



MINISTRY OF HEALTH

HIV Self-Testing

An operational manual
for the delivery of HIV
Self-Testing services
in Kenya



National AIDS and STI
Control Program

**BE
SELF
SURE**

THE HIV
**SELF-TESTING
KIT.**



Republic of Kenya

HIV SELF-TESTING

AN OPERATIONAL MANUAL FOR THE DELIVERY OF HIV SELF-TESTING SERVICES IN KENYA

NATIONAL AIDS & STI CONTROL PROGRAM
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National AIDS and STI Control Programme (NASCO)
Ministry of Health
PO Box 19361 – 00200
Nairobi, Kenya
Tel: +254 20 2729549 or 2729502
Email: head@nascop.or.ke
Website: www.nascop.or.ke

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Contents

| | |
|--|----|
| EXECUTIVE SUMMARY | 4 |
| FOREWORD | 5 |
| DEFINITION OF TERMS | 6 |
| ABBREVIATION & ACRONYMS | 7 |
| CHAPTER ONE: INTRODUCTION | 8 |
| CHAPTER TWO: APPROACHES FOR HIV SELF TESTING | 11 |
| CHAPTER THREE : HIV SELF-TESTING PACKAGE | 15 |
| CHAPTER FOUR: COMMODITY MANAGEMENT | 21 |
| CHAPTER FIVE: COORDINATION | 22 |
| CHAPTER SIX: QUALITY ASSURANCE | 25 |
| CHAPTER SEVEN: MONITORING & EVALUATION | 28 |
| APPENDICES | 29 |
| Appendix 1: | 29 |
| Appendix 2: | 33 |
| Appendix 3 | 34 |
| REFERENCES | 36 |



Executive Summary

Inadequate uptake of testing for HIV remains a primary bottleneck toward universal access to treatment and care as well as an obstacle to realizing the potential of new interventions for preventing HIV infection, including treatment for prevention and pre-exposure prophylaxis (PrEP).

HIV self-testing (HIVST) is a process whereby an individual conducts his or her own HIV test using a simple oral or blood-based test. It is an emerging approach that provides an opportunity for people to test themselves discreetly and conveniently, thereby empowering those who may not otherwise test, particularly among high-risk populations to know their HIV status.

HIVST has the potential of being a high impact, low cost intervention to reach population groups that are not testing, and to increase the number of people living with HIV who are identified and initiated on treatment. HIVST also provides an opportunity to provide linkages to HIV prevention services for those who test negative. Approaches to HIVST include community and facility based HIVST in both public and private sectors. Regardless of the approach applied, the testing model may either be directly-assisted by a provider or unassisted.

The HIVST strategy is guided by the principles of HIV testing services as outlined in the National HTS guidelines 2015 and Guidelines for Use of Antiretroviral Drugs for Treating and Preventing HIV Infections in Kenya 2016 . It shares many requirements with current HIV testing and counselling approaches including commodity management, quality assurance and linkage to care.

The coordination of HIV self-testing services will be a multi-faceted and multi-level activity that spans the national, county and lower level structures and needs to be done in line with the coordination mechanism as described in the Kenya HIV Testing Guidelines 2015 (Chapter 10). In addition, other key actors that include the regulatory bodies, professional associations and test kit manufacturers, distributors and vendors are also involved specifically to coordinate both the public and private sector.

These guidelines outline the programmatic approaches to HIV self-testing, describe the package of support services required under HIVST, describe commodity management system requirements and outline coordination mechanisms for HIVST. They also outline quality assurance strategies, and monitoring and evaluation for HIVST.



Foreword

HIV Self Testing (HIVST) has the potential to increase knowledge of HIV status and has the public health benefits that may significantly reduce the risk of HIV transmission. With the current optimal uptake of conventional HIV testing in the country, it is important therefore to implement innovative strategies with a view to widen the scope of HTS provision in this country. The development of this HIVST guideline was therefore necessitated by the need to increase the uptake of HIV testing in the country, given that HIV testing is the gateway to prevention, care and treatment.

HIV self-testing provides an opportunity for people to test themselves discreetly and conveniently and may provide opportunity to people who are not currently reached by existing HIV testing and counseling services with information about their HIV status. Thus self-testing has the capacity to significantly contribute to the national objective of universal knowledge of HIV status.

This operational manual presents information on the approaches, procedures and self-testing standards potential benefits and risks of HIV self-testing, as well as, client education materials as well as policies and regulatory considerations. The manual targets service providers in both private and public sector, NGOs, individual researchers and any other relevant healthcare workers providing HIV services within the community and clinical settings to ensure a wider reach and to increase on the use of self-testing.

