



## Review

## HIV Self-Testing In Central Africa: Stakes And Challenges

### *Autotest VIH en Afrique Centrale: enjeux et défis*

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#### RÉSUMÉ

Le dépistage de 90% de toutes les personnes vivant avec le VIH d'ici 2020 est le premier objectif de l'initiative « 90-90-90 » déclinée par l'ONUSIDA. L'autotest VIH constitue une stratégie complémentaire nouvelle pour le dépistage du VIH au sein de la population générale et des groupes à risque [professionnel(les) du sexe et leurs clients, hommes ayant des rapports sexuels avec des hommes, jeunes adolescents]. En Afrique, les premières études pilotes, principalement menées dans plusieurs pays anglophones, démontrent de bonnes acceptabilité, praticabilité et d'excellentes performances cliniques de l'autotest VIH. Des stratégies novatrices comme la traduction des notices d'utilisation de l'autotest VIH en langues vernaculaires associée à des pictogrammes pédagogiques devront être mises en œuvre et évaluées en Afrique subsaharienne pour le développement de l'autotest VIH.

**Mots-clés :** Autotest ; VIH ; Praticabilité ; Recommandations OMS ; Afrique

#### ABSTRACT

HIV self-testing constitutes a new complementary strategy for HIV testing for general populations as well as "key" populations such as sex workers and their clients, men who have sex with men, and young people, which may be used to reach the 90-90-90 UNAIDS objectives by 2020. In Africa, many pilot studies have been conducted mainly in English-speaking countries demonstrating high acceptability, practicability and clinical performance of HIV self-testing. Innovative strategies including the translation of HIV self-test notice in vernacular languages in association with educational pictograms should be developed and evaluated in sub-Saharan Africa to implement HIV self-testing.

**Key-words:** Self-test; HIV; Practicability; WHO recommendations; Africa

#### INTRODUCTION

Infection by HIV continues to be a major global public health issue. The vast majority of people living with HIV are located in low- and middle- income countries, with an estimated 26 million living in sub-Saharan Africa and 70 percent of all AIDS deaths. Although the incidence of new infections has declined, the HIV prevalence remains particularly high in sub-Saharan Africa ranging from 0.8 to 27.7 percent, with disparities across countries [1]. In addition, despite the high burden of this viral infection, about 44% of people infected with HIV in sub-Saharan Africa remain unaware of their infectious status (Figure 1) [2]. The main reasons for this low coverage of testing are the limited access to facilities or services for HIV testing and care, stigma, discrimination, lack of confidentiality and the long delays in communicating test results [3-6]. New HIV testing strategies are crucial for reaching undiagnosed people and improve the access to antiretroviral therapy [7].

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## HIV SELF-TEST DEFINITION

According to the World Health Organization (WHO), HIV self-test is a rapid diagnostic test (RDT) designed for personal use and allowing detecting HIV infection in less than 20 minutes. The individual who desire to know his/her HIV-status can perform HIV self-test himself, taking his/her own biological sample (gingival fluid or finger-stick capillary whole blood) and also interpreting the result himself, usually in a private or with another trusted person [8,9]. In addition, HIV-self-test does not required specific instrumentation other than constituents provided in the package with the test device [5]. The result of HIV self-testing should always be confirmed according to national algorithms of HIV testing [10]. Each step of use, since the sample collection to the final interpretation of the result, is essential in order to obtain a valid result [5]. HIV self-testing is a novel and complementary HIV testing strategy, potentially interesting for general population and high-risk "key" populations, such as sex workers and their clients, men who have sex with men and young people [9].

