

## Research Article

# Accuracy and Acceptability of the OraQuick™ HIV Self-Test Kit Among Female Sex Workers and Men Who Have Sex with Men Attending Projet San Francisco in Kigali, Rwanda

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## Abstract

HIV self-testing is the process where a person who wants to know his or her HIV status collects a sample and performs a test him/herself and interprets the test result in private. The overall objectives of this study were assessment of the accuracy of OraQuick™ HIV self-testing procedures used to detect HIV-1 and HIV-2 antibodies. This Research adopted a cross-sectional study design where participants were recruited voluntarily. The Self-Test Kits were provided to participants after receiving instructions on how to use them and verbal consent was obtained from respondents. A questionnaire was provided to participants to collect relevant information related to the study. The target population of the study was Female Sexual Workers and Men who have sex with Men attending project San Francisco clinic located in Kigali City, Rwanda. The sample size was 275 respondents. Data collected was stored in a database and further analyzed using SPSS. The study findings revealed that 57.5% of respondents were aged 18-29, 60% were male and 85% were single. The accuracy of the OraQuick™ HIV self-test was 99% and acceptability was at 93.6%. The findings revealed that respondents who ever diagnosed and treated for STI were about 8 fold more likely to have high acceptability of OraQuick™ HIV self-test. The OraQuick™ HIV self-test kit was found to be accurate and compare very well with the gold standard HIV kit using blood in laboratory. The use and adaptation of the self-test kit among the citizens of Rwanda is recommendable.

**Keywords:** HIV self-testing; OraQuick™; HIV-2 antibodies; Acceptability; Accuracy; Key populations (KP); Men who have sex with men (MSM); Sex workers (SW)

## Introduction

Globally, the incidence of HIV infections is rising: The world has committed to work hard on stopping the HIV/AIDS epidemic by 2030 [1]. In order to reach this bold target, health authorities such as the Centers of Disease Control strongly recommend regular HIV testing. Although HIV/AIDS testing is strongly recommended as a routine health service to everyone, new HIV infections are noticed late or not at all detected [2]. Globally, about 36.9 million average (31.1 million–43.9 million) people were living with HIV/AIDS in 2017 [3]. Only Sub-Saharan Africa have about 25.5 million individuals who are living with HIV infection with an incidence of 1.5 million annually [2,3].

Fear of stigmatization continues in most of the population where accessibility to HIV testing is a big issue in many regions and continues to hinder the acceptance of HIV testing and counseling services [4]. Globally, the acceptance of services offered for HIV counseling and testing remains very low mainly high number of groups who are at risk around the world. Fear of confidentiality breaching, stigma, discrimination from other members of the society lowers down the use of health services among risk groups [5].

In Rwanda, the prevalence of HIV has been stabilized to 3% since 2010. Although the country has a generalized epidemic, several means and channels are used among certain key populations which accelerate on increasing their risk behaviors and HIV transmission among the general populations [5].

Worldwide, women who exchange sex for money are at high risk of Human Immunodeficiency Virus (HIV), Sexually Transmitted Infections (STIs), and unplanned pregnancy, but are often less likely to seek HIV testing due to transportation costs, time constraints, and the stigma and discrimination associated with sex work and being HIV-positive [6]. There has been a long time formal discussion about the idea of HIV home-based testing, but approval of the test method has not been done. Recently, the discussion on home-based testing has been reopened again, after approving HIV self-testing kit using oral fluid in the United States of America [7]. The benefits would result from flagging new infections and initiating treatment as soon as it is detected as well as improving both effectiveness and cost-effectiveness [8].

The whole population is going to benefit from HIV self-testing especially those who are in high prevalence of HIV infection like key

population, community health workers and the priority populations in all settings and those who frequently keep on re-testing due to ongoing risk [6].

The presence of lower proportion among males and females attending HIV testing was attributed to different methodologies including stigma. HIV Self Testing methods has been discussed in UNAIDS/WHO documents however, several countries have addressed the issue and it is useful to consider the range of thinking on this issue while maintaining a focus on the particular context and needs of developing countries [9].

Acceptability of HIV self-testing which is conducted at home especially by those most-at-risk populations like MSM and FSW is one of the solutions in marginalized and stigmatized society in the world [10-12]. The main focus of this study is to evaluate the accuracy and acceptability of OraQuick™ HIV self-test use among female sex workers and men who have sex with men in Kigali Rwanda.