I strongly encourage Kenyans to expand and advocate the utilization of the HIVST in the country but within the framework of relevant national policies and the constitution.

The development of the HIV self-testing (HIVST) operational manual is a result of the efforts by the National HTS technical working group, drawn from different organizations and coordinated by NASCOP. I thank the NASCOP HTS Team for spearheading this process and working tirelessly with the other organizations to develop this HIVST guideline. Special and sincere appreciation also goes to our partners, NGOs, technical organizations, individuals and all members who participated in many meetings and workshops to share useful ideas towards the development of this document.



Martin Sirengo
Head NASCOP



Definition of Terms

HIV self-Testing: (HIVST), this is a process whereby an individual collects his or her specimen, performs a test and interprets the results, often in a private setting either alone or with someone he or she trusts. HIVST can either be directly assisted or non-assisted.

Unassisted HIV self-testing: Refers to an individual obtaining a kit for HIV self-testing and performing the HIV test following the instructions in the insert.

Directly assisted HIV self-testing: Refers to when individuals who are performing a self-test for HIV receive an in-person demonstration from a trained provider or peer before or during HIVST with instructions on how to perform a self-test and how to interpret the self-test result. This assistance is provided in addition to the manufacturer supplied instructions for use and other materials found inside HIVST kits.

Reactive results: It means that the test indicates that HIV antibodies are present in the blood or oral fluid sample. Anyone whose result is reactive to a rapid HIV test (including a self-test) must be followed by additional HIV testing services by a trained provider following the national HIV testing algorithm.

Non-reactive results: It means that the test indicates that HIV antibodies were not found in the blood or oral fluid sample. Anyone whose result is nonreactive to a rapid HIV test (including a self-test) does not need further testing but should be supported to re-test if they have had a recent potential HIV exposure or are at on-going HIV risk.

Service provider: In the context of HIVST is an organization, business or individual which offers service to others either in exchange for payment or for free.

Vendor: In the context of HIVST is an outlet which sells directly to the consumer e.g. chemists.

Distributor: An agent who supplies HIVST kits to stores and other businesses that sell to consumers e.g. wholesale.

Emancipated minor: A person who is not legally an adult but who because he or she is married is the mother/ father of a child or otherwise no longer dependent on the parents. S/he may not require parental permission for medical or surgical care.

HIV testing services: HIV Testing Services (HTS) indicate the full range of services that a client is offered together with HIV testing. This includes counseling (pre and post testing); linkage to appropriate HIV prevention, care and treatment services and other clinical support services. Coordination with laboratory services to support quality assurance and delivery of correct results is necessary.

Key Populations: Groups who, due to specific higher-risk behavior, are at an increased risk of contracting HIV, irrespective of the epidemic type or local context. Legal, cultural and social barriers related to their behavior increase their vulnerability to HIV. In Kenya these populations include: men who have sex with men (MSM); people who inject drugs (PWID) and sex workers (SW).



Abbreviations and Acronyms

| | |
|---------------|--|
| ART | Antiretroviral therapy |
| CHV | Community Health Volunteers |
| CIST | Client Initiated Self-testing |
| DHIS | District Health Information system |
| DICE | Drop in centre |
| HCMP | Health Commodity Management Platform |
| HIV | Human Immunodeficiency Virus |
| HIVST | HIV self-testing |
| HTS | HIV Testing Services |
| KAIS | Kenya AIDS Indicator Survey |
| KASF | Kenya AIDS Strategic Framework |
| KDHS | Kenya demographic health survey |
| MOH | Ministry of Health |
| MSM | Men who have sex with men |
| NASCOP | National AIDS and STI Control Program |
| NGO | Non –Governmental Organizations |
| PEP | Post Exposure Prophylaxis |
| PrEP | Pre Exposure Prophylaxis |
| PIST | Provider Initiated Self-testing |
| PWID | Persons who inject drugs |
| RDTs | Rapid diagnostic tests |
| SDP | Service Delivery Points |
| SOP | Standard operating procedure |
| SW | Sex workers |
| UNAIDS | The Joint United Nations Programme on HIV and AIDS |
| VCT | Voluntary Counselling Testing |
| VMMC | Voluntary Medical Male Circumcision |
| WHO | World Health Organization |



1

CHAPTER ONE: **Introduction**

1.1 Background

Globally, 36.7 million people are estimated to be living with HIV in 2015 (UNAIDS, 2016). Kenya continues to scale up HIV prevention, care, treatment and support services, making good progress in reducing the number of new HIV infections and reducing AIDS related mortality over the years. Over 1.4 million adults and 180,000 children are estimated to be HIV infected in Kenya.

