Rev. Fac. Med. Hum. July 2021;21(2):677-679.
DOI 10.25176/RFMH.v21i3.3941
LETTERS TO THE EDITOR
ISSN Versión Online: 2308-0531
Facultad de Medicina Humana URP

EVALUATION OF THREE BRANDS OF RAPID TESTS AGAINST BLOOD SAMPLES FOR THE DETECTION OF ANTIBODIES AGAINST HIV

EVALUACIÓN DE TRES MARCAS DE PRUEBAS RÁPIDAS FRENTE A MUESTRAS DE SANGRE PARA LA DETECCIÓN DE ANTICUERPOS CONTRA VIH

Ronal Briceño-Espinoza[1,a], Eduardo Miranda-Ulloa[1,b],Soledad Romero-Ruiz[1,c], Fany Cárdenas-Bustamante[1,c]

LETTERS TO THE EDITOR

Mr. Editor

One of the important factors to reduce the spread of the human immunodeficiency virus (HIV) in Peru is the accessibility of diagnosis through rapid tests (RP), which are applied even in the most remote communities. However, during the five years 2011 - 2015, health establishments acquired and used more than 10 different brands, generating confusion in applying the methodology described in the inserts and consequently erroneous results (false positives and false negatives)[1].

To standardize the use of RP of a certain brand in health establishments nationwide, in the last five years, the Ministry of Health commissioned the National Center for Supply of Strategic Health Resources (CENARES) to purchase it for national distribution. The RPs that CENARES acquires previously undergo a reactivity evaluation to observe if they comply with their diagnostic performance as reported in their inserts[1].

The problem is that the different brands of reagents purchased by CENARES are subjected to a reactivity evaluation only against panels of serum or plasma samples and are not evaluated against whole blood or capillary blood; this due to the complexity of the access to reference panels. However, during the national surveillance of HIV, RP application is mainly carried out in capillary blood, so much so that even though in serum or plasma they report sensitivity and specificity at 100.0%, false positives and negatives continue to be given. This leads us to deduce that it is probably because the tests carried out in the field are carried out on blood.

Within the framework of the National HIV Surveillance, we are responsible for technically assisting the Laboratory Network on activities related to diagnosis[1], for these reasons, it was proposed as an objective. The grounds were to evaluate the reactivity of three different commercial brands of RP acquired by CENARES against whole blood samples to detect antibodies against HIV.

A prospective observational study of diagnostic test evaluation was conducted during January 2020; the approval of an ethics committee was not obtained since it was necessary to provide this technical orientation due to the problems already mentioned.

The estimation of the sample size was designated for convenience, using a non-probabilistic sampling, corresponding to 100 reference samples of whole blood anonymized and decoded from the Hemoteca of the National Reference Laboratory of Sexually Transmitted Viruses HIV / AIDS of the National Institute of Health from Peru, of which 50 were HIV positive and 50 HIV negative, with Immunoblot being the reference test (sensitivity: 100.0%, specificity: 96.7%)[2]. The three brands processed all samples: Core test HIV 1/2

[1] Laboratorio de Referencia Nacional Virus de Transmisión Sexual VIH/SIDA, Centro Nacional de Salud Pública, Instituto Nacional de Salud (INS). Lima, Perú.
[a] Medical Technologist, [b] Biologist, Master in Microbiology, [c] Biologist.

Cite as: Ronal Briceño-Espinoza, Eduardo Miranda-Ulloa, Soledad Romero-Ruiz, Fany Cárdenas-Bustamante. Evaluation of three brands of rapid tests against blood samples for the detection of antibodies against HIV. Rev. Fac. Med. Hum. Julio 2021; 21(3):677-679.
DOI 10.25176/RFMH.v21i3.3941

Journal home page: http://revistas.urp.edu.pe/index.php/RFMH

Antibody Test Kit[3], Standard Diagnostics SD Bioline HIV-1/2 3.0[4], and CTK Biotech OnSite HIV combo rapid test[5], being the immunochromatographic tests carried out according to the manufacturer's instructions (insert). Finally, the diagnostic precision parameters were estimated using the Epidat v3.1 program and Excel.

Among the findings, we show that the three brands evaluated had concordant specificity results (100.0%); Likewise, we highlight that the sensitivity of OnSite (100.0%) was superior to Core test and SD Bioline (98.0% 95% CI 93.1-100.0). It was also found that the Youden index obtained for the three brands was higher than 0.97, which confirms the fact that the possibility of having false positives or negatives is low (Table 1).

EAmong other findings, it was found that OnSite did not obtain false negatives or positives, while Core test and SD Bioline did present a false negative. Since RPs is a screening test, the ideal would be for them to have the maximum sensitivity (100.0%) to avoid false negatives and thus avoid infected subjects transmitting HIV[1].

Our sensitivity results for OnSite (100.0%) agree with Miranda et al.[6]. However, they differ for SD Bioline (98.0% versus 100.0%)[6]. Likewise, when comparing with those reported in their inserts[3-5], we can refer that the sensitivity of OnSite was concordant (100.0%); however, SD Bioline and Core test showed some difference (98.0% versus 100.0% for both brands).