## Materials and Methods

### Research design and target population

The study was conducted under descriptive cross-sectional design, whereby data were collected on a group of the population at a point in time and then analyzed. This study adopts quantitative methods approach. Since this study envisaged the key population and it is not easy to get them everywhere at the field, the researcher preferred to enroll the section of key population as the target population of 670 FSW and MSM participants at Project San Francisco as routine clients attending the cite in Kigali Rwanda. This project is intended to help FSWs and MSM who are followed at the project's clinic in order to sustain their best livelihood by providing HIV prevention services mainly. All data represents the target research population of this study. Therefore, the target population consists of FSWs and MSM who are the beneficiaries of the project 'activities during research period.

### Sample Size and sampling technique

In this study, the sample was calculated by considering a cross-sectional study where the prevalence of acceptability is not well known for this type of population. Therefore, the researcher has adopted the Yamane formula to calculate the adequate sample to be used and the following formula was considered:

$$n = \frac{N}{1 + N * e^2}$$

where,

n = the sample size

N = the size of the target population

e = the error of 5 percentage points

For the purpose of this study, size of the target population under the study is equal to 670 and after all necessary calculations; the adequate sample size was approximately 250 participants. However, the researcher has taken into account the attrition that may arise during the collection of the data and the attrition rate was set to 10%. After considering this attrition rate the final sample size was 275 participants.

FSW and MSM normally come in after getting information from

key informants or radio advertisements. All KP who came for baseline and/or follow up were eligible for this study. After explanation and video demonstration, all clients who are eligible for HIV lab test were given OraQuick™ HIV Self-Test. The convenience sampling was used to the participants given the limitation in time and other resources necessary.

### Data collection methods and tools

Quantitative methods used by the researcher. Collecting data was done through different tools such as: Questionnaires survey, counseling messages. Instruments were used in Collection of data and other information quantitatively.

Used questionnaires were standards in order to produce accurate information. The questionnaire comprised of two sections as follows: The first section comprised of demographic data such as age, sex, occupation, living situation, marital status and education. The second section comprised of data describing the behaviors of beneficiaries about the sexual, HIV history and techniques of HIV self-testing.

The HIV test results from OraQuick™ HIV Self-Test were offered in Nurse's office, after each individual result was recorded on the designated sheet. The sheet shows the Date, Client ID, File number, Volunteer type, OraQuick™ HIV Self-Test results and Laboratory results. This sheet was filled by a trained nurse and blood specimen was taken to PSF Clinical Laboratory where HIV Rapid Test was used to test the sample as usual. Then the lab results were reviewed and recorded on the same sheet for comparison.

### Data analysis procedure

The data which are collected were processed and organized for statistical analysis. Data analysis involved first coding the responses; tabulating the data; and performing several statistical computations (i.e. averages, frequencies and percentages). Statistical Package for the Social Science (SPSS) was used in the analysis of the data.

To assess the validity of OraQuick self-test, the specificity and sensitivity as well as positive and negative predictive values were calculated by comparing the results provided by the self-test against the best existing currently used test as per the Ministry of Health algorithm which are the alere Combo Determine and the STAT-PAK considered as the confirmatory test.

Moreover, descriptive statistics using counts and percentage were computed to describe the basic demographic characteristics, sexual habits and acceptability of OraQuick self-test. A score assessment was used to determine the overall level of acceptability of OraQuick self-test. Five questions were considered with "yes" and "no" responses. The score 1 was given to "Yes" and score 0 for "No" and those who scored 3 and above were grouped with high acceptability and below 3 with low acceptability. Logistic regression and chi square test were performed to establish the factors associated with the level of acceptability for OraQuick self-test. Multiple logistic regressions were used to assess the independent factors associated with HIV self-testing acceptability by adjusting for potential confounders.

### Ethical consideration

Ethical clearance was obtained from Mount Kenya University Rwanda ethical review board. Values of voluntary participation, anonymity and protection of rights of respondents and from any

possible harm that could arise from participating in the study were considered in this study. Participants were requested to join the study on a voluntary basis and refusal or abstaining from participating was permitted.

