Autotests VIH
Rôle du pharmacien d'officine

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Académie nationale de Pharmacie

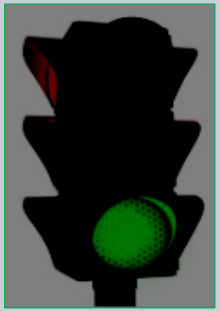
L' auteur déclare n'avoir aucun conflit d'intérêts
en relation avec cette présentation

Les autotests: pertinence médicale

Tests	Groupe 1 Utile	Groupe 2 À valider	Groupe 3 À éviter
Tests sanguins			
Anticorps anti-VIH			
Cholestérol total			
Ferritinémie			
TSH			
PSA			
Anticorps anti-*Helicobacter pylori* (*H. pylori*)			
IgE totales			
Anticorps antitétaniques			
Anticorps anti *Borrelia*			

Les autotests utiles

3



Autotest VIH

Dispositif additionnel de l'offre de dépistage

Mais: information et conseil indispensables

Autotest infection urinaire

Peut permettre une détection plus précoce d'une infection urinaire → antibiothérapie

Autotest tétanos

En cas d'absence d'anticorps protecteurs → vaccination

Autotest VIH

De loin le plus demandé

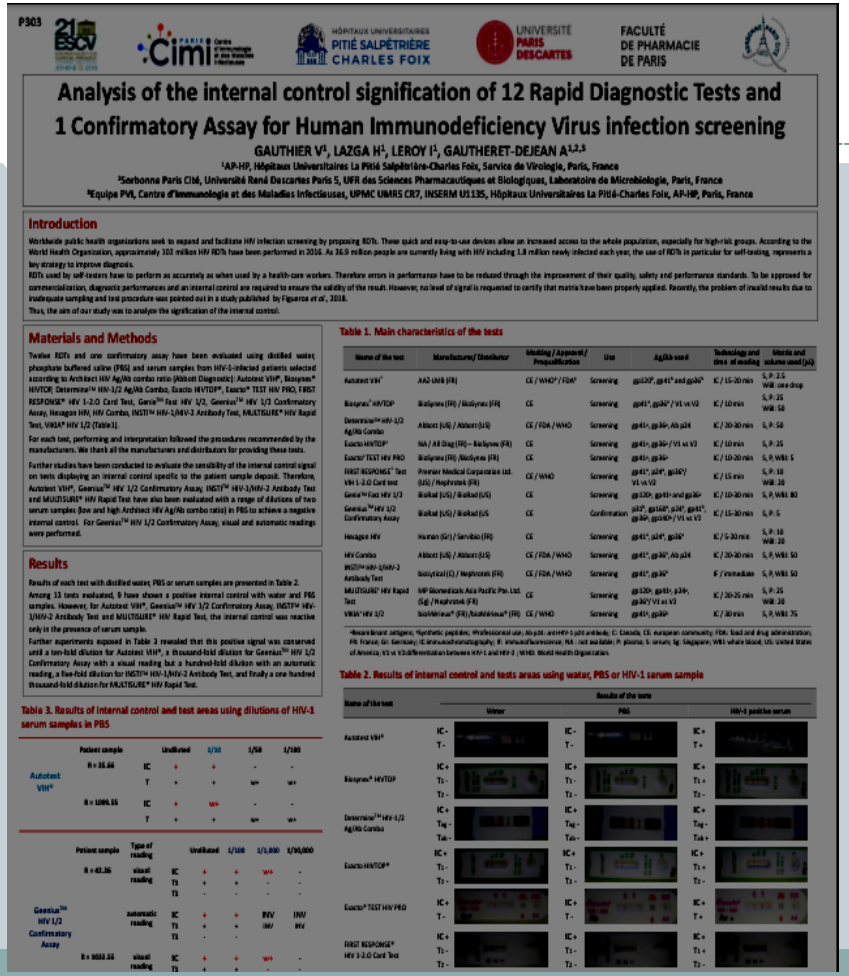
Nécessite : - la formation du dispensateur

- l'information du patient

- une procédure à l'officine

Tests disponibles :

. Recommandations :



P303

Analysis of the internal control signification of 12 Rapid Diagnostic Tests and 1 Confirmatory Assay for Human Immunodeficiency Virus infection screening

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Introduction

Worldwide public health organizations seek to expand and facilitate HIV infection screening by proposing RDTs. These quick and easy-to-use devices allow an increased access to the whole population, especially for high-risk groups. According to the World Health Organization, approximately 103 million HIV RDTs have been performed in 2016. As 36.9 million people are currently living with HIV including 1.8 million newly infected each year, the use of RDTs in particular for self-testing, represents a key strategy to improve diagnosis.