## HISTORY OF HIV SELF-TESTING

HIV self-testing has been the subject of several scientific publications over the past five years [11]. However, the HIV self-testing concept appears in 1996 in the United States (USA), when the Food and Drug Administration (FDA) had authorized the sale of previously unauthorized HIV self-sampling kits called "home-test". This early strategy allows the user to collect himself at home, finger blood with a puncture device and then sending it to an approved laboratory to obtain the test result as early as the next working day [12]. In 2000, for the first time, UNAIDS mentioned HIV self-testing, emphasizing the need to strengthen quality controls and the need to beware of the potential abuse before marketing home-testing kits [13]. From 2003 to 2013, several HIV self-tests were already available for illegal sale online in Nigeria, Namibia, South Africa and Tanzania (Figure 2) [1, 5]. Since 2017, formal HIV self-testing regulations exist in many African countries, while in other countries this regulations still under development or even informal HIV self-testing policies are tolerated (Figure 2) [14, 15].

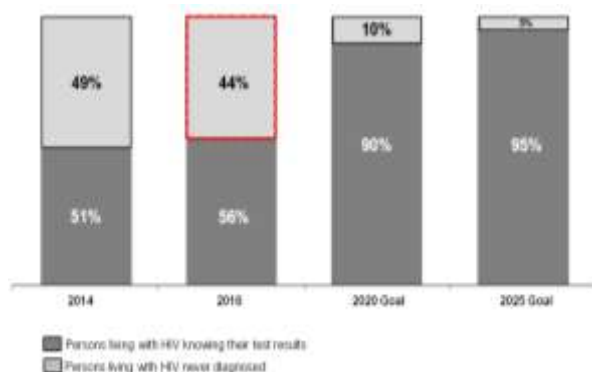


Figure 1. HIV testing in Africa since the UNAIDS 90-90-90 initiative [6,7].

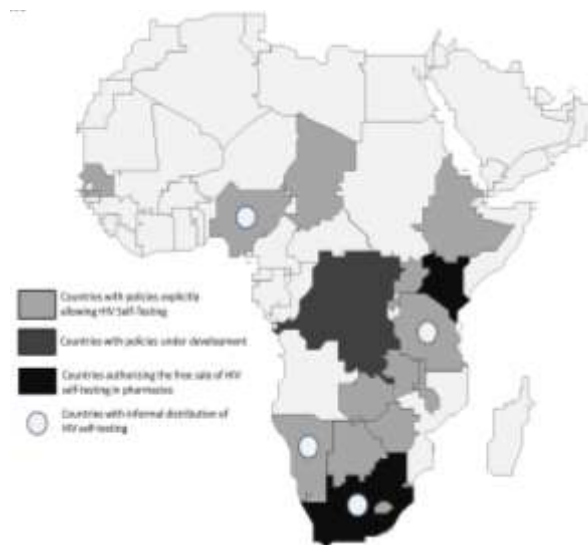


Figure 2. Monitoring of HIV self-testing policies in Africa by country [14].

Since December 2016, WHO has now recommended HIV self-testing as a complementary tool to HIV testing services [8]. People who have a positive HIV test result should contact national HIV testing services for the confirmation of the result and receive the appropriate care [6]. For people whose self-test result is negative, the HIV self-test is considered as part of the prevention "package" and thus participates in the interventions strategy [6].

## ECONOMICAL FINDINGS

The market of RDT for HIV detection is particularly complex and opaque. RDTs for HIV detection for "professional" use only (performed by health workers such as pre-trained physicians, nurses, and lab technicians) are fully part of testing strategies to reach the first "90" of the UNAIDS 90-90-90 initiative, which consist in diagnosing 90% of all people living with HIV by 2020 [5]. Several manufacturers are seeking to adapt and repackage their conventional RDTs for use as HIV self-testing [17, 18].

Currently HIV self-tests are manufactured by "Original Equipment Manufacturers" (or "OEM") and then developed by "Own Brand Labellers" (or "OBL") located mainly in developed countries such as the USA, Canada or European countries, thereby increasing the cost of HIV self-testing and significantly impeding the dissemination of these tests in resource-limited countries [19]. Indeed, the manufacturing cost of HIV-RDTs by the OEM is ranging from 0.5 to 1 €, while the sales price under the mark of the OBL increase considerably for reaching 15 to 30 €. The widespread use of the HIV self-testing in Africa will thus require a considerable reduction of its cost, which is possible because the cost of manufacturing a HIV-RDT is low. Thus, currently, manufacturers of HIV self-tests try to offer tests at 0.5-3 € per unit for developing countries. In addition,

