



HIV Self-Testing Pocket Guide



Frequently Asked Questions
(For medical and non-medical individuals)

May 2018

What is HIV self-testing?

HIV self-testing (HIV ST) refers to the process in which a person collects his or her own sample (oral fluid or blood) and then performs the test and interpret the results, often in a private setting, either alone or with someone he or she trusts. HIV ST can be done without supervision, only using the kit instructions (unassisted HIV ST) or under supervision by healthcare workers or peers who provide assistance by demonstrating, before or during HIV ST, how to perform and interpret the test (assisted HIV ST).

Why do we need self-testing for HIV?

Testing is the first step in the HIV cascade. Even though the global scale-up of HIV testing services (HTS) has been substantial, it was estimated in 2016 that 40% of people living with HIV globally, did not know their HIV status¹. In many settings, HTS coverage and uptake remains poorly focused, as majority of those at highest risk of HIV infection (such as men, adolescents, partners of people with HIV and key populations world-wide) remain unreached. HIV ST is an innovative and empowering way to reach first-time testers, people with undiagnosed HIV or those at on-going risk in need of frequent testing. In 2016, World Health Organization (WHO) released new guidelines recommending that HIV Self-Testing should be offered as an additional approach to HIV testing services.

Does HIV ST replace other HIV Testing strategies?

HIV ST is not intended to replace the traditional facility-based HIV testing; rather HIV ST is a complementary approach to existing HTS, with the benefit of reaching previously untested, hard-to-reach, and test-averse populations. HIV ST is a screening tool; a first step that should lead to a confirmatory testing (at a health facility) for those who test positive and treatment.

Is HIV self-testing already being used in resource limited settings?

Following WHO guidelines, countries have rapidly introduced national HIVST policies though some HST policies are at varying stages of implementation in different countries. Self-testing has already been piloted and included in many countries including South Africa, Kenya, Malawi, Botswana⁴.

What evidence is out there so far?

More than 200 studies have been done on HIV ST, looking at their diagnostic performance, uptake and feasibility of implementation, models of implementation, social harm, cost-effectiveness among others¹. Among these studies, a systematic review conducted by WHO concluded that, when compared to standard facility based testing, HIV ST^{2,3,4,5,6}:

¹ UNAIDS Prevention Gap Report, Geneva, 2016. http://www.unaids.org/sites/default/files/media_asset/2016-prevention-gap-report_en.pdf

² Katz D, Golden M, Hughes J, Farquhar C, Stekler J. HIV self-testing increases HIV testing frequency among high-risk men who have sex with men: a randomized controlled trial. Presented at: 8th International AIDS Society Conference; 19–22 July 2015; Vancouver, Canada; 2015.

³ Jamil M, Prestage G, Fairley C, Grulich A, Smith K, Chen M, et al. Access to HIV self-testing doubles the frequency of HIV testing among gay and bisexual men at higher risk of infection: a randomised controlled trial. Presented at: 21st International AIDS Conference; 18–22 July; Durban, South Africa; 2016.

⁴ Thirumurthy H, Masters S, Obonyo B, Napierala Mavedzenge S, Maman S, Omanga E, et al. Promoting male partner and couples HIV testing through secondary distribution HIV self-tests: a randomized trial. Presented at: 21st International AIDS Society; 18–22 July; Durban, South Africa; 2016.

⁵ Gichangi A, Wambua J, Gohole A, Mutwiwa S, Njogu R, Bazant E, et al. Provision of oral HIV self-test kits triples uptake of HIV testing among male partners of antenatal care clients: results of a randomized trial in Kenya. Presented at: 21st International AIDS Conference; 18–22 July; Durban, South Africa; 2016

⁶ Wang Z, Lau J, Ip M, Ho S. A randomized controlled trial evaluating the efficacy of promoting HIV self-testing and online real-time counseling on increasing HIV testing among men who have sex with men in Hong Kong. Presented at: International Congress of Behavioral Medicine; 7–10 December; Melbourne, Australia; 2016.

1. Increased the uptake of HIV testing among men and adolescents
2. Did not increase HIV risk behaviors or the number of bacterial sexually transmitted infections (STIs)
3. Did not increase social harm or other adverse events compared to conventional testing methods.