The Kenya AIDS Strategic Framework (KASF) 2014/15-2018/19 sets ambitious targets for HIV prevention, care and treatment to be achieved by 2019. KASF aims to reduce new infections by 75% and AIDS related mortality by 25% by 2019. Further, Kenya has adopted the ambitious United Nations 90-90-90 global targets with the expected results of ensuring that 90% of people living with HIV know their status, 90% of people diagnosed are put on antiretroviral drugs, and 90% of those on ARVs achieve viral suppression by 2020. HIV self-testing (HIVST) is an empowering and innovative way to help achieve the first of the United Nations 90-90-90 treatment targets (1) – for 90% of all people with HIV to know their status by 2020.

The Kenya Demographic Health Survey (KDHS, 2014) indicates that 83% of women and 71% of men aged 15-49 years have ever tested for HIV. However, only 53% of HIV infected individuals have correct knowledge of their HIV status (KAIS 2012). In order to meet these ambitious targets and increase individuals' knowledge of their HIV status, the Ministry of Health launched updated HIV Testing Services Guidelines (NASCO 2015).

These guidelines emphasize accelerated identification of HIV infected persons and outline testing strategies, specific populations and service delivery points for targeted HIV testing. One of the innovative strategies is self-testing to promote knowledge of individuals' HIV status.



1.2 Overview of HIV Self-Testing

HIV self-testing (HIVST) is a process whereby an individual collects his or her own specimen (oral fluid or blood), performs an HIV rapid diagnostic test and interprets the result, often in a private setting, either alone or with someone he or she trusts. HIV self-testing is a screening test and is not sufficient to make an HIV-positive diagnosis. A reactive (positive) self-test result should therefore be confirmed using the validated national testing algorithm by an HTS-trained service provider. A person testing negative is advised to re-test if they have been exposed to HIV in the preceding four weeks, or are at an ongoing risk of HIV exposure. (Refer to Chapter 3 for more information)

POTENTIAL BENEFITS OF HIVST

HIVST has a number of benefits which are summarized as follows:

- Promotes access to HIV testing services
- Increases autonomy
- Assures confidentiality
- Empowers
- Convenient

HIVST is intended as a HIV screening tool that has the potential to meet the needs and address challenges of increasing access to knowledge of HIV status. It is a complementary strategy to increasing knowledge of HIV status and uptake of prevention, care and treatment services. HIVST has been shown to be acceptable to many diverse population groups in a variety of settings. It is generally accurate when performed with regulated and quality rapid diagnostic tests. When provided in conjunction with adequate instructions for use and post-test support services, self-testing is also effective and is an efficient strategy requiring fewer human resources than other approaches. HIVST can also be convenient and empowering for individuals and support testing for people who do not attend health and other services offering HTS.

Evidence of Self Testing in various settings

Evidence from various research and pilot projects has shown high acceptability and feasibility for HIV self-testing as well as high consumer-demand. The Kenya Health Workers Survey (KHWS) reported anxieties about testing for fear of stigma from colleagues who may assume they are HIV positive and expressed desire for self-testing (NASCO, 2006). High uptake of self-testing has been reported in Kenya by health workers (Kalibala et al 2014) and elsewhere (Kabede et al 2013; Choko et al 2015). Additionally, high uptake of self-testing has specifically been reported among the youth, men and those who had tested before. (Choko et al 2015).

Although evidence shows that these tests have high sensitivity (99.6%) and specificity (100%) (Corbett et al.), it is important to note that HIVST does not provide a confirmed HIV positive result. All reactive self-test results must be confirmed using the recommended national HIV testing algorithm. Studies have shown evidence that those who self-test are able to access additional testing for confirming the HIV positive results and post-test counseling (Pant Pai et al. 2013).



HIVST has been reported to be less costly than provider based screening in resource limited settings (Linac, 2015). It is likely that HIVST will enhance health system efficiency by focusing health services and resources on people with a reactive self-test result who are in need of further testing, support and referral. In addition, by reducing the number of facility visits for frequent non-reactive testers and eliminating the need for individuals to travel distances or wait in long queues to access HIV testing, HIVST may also be more convenient for users.

1.2.3 Potential for harm

The potential for harm can be minimized if HIV self-testing is provided within a human rights framework, adequate information is provided, regulated and high- quality self-test kits are used, and there is adequate community involvement in decision making. Although available evidence suggests that there is no significant harm associated with HIVST, programs should be sensitive to risks associated with disclosure and coercion to forceful testing. As recommended with all HTS, programmes need to consider context-specific approaches to implementing HIVST in ways that are ethical, safe and acceptable. In addition, risk mitigation in relation to social harm and the establishment of active monitoring and reporting systems are important. An emergency helpline has been put in place for testing support and referral to additional support systems

1.3 Guidelines rationale and objectives

The HIVST operational manual has been written in line with the 2015 Kenya HIV testing services guidelines. It provides the framework within which HIVST can be implemented safely, effectively and accurately.