international grants that often include operational research focused on pilot projects (proposed in several African countries by UNITAID or the Global Fund to Fight AIDS, Tuberculosis and Malaria), also allow free distribution or the sale at very low price of HIV self-tests to vulnerable and key populations in developing countries [17, 20]. For example, the unit sales prices of the HIV self-test in the private sector are currently ranging from US \$ 2 to US \$ 4 in South Africa and to US \$ 3 in Kenya [17]. The Bill & Melinda Gates Foundation is participating in an extensive program to accelerate the delivery of the OraQuick In-Home HIV Test (Orasure Technologies LLC, Bethlehem, PA, USA) to US \$ 2.0 in over 50 countries, mainly located in sub-Saharan Africa. The potential self-test market is currently being evaluated in nine African countries (South Africa, Kenya, Malawi, Mozambique, Nigeria, Uganda, Tanzania, Zambia and Zimbabwe) under the Self-Testing African Project (STAR) pilot program financed by UNITAID [21].

### RECOMMENDATIONS FOR EVALUATION OF HIV SELF-TEST

Before commercialization, HIV self-test should be virologically and clinically evaluated. In the United States, the clinical validation of the HIV self-test schematically included four phases according to the FDA [22]: (i) evaluation by trained users in a controlled environment; (ii) evaluation based on observing untrained users interpreting a panel of simulated test results in a controlled environment; (iii) evaluation based on observation of untrained users with high-risk of HIV, performing the test and interpreting the results in a controlled environment; and finally (iv) assessment of self-test performance by untrained users under uncontrolled real-life conditions.

In Europe, the feasibility of the self-test for the general public as part of the IVD CE marking application required the completion of two of the FDA recommended evaluations [5], to demonstrate that the (lay) participants were in first able to correctly interpret the results of the HIV self-test and secondly to handle correctly the self-test to obtain a reliable result [23].

According to the 2015 WHO recommendations, consolidated in September 2016, virological validation of HIV self-testing should be carried out in at least two different geographical regions taking into account the genetic diversity of HIV, in order to determine the susceptibility and the specificity of the self-test [24, 25]. In addition, the feasibility assessment of the HIV self-test must now go through three stages: (i) assessment of the understanding of the test instructions; (ii) evaluation of the interpretation of simulated test results in a controlled environment; (iii) evaluation of self-testing by supervised lay individuals in a controlled environment [24, 25]. In April 2017, the OraQuick In-Home HIV Test was the first WHO pre-qualified HIV test [20].

### PRACTICALITY OF HIV SELF-TESTING IN SUB-SAHARAN AFRICA.

In Africa, several pilot or observational studies, mainly conducted in English-speaking countries, have demonstrated high levels of acceptability and feasibility of HIV self-testing, particularly among key populations [14]. More recently, excellent feasibility of HIV self-testing has been reported in the cultural context of Francophone Central Africa, in Bunia and Kisangani, in the Democratic Republic of Congo [26], and in Bangui, Central African Republic [27]. The use of African vernacular languages (Swahili, Lingala, Sango), often used as first language by poorly educated populations [28], and the adaptation of the instructions for use of the HIV self-test with educational pictograms have been found to be essential to make the self-test accessible to the general population.

### SUPERVISED OR UNSUPERVISED (FREE) HIV SELF-TESTING.

To implement HIV self-testing in Africa, two approaches, probably complementary, have been proposed by WHO in 2013 (Figure 3) [10, 29].