Informed consent for key informants was considered, where verbal consent used by nurse counselors. Respondent's confidentiality on the information and protection from any possible harm that may arise from the study was ensured.

## Results

### Characteristics of respondents

Out of the 275 distributed questionnaires, 200 were well answered and returned back with a response rate of 72.27%.

As shown in Table 1, the average age of the respondents was 30.6 years with majority (57.5%) were in the age group of 18 to 29 years. The proportions of males were more (60.0%) compare to 40.0% of females. The respondents were requested to indicate their marital status and large percentage were single (85.0%).

Regarding to the level of education, the table further indicated that 60.5% of the respondents acquired secondary level of education and this followed by those who attained primary education (24.0%) while the remaining (15.5%) were with tertiary level of education. About half (48.5%) were living alone and about a quarter (26.5%) were cohabiting. In terms of occupation, 48.0% were government employed followed by self-employed (31.0%).

### Sexual history and behavioural characteristics of the participants

The descriptive results of sexual habits and behaviors are displayed in Table 2.

Respondents were asked about whether they ever had sex

**Table 1:** Socio-demographic characteristics of the respondents.

Variables	Frequency	Percent
<b>Age in groups</b>		
18-29	115	57.5
30+	85	42.5
<b>Sex</b>		
Male	120	60.0
Female	80	40.0
<b>Marital status</b>		
Married	15	7.5
Single	170	85.0
Divorced/widowed/widower	15	7.5
<b>Education</b>		
Primary	48	24.0
Secondary	121	60.5
Tertiary	31	15.5
<b>Living situation</b>		
Live with parents	11	5.5
Live alone/roommates	136	68
Cohabiting	53	26.5

**Table 2:** Sexual history and behavioural characteristics of the participants.

Variables	Frequency	Percent
<b>Ever had sex</b>		
Yes	200	100.0
<b>Oral sex</b>		
Yes	32	16.0
No	168	84.0
<b>Vagina sex</b>		
Yes	192	96.0
No	8	4.0
<b>Anal sex</b>		
Yes	49	24.5
No	151	75.5
<b>Even been tested for HIV</b>		
Yes	194	97.0
No	6	3.0
<b>Frequency of partners had vaginal sex within last 7 days</b>		
None	39	19.5
Once	98	49.0
Twice	52	26.0
Three and above	11	5.5
<b>Number of partners had anal sex in the last 7 days</b>		
None	176	88.0
Once	24	12.0
<b>Diagnosed and treated for STI for the last 12 months</b>		
Yes	147	73.5
No	53	26.5

and all of them indicated that they had ever experienced sex. The respondents were also asked the different types of sex namely oral sex, vaginal sex or anal sex and 16.1%, 96.0% and 24.5% revealed that they had practiced oral, vaginal and anal sex respectively. Almost all of the respondents (97.0%) indicated that they have ever tested for HIV. About half of them had once vaginal sex within one week followed by those who had vaginal sex twice (26.0%). However, there were only 12.0% had anal sex within the last 7 days. About a three quarter (73.5%) had ever diagnosed and treated against STI in the last one year (Table 2).

### Accuracy of OraQuick™ HIV self-test kit

The first objective sought of assessing the accuracy of OraQuick™ HIV self-test kit against the gold standard HIV using blood in laboratory among Key Populations in PSF Kigali Rwanda.

To achieve this objective, we administered two independent tests, one using the OraQuick™ HIV self-test kit and another test in the laboratory using the standard HIV kit. The results for 206 respondents, 195 participants were HIV negative results on both tests while 10 participants were confirmed have HIV positive results. Only 1 participant had discrepancy where she had negative result on OraQuick™ HIV self-test and HIV positive result on Gold standard test. It's indicated on package insert that a HIV patient who is taking

**Table 3:** Accuracy of OraQuick™ HIV self-test kit.

Result from screening test OraQuick™ HIV self-test	Status of HIV according to Gold standard		Total
	Positive, n(%)	Negative, n(%)	
Positive	10(90.9)	0(0.0)	10
Negative	1(9.1)	195(100.0)	196
Total	11	195	206