The specific objectives of this guideline are to:

1. Outline programmatic approaches to HIV self-testing
2. Describe the package of support services required under HIVST
3. Describe commodity management systems required for HIVST
4. Outline the coordination mechanisms for HIVST
5. Outline quality assurance strategies in HIVST
6. Describe the monitoring and evaluation strategy for HIVST

1.5 Target audience

The target audience for this guideline include:-

- National and County Program managers responsible for the HIV response.
- Service providers and program officers involved in HIV prevention ,care and treatment services
- All HTS implementers in public and private sectors, including international and national NGOs, civil society and community based organizations
- Test kit manufacturers, vendors and distributors



2

CHAPTER TWO: **Approaches for HIV Self Testing**

This section outlines the various service delivery channels across public and private sectors through which HIVST will be implemented.

2.1 Hivst delivery approaches

HIVST can be delivered through two distinct approaches to reach different target populations. The approaches vary in terms of the level and type of support provided

APPROACH 1:

Directly-assisted HIVST:

Refers to trained providers, peer educators or community health workers giving an individual an in-person demonstration before or during HIVST on how to perform the test and interpret the test result. This approach can be used to support self-testers with disabilities, low literacy levels, and individuals who may require or request direct assistance in the form of in-person demonstrations and explanations before, during and/or after testing. This is especially recommended for the under 18 year olds who will require additional support and counselling..

APPROACH 2:

Unassisted HIVST;

Unassisted HIVST refers to when an individual self-tests for HIV and uses an HIVST kit with instructions for use provided by the manufacturer without the help of a trained provider or peer.



Both directly assisted and unassisted HIVST may include additional tools such as telephone helplines, mobile phone text messages, videos, social media and internet based applications which provide technical support, counselling and referrals for further HIV testing, prevention, care treatment and support services.