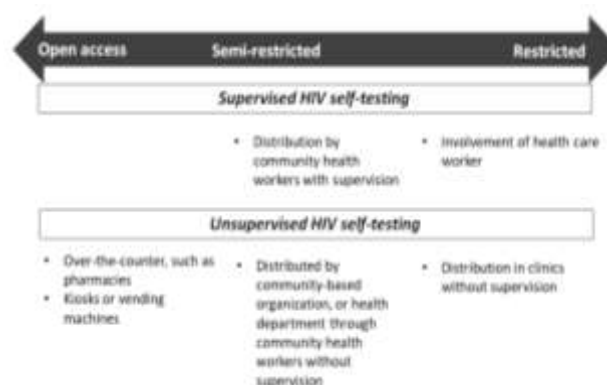


Figure 3 **Figure 3.** Possible models for access to HIV self-test [10].

In the so-called "*supervised*" approach, a health worker in the community or health center takes part at different levels in the dispensation, performing, and interpretation of the HIV self-test; while in the "*unsupervised*" approach, self-test is distributed by a health worker at the community or health center without supervision [10]. The educational level of people performing HIV self-testing would be one of the main selecting factors between unsupervised and supervised self-testing [26, 27]. Thus, among lay individuals with a high educational level, the difficulties and risks of errors in performing the self-test and in interpreting the results are low [26, 27]. In contrast, supervised HIV self-testing is the recommended strategy to limit the risk of errors in poorly educated or illiterate individuals [26, 27, 29]. Assessments of the choice between finger-stick whole-blood self-testing or salivary self-testing and the choice between HIV self-testing or the traditional method of voluntary counseling and testing center showed that salivary self-testing was generally preferred in the African context because it is non-invasive and very easy

to use [29]. However, in areas of low prevalence of HIV infection, finger-stick whole-blood self-testing may be preferable because of its higher sensitivity [18, 30-32]. The difficulty of using the lancet could be an obstacle to use finger-stick whole-blood self-testing, but this difficulty could easily be controlled in a supervised approach.

Counseling has always been considered essential in the psychological support of people wishing to be screened [9]. The modalities of counseling vary depending on the approaches to self-screening (supervised or unsupervised), or the educational level and the socio-economic context. In Malawi, participants indicated that counseling after self-screening was essential [33], with face-to-face counseling being preferred over telephone or internet strategies [33]. Demonstration that HIV self-testing promotes access to care facilities for HIV-infected patients is not unambiguous in sub-Saharan Africa [34], although nearly 90% of those reporting positive HIV self-testing in Zambia were able to demonstrate their willingness to be promptly treated for antiretroviral therapy [35]. All these observations support the strategy of HIV self-testing in resource-limited settings, even though the risks of stigma and discrimination could represent a barrier limiting the access of key populations to HIV self-testing, creating a real vicious circle [29]. In Kenya, participants fearing to be monitored during the manipulation of HIV self-testing in a supervised approach, finally preferred unsupervised self-screening [16].

### THE CASE FOR HIV SELF-TESTING EXPERIENCE IN THE CENTRAL AFRICAN REPUBLIC

#### A. HIV ST acceptability in general population.

A preliminary survey was on the problematic of HIV testing mainly focused on HIVST was conducted using a self-administered questionnaire by the Ministry of Health and Population, Central African Republic, in students (>18 years) living in Bangui, including college or

university students (n=1,782; 837 males, 945 females; mean age, 21 years; age range, 18-31), and the key group of men who have sex with men (MSM) (n=396; mean age, 23 years; age range, 18-39) and female sex workers (n=1,306; mean age, 23 years; age range, 18-47 years). The college or university students from recruited from 13 secondary schools and university places in Bangui, after permission. Only major students were subjected to anonymously answer to the questionnaire. The MSM attended the *Centre National de Référence des Infections Sexuellement Transmissibles et de la Thérapie Antirétrovirale* for care, counselling and adapted intervention and treatment of sexually transmitted infections and possibly HIV infection, as described previously [30]. FSW were included in a descriptive, quantitative, population-based cross-sectional survey to assess the typology of female commercial sex work in Bangui, as described previously [31]. The population of FSW in Bangui is remarkably heterogeneous [31]. Thus, "official" or "professional" FSW (33%) who report themselves to have their main resources from paid sexual transactions are divided in two categories: the so-called "pupulenge" (14%), i.e. dragonflies consisting of roamers, who travel around the city to hotels and nightclubs seeking wealthy clients, and the category of kata (19%), i.e. whores working in poor neighbourhoods. In addition, the "clandestine" or "nonprofessional" FSW (67%) constitutes women who did not identify themselves as sex workers, reporting another activity as their main source of income or were still secondary or university students, but who nevertheless had sexual transactions during the prior three months and reported having at least two sexual partners outside their regular partner in this period.