RDTs used by self-testers have to perform as accurately as when used by a health-care workers. Therefore errors in performance have to be reduced through the improvement of their quality, safety and performance standards. To be approved for commercialization, diagnostic performances and an internal control are required to ensure the validity of the result. However, no level of signal is requested to certify that matrix have been properly applied. Recently, the problem of invalid results due to inadequate sampling and test procedure was pointed out in a study published by Figueroa et al., 2018.

Thus, the aim of our study was to analyze the signification of the internal control.

Materials and Methods

Twelve RDTs and one confirmatory assay have been evaluated using distilled water, phosphate buffered saline (PBS) and serum samples from HIV-1-infected patients selected according to Architect HIV Ag/Ab combo ratio (Abbott Diagnostic): Autotest VIH®, Biosynex® HIVTOP, Determine™ HIV-1/2 Ag/Ab Combo, Exacto HIVTOP®, Exacto® TEST HIV PRO, FIRST RESPONSE® HIV 1-2.0 Card Test, Genie™ Fast HIV 1/2, Geenius™ HIV 1/2 Confirmatory Assay, Hexagon HIV, HIV Combo, INSTI™ HIV-1/HIV-2 Antibody Test, MULTISURE® HIV Rapid Test, VIKIA® HIV 1/2 (Table1).

For each test, performing and interpretation followed the procedures recommended by the manufacturers. We thank all the manufacturers and distributors for providing these tests.

Further studies have been conducted to evaluate the sensibility of the internal control signal on tests displaying an internal control specific to the patient sample deposit. Therefore, Autotest VIH®, Geenius™ HIV 1/2 Confirmatory Assay, INSTI™ HIV-1/HIV-2 Antibody Test and MULTISURE® HIV Rapid Test have also been evaluated with a range of dilutions of two serum samples (low and high Architect HIV Ag/Ab combo ratio) in PBS to achieve a negative internal control. For Geenius™ HIV 1/2 Confirmatory Assay, visual and automatic readings were performed.

Results

Results of each test with distilled water, PBS or serum samples are presented in Table 2.

Among 13 tests evaluated, 9 have shown a positive internal control with water and PBS samples. However, for Autotest VIH®, Geenius™ HIV 1/2 Confirmatory Assay, INSTI™ HIV-1/HIV-2 Antibody Test and MULTISURE® HIV Rapid Test, the internal control was reactive only in the presence of serum sample.

Further experiments exposed in Table 3 revealed that this positive signal was conserved until a ten-fold dilution for Autotest VIH®, a thousand-fold dilution for Geenius™ HIV 1/2 Confirmatory Assay with a visual reading but a hundred-fold dilution with an automatic reading, a five-fold dilution for INSTI™ HIV-1/HIV-2 Antibody Test, and finally a one hundred thousand-fold dilution for MULTISURE® HIV Rapid Test.