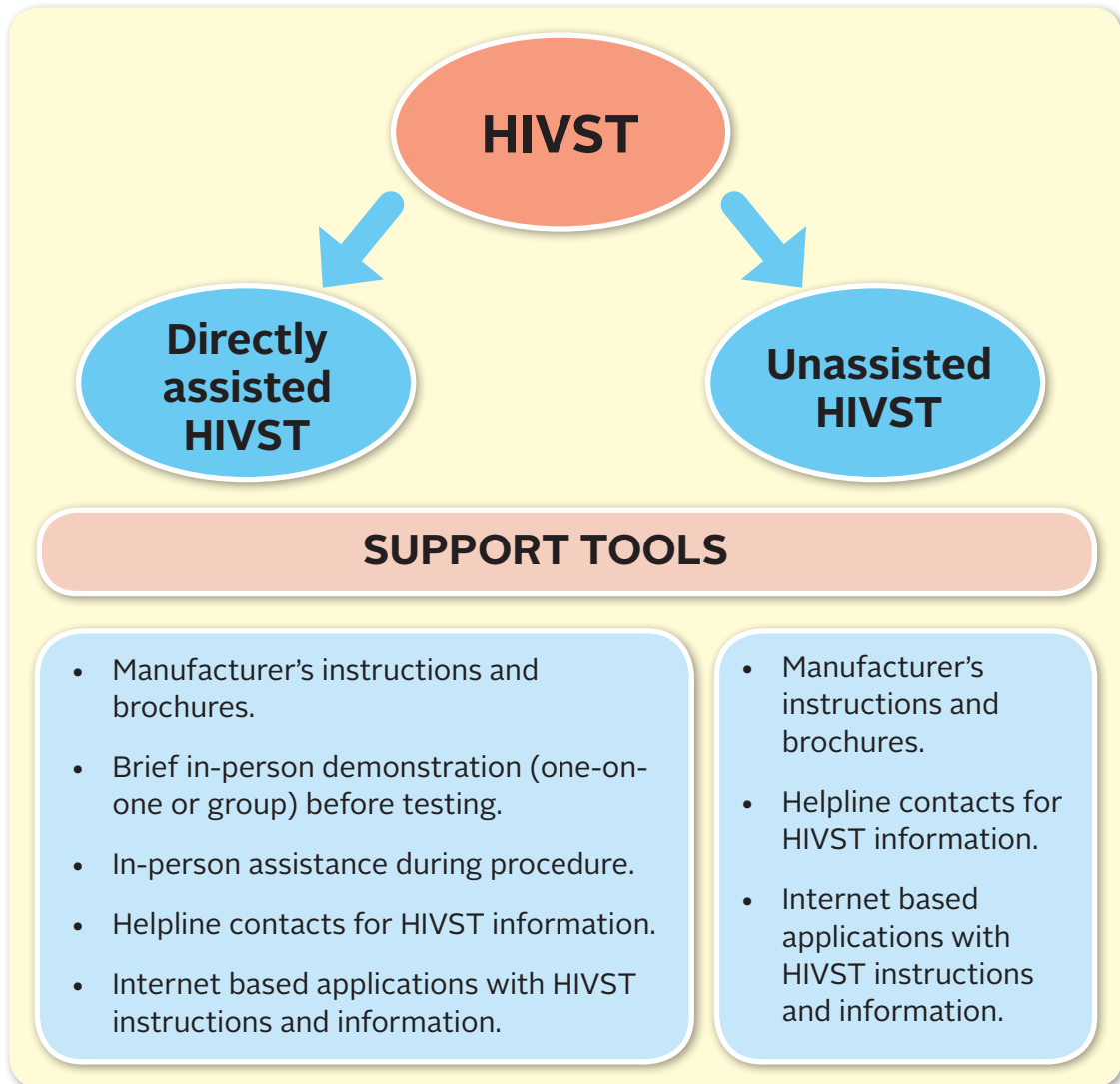


Fig 1: HIVST Approaches and Support Tools

2.2 HIVST Service Delivery Channels

The selection of HIVST service delivery channels should be dependent on the context, setting and target population. The channels used should complement other existing HIV testing models such as Provider Initiation Testing and Counselling (PITC), and address any gaps in coverage. The channels can be facility based, community based or through other conduits such as vending machines, the internet or other public and private sector channels. These are shown in figure 2.



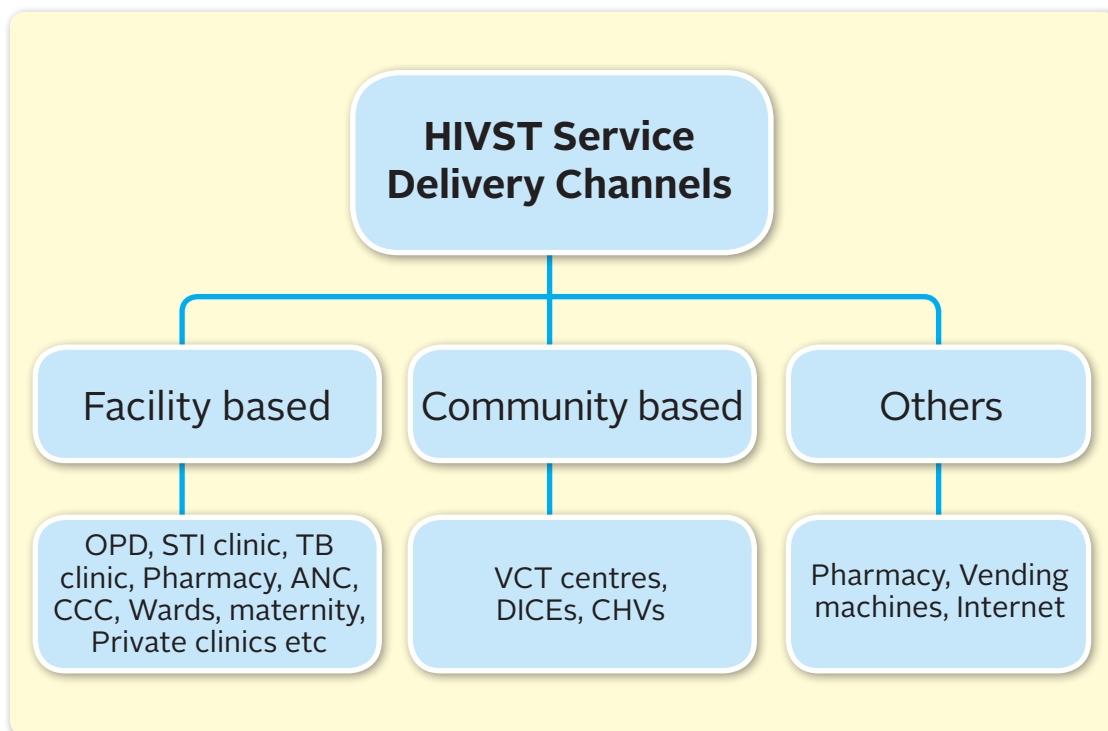


Fig 2: HIVST service delivery channels

Facility based channels: Self-testing can be accessed at both public and private health facilities. All clients seeking health services can be offered an opportunity to self-test for HIV while waiting for other services or be provided with a self-test kit to take home for use on themselves or distribution to a sexual partner. Self-testing is complementary to the existing approaches for HIV testing.