A total of 3,484 adult volunteers were then subjected to a simple questionnaire on HIV testing and HIVST based on 6 principal questions depicted in the Table 1.

**Table 1. Acceptability of HIV self-test in college and university students population and key populations including men who have sex with men and professional and clandestine female sex workers living in Bangui (n = 3,484). The results are shown as number and percentage in brackets.**

	Adult student population <sup>II</sup> (n = 1,782)			MSM (n = 396)	Female sex workers <sup>IIIII</sup> (n = 1,306)				
	Female (n=945)	Male (n=837)	P <sup>£</sup> female vs male		Official (n = 881)	Pupulenge (n = 487)	Kata (n=394)	Clandestine (n = 425)	P <sup>£</sup> official vs clandestine
Ever tested for HIV in VCT	236 (25) <sup>§</sup>	150 (18)	0.001	36 (9)	205 (42)	59 (15)	< 0.001	102 (24)	NS
Ever heard of HIVST before	926 (98)	728 (87)	< 0.001	305 (77)	414 (85)	394 (100)	< 0.001	378 (89)	NS
Willing to use HIVST if it was available	652 (69)	652 (78)	0.001	384 (97)	463 (95)	335 (85)	< 0.001	315 (74)	< 0.001



<b>Pre-test counselling is necessary to HIVST</b>	510 (54)	226 (27)	< 0.001	59 (15)	122 (25)	91 (23)	NS	208 (49)	< 0.001
<b>Post-test counselling is necessary to HIVST</b>	699 (74)	795 (95)	< 0.001	348 (88)	472 (97)	292 (74)	< 0.001	378 (89)	NS
<b>Willing to buy HIVST</b>	302 (32)	644 (77)	< 0.001	364 (92)	458 (94)	83 (21)	< 0.001	208 (49)	< 0.001
<b>Willing to test partner using HIVST kits</b>	491 (52)	652 (78)	< 0.001	384 (97)	477 (98)	256 (65)	< 0.001	230 (54)	< 0.001

<sup>s</sup>Number (%); <sup>‡</sup> Statistical analysis were carried out using Pearson's  $\chi^2$  test;

<sup>¶</sup>The students were recruited from recruited from 13 secondary schools and university places in Bangui;

<sup>¶¶</sup>MSM were included at the *Centre National de Référence des Infections Sexuellement Transmissibles et de la Thérapie Antirétrovirale* for care, counselling and adapted intervention and treatment of sexually transmitted infections and possibly HIV infection, as described previously [36];

<sup>¶¶¶</sup>FSW were included in a descriptive, quantitative, population-based cross-sectional survey to assess the typology of female commercial sex work in Bangui, as described previously [37,38].

Female sex worker: FSW; HIVST: HIV self-testing; MSM: Men who have sex with men; NS: Not significant. VCT: conventional centres for HIV counselling and testing)

The results of the answers to the questionnaire on HIV testing and HIVST in various populations of adults living in Bangui are depicted in the Table 1. Interestingly, previous HIV testing in conventional centres for HIV counselling and testing was relatively infrequent, especially in male students (18%), kata FSW (15%) as well as MSM population (9%). The majority of individuals involved in the survey had ever heard of HIVST (77-98%), were willing to use HIVST if it was available (69-97%), though that post-testing counselling is necessary to HIVST (74-95%) and were willing to test their partner using HIVST kits (52-98%). Pre-test counselling before HIVST was generally considered as unnecessary. Finally, some groups were willing to buy HIVST, if available, mainly male students (77%), MSM (92%) and pupulengue FSW (94%), whereas others groups, including female students (32%) and kata FSW (21%), did not. Finally, the acceptability of HIVST may be globally estimated as elevated, although high heterogeneity of answers could be observed between groups.