Table 1. Main characteristics of the tests

Name of the test	Manufacturer/ Distributor	Marking / Approval / Prequalification	Use	Ag/Ab used	Technology and time of reading	Matrix and volume used (µL)
Autotest VIH®	AAZ-LMB (FR)	CE / WHO* / FDA*	Screening	gp120*, gp41* and gp36*	IC / 15-20 min	S, P: 15 Wll: one drop
Biosynex® HIVTOP	BioSynex (FR) / BioSynex (FR)	CE	Screening	gp41*, gp36* / V1 vs V2	IC / 10 min	S, P: 25 Wll: 50
Determine™ HIV-1/2 Ag/Ab Combo	Abbott (US) / Abbott (US)	CE / FDA / WHO	Screening	gp41*, gp36*, Ab p24	IC / 20-30 min	S, P: 50
Exacto HIVTOP®	NA / All Diag (FR) – BioSynex (FR)	CE	Screening	gp41*, gp36* / V1 vs V2	IC / 10 min	S, P: 25
Exacto® TEST HIV PRO	BioSynex (FR) /BioSynex (FR)	CE	Screening	gp41*, gp36*	IC / 10-20 min	S, P, Wll: 5
FIRST RESPONSE® Test VIH 1-2.0 Card test	Premier Medical Corporation Ltd. (US) / Nephrotek (FR)	CE / WHO	Screening	gp41*, p24*, gp36*/ V1 vs V2	IC / 15 min	S, P: 10 Wll: 20
Genie™ Fast HIV 1/2	Bioklal (US) / Bioklal (US)	CE	Screening	gp120*, gp41* and gp36*	IC / 10-30 min	S, P, Wll: 80
Geenius™ HIV 1/2 Confirmatory Assay	Bioklal (US) / Bioklal (US	CE	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*, p24*, gp36*	IC / 5-30 min	S, P: 10 Wll: 20
HIV Combo	Abbott (US) / Abbott (US)	CE / FDA / WHO	Screening	gp41*, gp36*, Ab p24	IC / 20-30 min	S, P, Wll: 50
INSTI™ HIV-1/HIV-2 Antibody Test	bioLytical (C) / Nephrotek (FR)	CE / FDA / WHO	Screening	gp41*, gp36*	IC / immediate	S, P, Wll: 50
MULTISURE® HIV Rapid Test	MP Biomedicals Asia Pacific Pte. Ltd. (Sg) / Nephrotek (FR)	CE	Screening	gp120, gp41, p24, gp36*/ V1 vs V2	IC / 20-25 min	S, P: 25 Wll: 20
VIKIA® HIV 1/2	BioMérieux® (FR) /BioMérieux® (FR)	CE / WHO	Screening	gp41*, gp36*	IC / 30 min	S, P, Wll: 75

*Recombinant antigens; *Synthetic peptides; *Professional use; Ab p24: anti-HIV-1 p24 antibody; C: Canada; CE: european community; FDA: food and drug administration; FR: France; Gr: Germany; IC: immunochromatography; M: immunofluorescence; NA : not available; P: plasma; S: serum; Sg: Singapore; WHO: whole blood; US: United States of America; V1 vs V2: differentiation between HIV-1 and HIV-2 ; WHO: World Health Organization.

Table 2. Results of internal control and tests areas using water, PBS or HIV-1 serum sample

Name of the test	Results of the tests: 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-1/2 Ag/Ab Combo	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 1-2.0 Card Test	IC + T1 - T2 -	IC + T1 - T2 -	IC + T1 + T2 -

Table 3. Results of internal control and test areas using dilutions of HIV-1 serum samples in PBS

	Patient sample		Undiluted	1/10	1/50	1/100
Autotest VIH®	R = 36.66	IC	+	+	-	-
		T	+	+	w+	w+
	R = 1099.55	IC	+	w+	-	-
		T	+	+	w+	w+

	Patient sample	Type of reading		Undiluted	1/100	1/1,000	1/10,000
Geenius™ HIV 1/2 Confirmatory Assay	R = 42.26	visual reading	IC	+	+	w+	-
			T1	+	+	-	-
			T2	-	-	-	-
		automatic reading	IC	+	+	INV	INV
			T1	+	+	INV	INV
			T2	-	-		
	R = 3033.55	visual reading	IC	+	+	w+	-
			T1	+	+	-	-

Le principal challenge : faire évoluer les pratiques des pharmaciens

Enquête transversale observationnelle... dans les pharmacies de Caen
sans modification de pratiques.

En résumé :

. Moins de la moitié des pharmacies avaient l'autotest disponible

. Moins d'un tiers réorientaient le patient vers un autre mode de dépistage

. Moins de 20% ont évalué la possibilité d'une situation d'urgence

. Moins de 5% ont proposé l'espace de confidentialité

. Sujet des autres infections sexuellement transmissibles, fourniture d'une liste de ressources locales disponibles : Nul...

Une nouvelle façon d'exercer !

- Les pharmaciens doivent changer leurs pratiques...

Vite !

TROD et Autotests : des outils intégrés dans un plan plus vaste.

« La prévention doit devenir centrale dans toutes les actions qui visent à améliorer la santé de nos concitoyens »

Formation du pharmacien d'officine

Informer

Conseiller

Formation initiale

Formation continue

Conclusion

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Rapport

de l'Académie nationale de Pharmacie

Autotests-TROD

Rôle du pharmacien d'officine

Décembre 2017

Rapport adopté par le Conseil de l'Académie nationale de Pharmacie le 13 décembre 2017
Les auteurs déclarent ne pas avoir de conflits d'intérêts en relation avec ce rapport

http://www.acadpharm