The difference shown could be because we evaluated the RP against whole blood, while the inserts and those of Miranda et al. were against serum and plasma[3-6]. It should be said that in general, the results of the parameters of reactivity differ according to the type of biological sample; Another difference could also be because the OnSite brand strip contains the following recombinant antigens: HIV-1 p24, gp41, HIV-1 gp120, and HIV-2 gp36, while the SD Bioline and Core test contain the same antigens, but not includes gp120[3-5].

The sensitivity and specificity results obtained in the present study represent more of our reality since we use whole blood to evaluate simultaneously that health facilities use mostly capillary blood. A limitation of the study was the non-inclusion of interfering samples due to their unavailability.

The three brands evaluated obtained a validity index greater than or equal to 99.0% (Table 1), which qualifies them as tests of good diagnostic performance; Likewise, knowing that the World Health Organization considers a sensitivity and specificity greater than or equal to 99.0%[1], we conclude that In this study, the CTK Biotech OnSite HIV ½ rapid test was the kit that demonstrated the best diagnostic performance, complying with the ideal characteristic of a screening test.

Table 1. Reactivity results of the three rapid test brands evaluated against whole blood samples to detect antibodies against HIV.

	Core test HIV 1/2		SD Bioline HIV 1-2 3.0		OnSite Hiv 1/2	
Parameter	Value	(IC 95%)	Value	(IC 95%)	Value	(IC 95%)
Sensitivity (%)	98.0	(93.1-100.0)	98.0	(93.1-100.0)	100.0	(99.0-100.0)
Specificity (%)	100.0	(99.0-100.0)	100.0	(99.0-100.0)	100.0	(99.0-100.0)
Validity index (%)	99.0	(96.6-100.0)	99.0	(96.6-100.0)	100.0	(99.5-100.0)
Positive predictive value (%)	100.0	(99.0-100.0)	100.0	(99.0-100.0)	100.0	(99.0-100.0)
Negative predictive value (%)	98.0	(93.3-100.0)	98.0	(93.3-100.0)	100.0	(99.0-100.0)
Youden index	0.98	(0.94-1.00)	0.98	(0.94-1.00)	1.00	1.00-1.00)

CI: Confidence interval 95%

Authorship contributions: The authors participated in the conception and design of the study; collection, analysis and interpretation of the results; writing, critical review and approval of the final version of the letter.

Financing: The study was carried out within the framework of the regular activities of the National Institute of Health (national surveillance of HIV). The diagnostic kits for the three rapid test brands were provided by CENARES / MINSA.

Interest conflict: The authors declare that they have no conflict of interest.

Received: May 31, 2021

Approved: June 14, 2021

Correspondence: *Eduardo Miranda Ulloa.*
Address: *Defensores del Morro 2268, Chorrillos, Perú.*
Telephone: *(+51) 977783088*
Email: *fernandoul@hotmail.com*

BIBLIOGRAPHIC REFERENCES

1. Norma técnica de salud de atención integral del adulto con infección por el Virus de la Inmunodeficiencia Humana (VIH). NTS N° 169- MINSA/2020/DGIESP (Resolución Ministerial N°:1024-2020/MINSA) Ministerio de Salud, Perú, 2020. [Citado el 30 de mayo de 2021]. Disponible en: https://cdn.www.gob.pe/uploads/document/file/1482085/Resoluci%C3%B3n%20Ministerial%20N%C2%B01024-2020-MINSA.PDF
2. Fujirebio. INNO-LIA™* HIV I/II Score [Internet]. Fujirebio: Bélgica; 2017 [Citado el 30 de mayo de 2021]. Disponible en: http://www.peramed.com/peramed/docs/80540_EN.pdf
3. Core test HIV 1/2 Antibody Test Kit. [Internet]. Core Tecnology: China [Citado el 30 de mayo de 2021]. Disponible en: https://www.alibaba.com/product-detail/Blood-Analysis-System-One-Step-Rapid_62282551202.html
4. Standar Diagnostics SD HIV-1/2 3.0. [Internet]. República de Korea: Abbott; 2018 [Citado el 30 de mayo de 2021]. Disponible en: https://www.alere.com/en/home/product-details/sd-bioline-hiv-1-2-3-0.html
5. CTK Biotech OnSite HIV Ab/Ag 4TH combo rapid test. [Internet]. San Diego, USA: CTK Biotech; 2017 [Citado el 30 de mayo de 2021]. Disponible en: https://ctkbiotech.com/product/hiv-1-2-ab-plus-combo-rapid-test/#demoTab2
6. Miranda-Ulloa E, Romero-Ruiz S, Briceño-Espinoza R, Santos-Anaya D. Evaluación de tres marcas comerciales de pruebas rápidas para la detección de VIH. Rev. Perú. med. exp. salud pública [Internet]. 2015 Abr [Citado el 30 de mayo de 2021]; 32(2): 404-405. Disponible en: http://www.scielo.org.pe/scielo.php?script=sci_arttext&pid=S1726-46342015000200036