### B. Usability evaluation of HIV self-test prototype.

The usability evaluation of the Exacto<sup>®</sup> Test HIV (Biosynex) is a multicenter cross-sectional study performed between June and July 2016 in Bangui, Central African Republic, consisting in face-to-face and self-administered questionnaires, according to the WHO recommendations [25]. The prototype self-test Exacto<sup>®</sup> Test HIV (Biosynex, Strasbourg, France) was used to assess the usability of HIVST in 300 adults living in Bangui, according to WHO technical recommendations. Simplified and easy-to-read leaflet was translated in French (Figure 4) and Sango (Figure 5). The notice in French and Sango of Exacto<sup>®</sup> Test HIV were chosen in 242/300 (80.6%) and 58/300 (19.4%), respectively (Figure 6). It was correctly

understood in 273/300 (91.0%). The majority (275/300; 91.6%) correctly performed the HIV self-test; however, 71/300 (23.0%) asked for oral assistance.

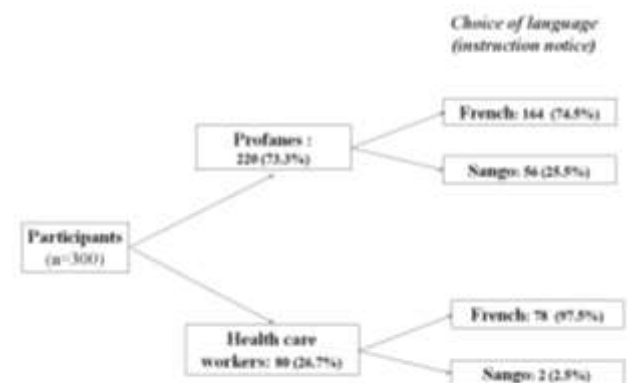


Figure 6. Flow chart showing the choice of language (French or Sango) of the instruction notice. The majority of participants were profanes. A subgroup of health care workers (26.7%) was also included, as requested by WHO recommendations [25].

Most of participants (273/300; 91.0%) found that performing of the self-test was very easy or easy, and less than 1.0% (2/300) found it difficult. Overall, the results were correctly interpreted in 96.9% (3,782/3,900), the reading/interpretation errors concerned the positive (96/1,800; 5.3%), invalid (17/600; 2.8%) and negative (5/1,500; 0.3%) self-tests (Figure 7). The Cohen's  $\kappa$  coefficient was 0.94. The main obstacle for HIVST was the educational level, with interpretation difficulties in poorly educated people. Finally, our observations on profane adults living in Central Africa, demonstrate: (i) the need to adapt the notice of instruction to African public, including educational pictograms as well as notice in

vernacular language(s); (ii) the frequent difficulties in understanding the notice with frequent misinterpretation of test results; (iii) and the generally good usability of the HIV self-test despite these latter pitfalls. More research on exploring the best strategy (i.e. supervised versus unsupervised strategies) for different high- and low- risk populations in resource-constrained settings remains needed.

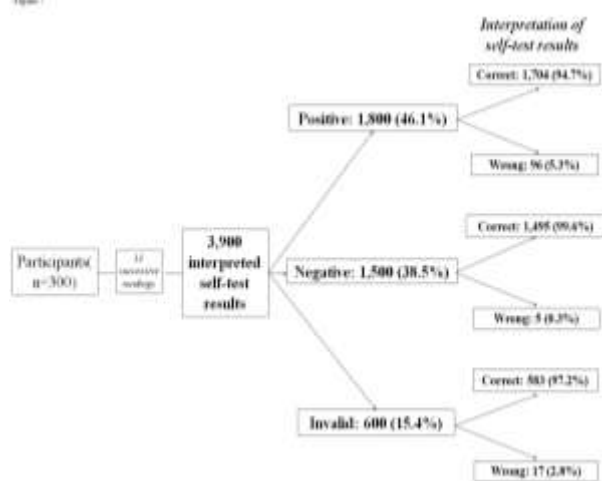


Figure 7. Flow chart showing the ability of participants to read and interpret (correctly or wrongly) the 3,900 results of the Exacto® Test HIV (Biosynex) obtained from successive random selection of a panel of 13 standardized tests, including 6 positive, 4 negative or 2 invalid.