Percentage of HIV =  $11/206 \times 100 = 5.3\%$

Sensitivity =  $10/11 \times 100 = 90.90\%$

Specificity =  $195/195 \times 100 = 100\%$

Positive predictive value =  $10/10 \times 100 = 100\%$

Negative predictive value =  $195/196 \times 100 = 99.50\%$

**Table 4:** Acceptability of OraQuick™ HIV self-test use.

Variables	Frequency	Percent
<b>Ever heard HIV of self-test</b>		
Yes	50	25.0
No	150	75.0
<b>Willing to pick up a self-test at a pharmacy</b>		
Yes	195	97.5
No	5	2.5
<b>Willing to pick up a self-test at a condom distribution center</b>		
Yes	174	87.0
No	26	13.0
<b>Willing to pick up a self-test for friend or a partner</b>		
Yes	178	89.0
No	22	11.0
<b>Willing to share your experience with us about self-testing</b>		
Yes	151	75.5
No	49	24.5

Antiretroviral treatment gives false negative result when tested using oral fluid. OraQuick™ HIV self-test. It is presented in Table 3.

As indicated in Table 3, the proportion of HIV among the key population was 5.3% according to the gold standard. Regarding to accuracy, 90.9% of the OraQuick™ HIV was sensitive to detect HIV infection and it has 100% specificity to identify true negative of HIV. Moreover, the positive and negative predictive values were 100% and 99.5% respectively.

#### Acceptability of OraQuick™ HIV self-test use among key populations

The respondents were requested to respond to the questions on the acceptability and willingness to pick self-tests at various places. The responses are presented in Table 4.

The overall score of acceptability to OraQuick™ HIV self-test was generated by aggregating the scores according to the five statements presented in Table 4. Score 1 was for "Yes" and score 0 for "No". Based on the scores the maximum was five and the minimum was 0. Then low acceptability was considered for those who scored below 3 and those who scored 3 and above were classified with high acceptability.

As shown in Table 4, only 25.0% of the respondents hard about HIV self-test. However, big percentages (97.5%) were willing to uptake the self-test from pharmacy. Regarding willingness to pick

**Table 5:** Multivariate analysis for factors associated with OraQuick™ HIV self-test acceptability.

Variable	AOR	95% CI		p value
		Lower	Upper	
<b>Full model</b>				
<b>Sex</b>				
Male	Ref			
Female	3.66	0.43	31.12	0.235
<b>Anal sex</b>				
Yes	Ref			
No	8.82	2.05	38.02	<b>0.004</b>
<b>Diagnosed and treated for STI for the last 12 months</b>				
Yes	6.74	1.60	28.34	<b>0.009</b>
No	Ref			
<b>Reduced model</b>				
<b>Anal sex</b>				
Yes	Ref			
No	11.91	2.91	48.82	<b>0.001</b>
<b>Diagnosed and treated for STI for the last 12 months</b>				
Yes	8.38	2.06	34.06	<b>0.003</b>
No	Ref			

AOR: Adjusted Odds Ratio; CI: Confidence Interval.

up a self-test at a condom distribution center, 87.0% agreed on the statement. Of the 200 participants, 89.0% exhibited the willingness to pick up a self-test for friend or a partner. Majority (75.5%) were also willing to share their experience with us about self-testing.

After considering all the questions presented in Table 4, 93.6% had high acceptability on OraQuick™ HIV self-test while the remaining had low acceptability level.

#### Factors associated with OraQuick™ HIV self-test acceptability

Multiple logistic regression analysis was conducted to know the factors influencing high acceptability level. This was also conducted to control the confounding variables. All the three significant variables during the bivariate analysis were considered together in multivariate analysis by using "Backward Conditional" method. After running the multivariate analysis, 2 out 3 variables remained in the final model as presented in Table 5.

Surprisingly, respondents who never practiced anal sex were 11.91 times more likely to have high acceptability of OraQuick™ HIV self-test {AOR=11.91; 95%CI= 2.91-48.82} compared to those who indicated otherwise. Furthermore, respondents who ever diagnosed and treated for STI for the last 12 months were about 8 fold more likely to have high acceptability of OraQuick™ HIV self-test.

