subgroup
Exacto [®] TEST HIV PRO	69/75	92.8 (83.6-96.3)	8/14	57 (33-78)
Genie [™] Fast HIV 1/2	66/75	88.0 (78.7-93.6)	8/14	57 (33-78)
HIV 1/2 STAT-PAK [®]	57/75	76.7 (65.2-84.2)	1/14	7 (1-31)
Assay				
INSTI [™] HIV-1/HIV-2	57/75	76.7 (65.2-84.2)	1/14	7 (1-31)
Antibody Tests				
SURE CHECK [®] HIV 1/2	57/75	76.7 (65.2-84.2)	1/14	7 (1-31)
VIKIA [®] HIV 1/2	62/74	83.8 (73.8-90.5)	4/14	31 (13-58)
FIRST RESPONSE [®] Test	57/74	77.0 (66.3-85.1)	4/14	29 (12-55)
VIH 1-2.O CARTE				
Hexagon HIV	62/70	88.6 (79.0-94.1)	6/14	43 (21-67)
MULTISURE HIV Rapid	57/75	76.7 (65.2-84.2)	2/14	14 (4-40)
Test ^a				
MULTISURE HIV Rapid	56/75	74.7 (63.8-83.1)	1/14	7 (1-31)
Test ^b				

Results are expressed as percent (95% CI). Early seroconversion subgroup is defined as the absence of HIV-1 antibodies on the Western blot associated with both viral and p24 antigen positivity.

^a Visual reading.

^b Automatic reading.

Table 3. P values for pairwise Chi-squared tests.

	Genie™ Fast HIV 1/2	HIV 1/2 STAT-PAK® Assay	INSTI™ HIV-1/HIV-2 Antibody Tests	SURE CHECK® HIV 1/2	VIKIA® HIV 1/2	FIRST RESPONSE® Test VIH 1-2.O CARTE	Hexagon HIV	MULTISURE HIV Rapid Test ^a	MULTISURE HIV Rapid Test ^b
Exacto® TEST HIV PRO	0.41	0.0075	0.0075	0.0075	0.12	0.011	0.48	0.0075	0.0044
Genie™ Fast HIV 1/2		0.056	0.056	0.056	0.46	0.078	0.91	0.056	0.036
HIV 1/2 STAT-PAK® Assay			1	1	0.24	0.88	0.049	1	0.85
INSTI™ HIV-1/HIV-2 Antibody Tests				1	0.24	0.88	0.049	1	0.85
SURE CHECK® HIV 1/2					0.24	0.88	0.049	1	0.85
VIKIA® HIV 1/2						0.3	0.41	0.24	0.17
FIRST RESPONSE® Test VIH 1-2.O CARTE							0.068	0.88	0.74
Hexagon HIV								0.049	0.032
MULTISURE HIV Rapid Test ^a									0.85
MULTISURE HIV Rapid Test ^b									

Significant values are in bold.

^a Visual reading.

^b Automatic reading.