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ABSTRACT:

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

Introduction

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

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

Methods

Sample collection

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

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

Sample processing

Samples were prospectively analyzed within the same freezing defrosting cycle with all the nine HIV rapid tests: INSTI™ HIV-1/HIV-2 Antibody Test (INSTI) (Biolytical, Canada), MULTISURE HIV Rapid Test (MULTISURE) (MP Diagnostics Asia Pacific Pte. CE Ltd), SURE CHECK® HIV1/2 (SURE CHECK) (Chembio Diagnostics, Medford, USA), HIV 1/2 STAT-PAK® Assay (STAT-PAK) (Chembio Diagnostics, Medford, USA), Exacto® TEST HIV PRO (Exacto) (Biosynex, Illkirch-Graffenstaden, France), Genie™ Fast HIV 1/2 (Genie) (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) and Hexagon HIV (Hexagon) (Human, Wiesbaden, Germany). For MULTISURE, visual and automation readings were performed. For Hexagon, FIRST RESPONSE and VIKIA, 71, 74 and 74 of the 75 samples were tested, respectively, due to an insufficient sample quantity. Assays are described Table 1. Each assay was performed and interpreted according to the manufacturers' recommendations by two independent operators. Samples with invalid results according to the manufacturers' recommendations were controlled once.

Statistical analysis

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

Ethics

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

Results

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

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

(Table 2), with sensitivities ranging from 7% (1-31%) for MULTISURE (automatic reading), INSTI, STAT-PAK and SURE-CHECK to 57% (33-79%) for Exacto and Genie Fast.

Of note, three samples had a negative HIV-antibody signal (S/CO <1) with Liaison XL. The first, with a 0.515 S/CO signal was non-reactive for all rapid tests, the second, with a 0.661 S/CO signal had a trace for Exacto and Multisure. The last, with a 0.973 S/CO value had a trace for Exacto and Genie. These few results might imply that lack of sensitivity during early seroconversion stage could result directly from a lack of HIV antibody, although much more samples would be needed to address this point. As expected, Liaison XL p24 S/CO signal was highly positive for the three samples.

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

Discussion

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

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

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

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

Conclusions

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

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.

Author contributions

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

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Data Availability Statement

The data that support the findings are available as supplementary table 1 for HIV rapid tests, Liaison XL S/CO values and Western blot results.

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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, WBl / 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, WBl / 80	Professional purpose
HIV 1/2 STAT-PAK® Assay	Chembio (US)	None / Gp41[a] and gp36[a]	Sandwich [d]	IC / 15 min	S, P, WBl / 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, WBl / 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, WBl / 1 drop	Self-testing
VIKIA® HIV 1/2	bioMérieux® (FR)	None / Gp41[b] and gp36[b]	Sandwich [d]	IC / 30 min	S, P, WBl / 75	Professional purpose
FIRST RESPONSE® Test VIH 1-2.O CARTE	Premier Medical (India)	None / Gp41[a], p24[a] and gp36[a]	Sandwich [d]	IC / 15 min	S, P / 10 WBl / 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 WBl / 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 WBl / 20	Professional purpose

[a] Recombinant antigens.

[b] Synthetic peptides.

[c] Not specified

Ag, antigen; Ab, antibody; IC, immunochromatography; IF, immunofiltration; S, serum; P, plasma; WBl, 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® Assay	57/75	76.7 (65.2-84.2)	1/14	7 (1-31)
INSTI™ HIV-1/HIV-2 Antibody Tests	57/75	76.7 (65.2-84.2)	1/14	7 (1-31)
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 Test[a]	57/75	76.7 (65.2-84.2)	2/14	14 (4-40)
MULTISURE HIV Rapid Test[b]	56/75	74.7 (63.8-83.1)	1/14	7 (1-31)

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.