## CONCLUSION.

HIV self-testing constitutes an innovative complementary HIV testing strategy that can help to refer people who have a non-reactive test to prevention services and people who have a reactive test to health centers for confirmation of the HIV-positive test results and, when appropriate, to offer antiretroviral therapy [8, 9]. This screening strategy is progressively spreading in sub-Saharan Africa. However, many issues and challenges persist. African governments, non-governmental organizations, international institutions, researchers and private partners will ultimately need to work in synergy to guide the planning and reflection of different stakeholders exploring the potential role of HIV self-testing in Africa.

## CONFLICT OF INTEREST

The authors declare that they have no competing interests.

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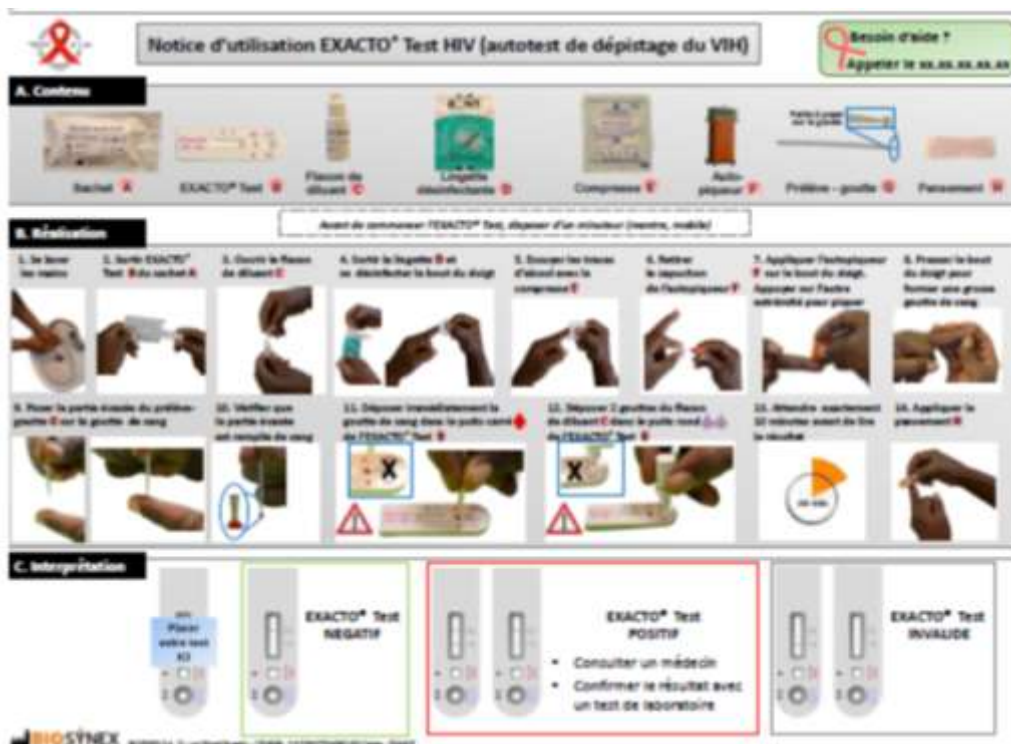


Figure 4. Instruction notice of the selftest Exacto® Test HIV (Biosynex) designed for African public using typical pictures representative the principal steps of the manufacturer’s instructions with explanations written in French.



Figure 5. Instruction notice of the selftest Exacto® Test HIV (Biosynex) designed for African public using typical pictures representative the principal steps of the manufacturer’s instructions with explanations written in Sango, the most frequently used vernacular language of the Central African Republic.