Community based channels: HIVST can be offered to community members and targeted populations such as key populations, youth and adolescents through existing community based structures such as VCT centres, Community Health Volunteers (CHVs), home based HTS, Drop In Centres (DICEs) and during outreach services.

Other channels: Alternative HIVST service delivery approaches include provision of HIVST services through:

- Couples and Partners testing e.g. providing women in antenatal or postpartum care and sex workers at DICEs with HIVST kits to distribute to their male sexual partner(s) and social networks.
- Outreach services through integration with other models across existing HIV, MNCH and public health programmes such as the VMMC programmes, programmes targeting TB, STI and viral Hepatitis patients and those providing contraceptive services.
- Workplace programmes, which may provide an opportunity to introduce HIV testing

within workplace wellness and occupational health initiatives. This can be used to reach men in high risk settings such as truck drivers, as well as health workers and their partners. Other options that employees find suitable and discreet enough to access the HIVST kits include through pharmacies, mobile phone applications etc.

- Public-private sector channels such as pharmacies or drug stores, internet, vending machines, voucher programmes, technology-home based delivery (Dial-a-Kit) etc
- Sale or distribution at institutions of higher learning, youth recreation centres and youth focused events.

2.3 Access to HIVST Rapid Test Kits

HIVST kits will be available for public health programs as well as for general public consumption through the channels shown in figure 2 above. For programmatic utilization, HIVST will be distributed through the existing HTS program both at facility and community levels. At community level, HIVST kits will be delivered through existing community programs for health programs and general public use. The general public will also access kits through other service delivery channels such as the pharmacy and vending machines.



3

CHAPTER THREE : HIV Self-Testing Package

This section covers the components of a HIVST service package. The section provides guidance on:

- The guiding principles of HIVST
- The standards and procedures for HIVST
- HIVST information package and support tools
- Linkage and referral
- Partner disclosure

3.1 Guiding Principles of HIVST

The HIVST strategy is guided by the principles of HIV testing services as is outlined in the national HTS guidelines 2015 (reprint).

THE 5CS

All forms of HTS, including HIVST, regardless of approach, are guided by core principles (5 Cs) i.e. Consent, Confidentiality, Counselling, Correct results and Connection - linkage to care and other appropriate post-test services. All HTS, including HIVST, must always be voluntary, and consent for testing must be informed by pre-test information. The 5 Cs principles of HTS apply and should be underscored in HIVST with additional emphasis as highlighted below:

i. Consent

Informed consent is important for persons who wish to undertake an HIV test. Clients for HIVST should be well informed and should voluntarily do the test without any form of coercion. For assisted HIVST, verbal consent is sufficient.

ii. Confidentiality

HIVST enables people to screen themselves for HIV in the privacy of their preferred space, hence there is no fear of breach of confidentiality. In instances of assisted HIVST, confidentiality should be maintained. Shared confidentiality with partner,

relevant others and health care providers should be encouraged to clients with reactive test results and can be of great benefit.

iii. Counseling

Everyone who wishes to carry out HIVST is entitled to adequate information before and after the test. Clients should utilize information provided in the test kit inserts. Information can be provided by HTS providers one on one, test kits dispensing points, phone helpline, and computer based applications such as live online two-way text, brochures and flyers, audio or video counseling services and YouTube videos.

iv. Correct results

Adequate and clear instructions with graphic illustrations on how to conduct self-testing should be provided with the test kits to ensure a person obtains the correct results. Clients should follow manufactures instructions in the test kits insert. **Specific quality assurance measures should be in place to ensure correct test result.**

v. Connection

All clients seeking HIVST should be advised on available linkage and referral HIV post-test services based on outcome of the test and other needs. Those with HIV negative results but with recent exposure or with an ongoing risk should seek advice from a health provider. It is recommended that individuals whose self-test results are reactive seek HIV testing services from a qualified service provider for additional testing using the national algorithm. All inserts should clearly display information on this requirement. A catalogues of health facilities can be accessed through the NASCOP website.

3.2 Standards and procedure for HIV self-testing

HIVST must be conducted using the nationally approved HIV rapid self-test kits (see Chapter 4 and 5 on kit selection and procurement).