Like other HIV rapid tests using blood samples, HIV Self Testing has the potential to increase the number of people living with HIV who have access to testing, know their status and early initiation to antiretroviral treatment. This study was conducted to determine accuracy of OraQuick™ HIV self-test kit against the gold standard HIV kit using blood in laboratory among Key Populations in Projet San Francisco Kigali Rwanda and to assess the acceptability of

OraQuick™ HIV self-test use among Key Populations in PSF Kigali Rwanda. About 93.6% had high acceptability on OraQuick™ HIV self-test while the remaining had low acceptability level. Acceptability of HIV self-testing which is conducted at home especially by those most-at-risk populations like MSM and FSW is going to be one of the solutions in marginalized and stigmatized society in this country.

Establishment of the factors associated with OraQuick™ HIV self-test acceptability among participants where they were asked if they are willing to pick up HIVST kits to take home for their partners and to choose convenient places where they can find them. This revealed that up to 86% of the respondents were willing to pick the kit from both pharmacies and distribution centers) while 88.5% of the respondents indicated they were willing to pick up the test for a friend or partner.

The accuracy of OraQuick™ HIV self-test was assessed using sensitivity to see positive values and negative values and research revealed a higher level of accuracy of the OraQuick™ HIV self-test at 99% of accuracy and it has 100% specificity to identify true negative of HIV. Moreover, the positive and negative predictive values were 100% and 99.5% respectively

The study found that the sensitivity of OraQuick™ HIV self-test has 90.9% capacity to detect HIV infection. This shows that it has high sensitivity and can be adopted to help those in need.

## Discussion

Various studies on HIV self-test accuracy have indicated that it yields a high sensitivity and specificity as well. In line with the current findings, studies conducted in UK reported about HIV self-testing using saliva kits as accurate way and has sensitivity of at least 91.7% and its specificity of at least 97.9% [4]. Although HIV Self-tests is generally accurate, their sensitivity, specificity and positive/ negative predictive values can be affected by the prevalence of HIV among the population and by user errors. User-friendly specimen collections allow RDTs to be performed by anyone and do not require medical training.

Disagreement between health staff and study participant's results was mainly caused by invalid test results due to performance errors. Overall, no false positive test results occurred and the few false negative or inconclusive test results were mainly related to misinterpretation of very faint lines.

In according with the results from this study, a study conducted in China found that self-testers performed tests as accurately as health staff with 99% of tests being valid results [13]. In contrast, despite the fact that administered self- tests were performed with high accuracy in Uganda, overall sensitivity (97.9%) remained slightly lower than sensitivity claimed by the manufacturers and was even lower (96.4%) among those who were previously not known to be HIV-positive [14].

Several studies have found consistently high levels of HIV Self-Testing acceptability among the general population and higher-risk subgroups including MSM and FSWs who may not access easily other testing services [15,16]. Some evidences suggest that acceptability of oral fluid-based self-testing is higher compared to blood-based testing. In other studies, which were done previously, acceptability of oral fluid-based self-testing has been high, ranging from 74 to 95%

[17-19].

Diagnosis and treatment of STIs was associated with the uptake of HIVST acceptability among key population in Rwanda. These factors were not studied in other studies. We did not found any association between demographic characteristics and acceptability of HIVST. In contrast a study conducted in Kenya found that Factors that were positively associated with the use of an HIVST kit were being female and single, but survey respondents who were married or in a steady relationship were less likely to use an HIVST kit or participate in the information sessions [20].

## Conclusion

According to the findings of this research, the researcher was able to draw up conclusions on the study variables. First and foremost, the OraQuick™ HIV self-test kit was found to be accurate and compare very well with the gold standard HIV kit using blood in laboratory. From our field experience, oral fluid based testing offers many advantages over blood-based testing, especially with self-testing on the horizon.

This implies that the self-test kit can be implemented for use. In addition to this, majority of the respondents indicated that they were comfortable with self-test which they considered to be easy to use and more confidential than the lab test method. To this then, the self-test method can easily find acceptability to the large population and to a higher degree be used by many people.

## Recommendations

In light of the findings from this study, the researchers recommend the use and adaptation of the self-test kit among the citizens in Rwanda. A cost analysis of rapid test on national algorithms from health systems perspective should be performed including OraQuick™ HIV self-test. Further, the researchers suggested that there is need to create awareness of the self-test kit to the general population in Rwanda as a measure of knowing the HIV status.

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