What are the concerns around introducing HIV self-testing?

1. As with all HTS approaches, rates of linkage to care from HIV ST are suboptimal and require further intervention with follow-up and prevention services particularly for key populations, especially in settings with restrictive laws and policies¹. Where self-tests are distributed to be performed independently, support systems need to be put in place to ensure queries can be answered, counseling can be offered on demand, and linkage to HIV care is maximized. Innovative strategies for linkage to care could include set-up of hotline, voluntary visit by community health care worker (HCW), mobile phone calls among other means.
2. While HIV ST has a high sensitivity and specificity, its performance may be reduced in individuals with prior exposure to ARV (e.g. people on ART or receiving PrEP or completing PEP) leading to false negative results. This can lead to misinterpretation of HIV test results and the wrong perception of cure, which can incite people to interrupt treatment and exit from HIV care. Therefore, HIV ST should not be performed in these populations. This underscores the importance of adequate awareness of this possibility, counseling and patient education.
3. Results from randomized trial studies have shown that HIV ST does NOT increase the risk of intimate partner violence (IPV) compared to regular testing⁷. It is therefore critical for programs to recognize the importance and complexity of monitoring, reporting, evaluating and assessing social harm in relation to HIV ST¹.
4. Interpretability of HIV ST results; improvements in the demonstration of result interpretation (especially weak positive test results) is still needed in certain populations.

Which HIV Self-Test kits are available for use?

A mixture of both oral fluid and blood specimen based HIV ST kits are available in the market with different regulatory approvals. Some of the available HIV ST kits are shown below:

Table 1: Some of the available HIV Self-Test kits brands (Oct 2017)

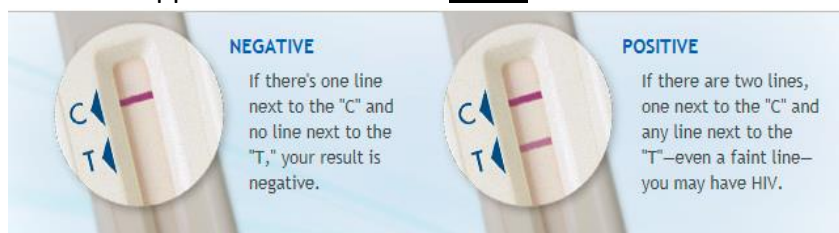
HIV ST brand	Manufacturer	Sample type	Time to results
OraQuick HIV Self-Test	OraSure Technologies, USA	Oral fluid	20 minutes
INSTI HIV Self-Test	bioLytical, Canada	Blood	1 minute
BioSURE HIV Self-Test	BioSure UK	Blood	15 minutes
Autotest VIH	AAZ LMB, France	Blood	15 minutes
AtomoRapid HIV Self-Test	Atomo, Australia	Blood	15 minutes

At present, MSF recommends oral self-testing using OraQuick HIV Self-Test, which has recently received WHO Prequalification⁷. Many low- and middle-income countries can access the preferential pricing of the OraQuick HIV Self-Test.

Steps on using the OraQuick HIV Self-Test



1. Open the package and remove the two components: the 'testing swab' and the 'developing solution' and place them on a flat surface
2. Use the test swab to gently swipe it along your upper gums once and your lower gums once (do not use saliva or swab roof of the mouth or tongue)
3. Then insert the swab into the test tube filled with the developing solution
4. Place the test tube back on a flat surface and set a timer for exactly 20 minutes
5. After 20 minutes, read your result at the top of the test stick:
 - a. one C-Line indicates a HIV negative result;
 - b. one C-line and one T-line indicates a HIV positive result;
 - c. if no lines appear then the test is invalid



*A positive self-test result must be followed up by a confirmatory traditional blood based test at a health facility, where someone can be started on treatment.

MSF in HIV ST

Historically MSF has limited investments in the development of innovative models around HIV testing, often leaving this to other implementing partners whilst focusing primarily on strategies to improve treatment (ARVs) and retention in care. However, with the implementation of "test and treat"⁸, reassessing current testing strategies and complementing them with innovative models is essential to identify and initiate those in need of treatment.