The kit will include instructions in English and Kiswahili as well as pictorial diagrams to aid ease of use and correct interpretation of results. It is recommended that all HIVST kits distributed must also be accompanied with client education material such as e.g. FAQs. (See Appendix 1 Figure 1)

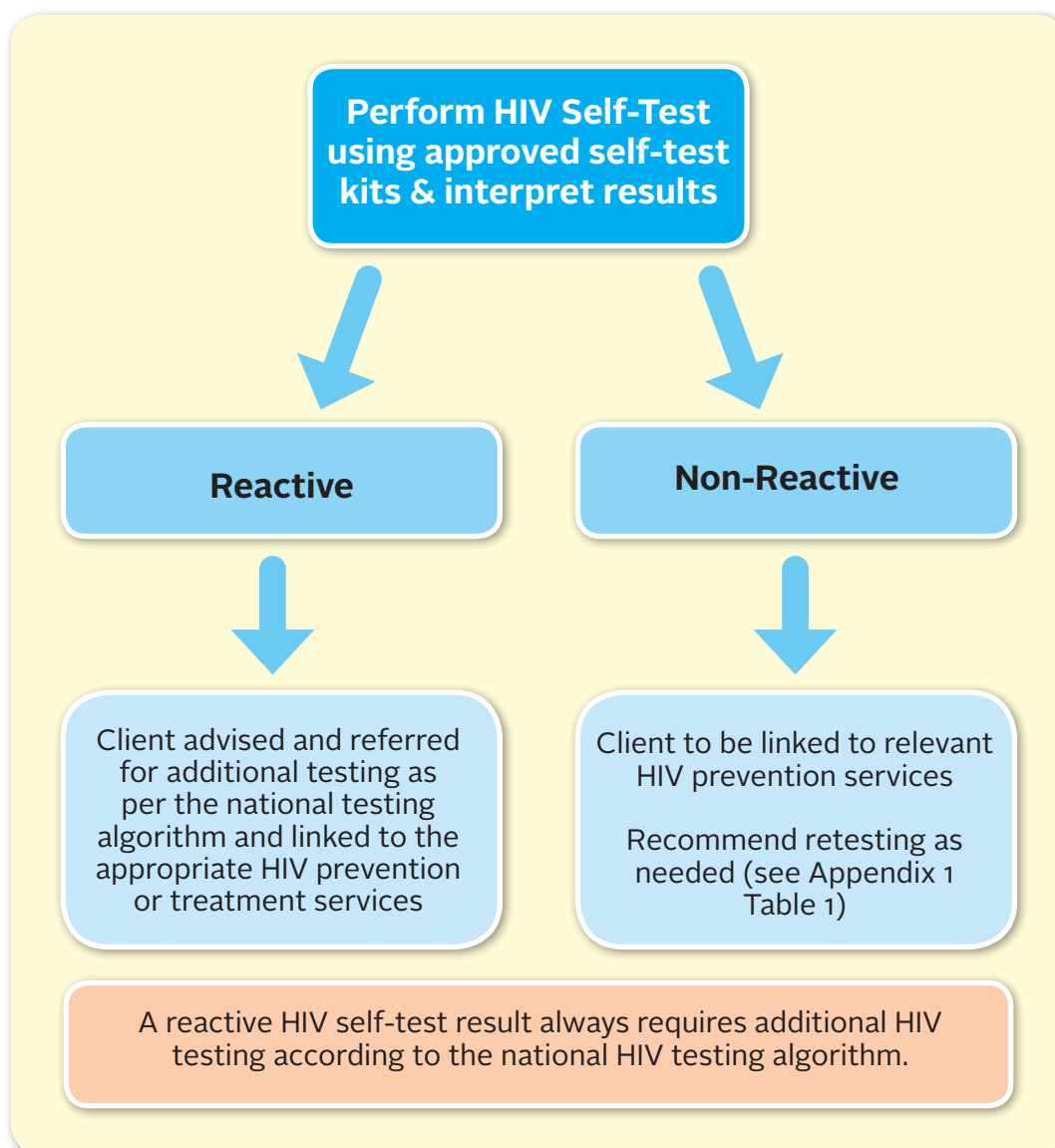
All distribution points should display illustrations or instructions on HIVST procedures should a tester require further explanation or testing support. Please refer to Appendix 1 Figure 2. In addition, all outlets must have a separate, private space especially for directly-assisted testing.

Individuals with non-reactive self-test results should be advised to re-test as per their risk to HIV infection as outlined in the national HTS guideline retesting recommendations. See



Appendix 1 Table 1. If the HIVST test result is reactive, the individual should be advised to seek further testing from a trained HTS provider, where the approved national HIV testing algorithm will be utilized to conduct the HIV test. This is shown in figure 3 below.