⁷ http://www.who.int/diagnostics_laboratory/evaluations/pq-list/170720_final_amended_pqdx_0159_055_01_oraquick_hiv_self_test_v2.pdf?ua=1

⁴ <http://apps.who.int/iris/bitstream/10665/251713/1/WHO-HIV-2016.24-eng.pdf>.

MSF is investing and coordinating intersectionally on HIV ST in multiple settings. Our teams are working on a variety of research questions that so far remain unaddressed in the area of HIV ST, including acceptability and feasibility in low HIV prevalence settings and linkage to care.

Where can HIV self-testing be introduced in programmes?

A continuum of different HIV ST service delivery approaches can be considered depending on the context, setting and population that the program aims to reach.

Summary of HIV ST delivery approaches:

1. Community based distribution; door to door, mobile testing campaigns, or could be linked with distribution of other commodities (bed-nets, nutrition, etc.)
2. Couples and partners testing; providing women (at ANC or postpartum care) and Sex Workers (SW) with HIV ST kits to distribute to their male partner(s) and social networks
3. Facility based; (especially in generalized epidemic settings) individuals presenting at facilities could be given HIV ST kits to self-test whilst waiting for other services or take the kit home for self-testing or sharing with partner.
4. Integration of services and outreach; based on other existing models like VMMC, TB programs, contraception, key population outreach, immunization campaigns
5. Pharmacy based distribution

Frequently Asked Questions (FAQs) about HIV ST

1. **HIV ST uses oral fluid, does it mean HIV is transmitted from saliva?** HIV ST detects antibodies to HIV from oral fluid (an ultra-filtrate of blood). HIV (*the actual virus*) is not found and cannot be spread through urine, sweat or saliva. HIV is not transmitted in oral fluid, unless one has open sores or bleeding and has fluid exchange with another individual with sores in their mouth.
2. **What are the age groups for conducting HIV ST?** Children 18 months or older who are suspected of living with or being exposed to HIV can be tested by HIV ST kit. Evidence remains limited on use in infants and children younger than 18months.
3. **What measures are in place to assure quality of results from HIV ST kits?**
Before getting regulatory approvals status (CE, FDA and WHO approvals), HIV ST are subjected to rigorous scientific and quality testing to make sure that, not only are they of the highest quality with exceptional accuracy, but also that an untrained individual would be able to use them (un-assisted self-testing). All parts of the kit have been checked for safety and accuracy and the instructions have been reviewed by numerous medical and consumer safety experts to make sure ordinary people are able to use it safely.
4. **I'm worried I have been exposed to HIV within the past 72 hours, can I still use this HIV ST?** The HIV ST will not detect any acute infections. You need to visit a healthcare professional as soon as possible, where you may be able to access a course of Post Exposure Prophylaxis (PEP) and have a blood sample taken to the laboratory for specialized testing. A negative HIV ST result may not be accurate until 3 months after potential exposure because it can take your body that long to produce enough antibodies.

5. **Between blood and saliva based HIV ST kits, which ones are more accurate and affordable?** Oral fluid has less HIV antibodies than whole blood, however, oral fluid tests are nearly as accurate as blood based tests. Oral fluid based HST are very easy to use without any need for pricking an individual.
6. **Does test performance differ between supervised and unsupervised HIV ST?** While supervision can lead to better adherence to test procedures and therefore fewer user errors, there is no significant difference in performance between the two testing approaches.
7. **Can people taking ARVs use the HIVST?** HIV ST kits should NOT be used by people taking ARVs as the test may give false negative results. This is also true of blood-based tests though the risk is higher with oral fluid tests. The extent of the risk of false-negative results is not yet fully understood.
8. **When do I need to run control samples on HIV ST kits?** HIV ST control test should be run intermittently at the health facility upon receipt of a new batch/lot/shipment or when storage temperatures are outside 2-27°C
9. **Can one share the test with another individual? How do I dispose of the test after use?** Each HIV ST kit is for single use and cannot be shared between individuals. The used HIV ST kit can be disposed of in a regular bin.