Figure 3: HIVST Flow chart



3.3 HIVST information package

Persons dispensing HIVST kits should be in a position to provide all the necessary information on the use of the kits. Further information on the client education package can be found in Appendix 1 Figure 1

HIVST information to self-testers will cover;

- The general instructions on how to use the test kit
- How to handle and store the test kits before undertaking the test
- How to interpret the test results
- What to do after reading the results, including information on available post-test services, such as counseling, further testing and care and treatment
- How to safely dispose of the used test-kits
- The ethical and legal obligations, such as that no one should test a third party without their consent

Support to undertake HIVST is highly recommended as part of HIVST package. Such support may include a demonstration on how to use the test kit, interpretation of results, post- test information and referrals to additional services. Tools can also be provided as part of the support.

Providers and users should be made aware that HIVST is NOT recommended for people who are already taking ARV drugs, because rapid HIV tests (including HIVST) may give false negative results as antibody levels may be lower when people with HIV are on ART. The user should also be informed that they may be required to provide some information to facilitate documentation and accountability of the kits. A short and simple self-administered tool should be used to document the details of the user. Please refer to Chapter 7: Monitoring and Evaluation and Appendix 1 Table 2. The users should also be assured that any information provided will be treated confidentially.

3.4 Referral and Linkage

In addition to delivery of effective HIVST service in Kenya, strategies should be put in place to facilitate linkage to HIV prevention, care, treatment and support following HIVST. These strategies should be integrated within the current HTS services (see Figure 4: Linkage Approaches for HIVST).

Individuals whose self-test results are reactive must seek HIV testing services by a qualified HTS service provider. The HTS provider should provide appropriate referral and linkage in line with National HIV testing services guidelines. Information on referral services can be made available through referral directories at the outlet or through internet geo-location of health facilities as well as through making enquiries via the helpline.



Figure 4: Linkage approaches for HIVST

Linkage approaches for HIVST

- Community based follow up by trained community health care workers, peer and outreach workers through telephone or SMS. This is especially applicable where HIVST is offered at community level
- Vouchers, coupons or rebates – applicable mostly to key populations
- Online audio or video counselling services and step-by-step instructions on what to do following a reactive self-test may be provided by internet, computer-based programs and applications (such as WhatsApp, Twitter etc.)
- Telephone helpline where users call for pretest and posttest counselling and technical support can still offer linkage to HTS
- Bulk mobile phone text message services to provide information, reminders and linkage messages
- Through public gathering (barazas) conducted by local administration and in market places where information on where to find HTS services is given

3.5 HIV Self-Testing Promotion and Communication

To create awareness and increase utilization of HIVST, advocacy and communication strategies should aim to emphasize on correct usage of the self-test kits, and ensure correct interpretation of results and create awareness of the need for linkage for additional testing, HIV prevention, care and treatment. These can be enhanced through the following communication strategies:

Healthcare providers

- Sensitization of healthcare providers on HIVST as an additional strategy for increasing access for HTS. This can be done through guidelines dissemination, Continuous Medical Education sessions (CMEs), On the Job Training (OJTs), Information Education Communication (IEC) materials, etc.
- Integration of HIVST into existing programs e.g. PMTCT, PrEP/PEP, HTS, VMMC, key population programs, care and treatment and other routine health services
- Encouraging healthcare providers to advocate for use of HIVST to increase testing among PMTCT clients, partner testing and key populations.

General population

- Sensitization and awareness creation of general population on HIVST as an option for knowing one's HIV status. This can be done through health talks, mass media campaigns, brochures and flyers, billboards, digital platforms such as the internet, social media platforms WhatsApp, Facebook, Twitter etc.
- Use of self-testing champions drawn from CHVs, peer educators, expert patients to promote the use of HIVST
- Leverage on existing workplace wellness programs to promote HIVST. This could be



useful in reaching those who are hesitant to access existing HTS services in the workplace due to stigma and discrimination as well as reaching men and other key populations

- Leverage on opinion leaders and civil society groups to engage their networks, creating demand and offering HIVST support and encourage linkage

3.6 Partner Notification and Disclosure

- Clients should be informed about the potential health benefits of disclosing their HIV status to significant others prior to receiving their self-testing kits. This information should be included in the clients' information pack. Clients with reactive HIVST results should be encouraged to visit an HTS service point with their partners for further testing as per the national HTS testing algorithm and receive supported disclosure. Clients whose test result is non-reactive should also be encouraged to disclose their status to their sexual partners and encourage their partners to know their HIV status through use of HIVST kits or a visit to an HTS service point.
- Health providers should assess for possible social harm and/or violence following disclosure, such as intimate partner violence, and provide guidance and referral as appropriate.



4

CHAPTER FOUR: **Commodity Management**

This section covers the management of commodities and commodity data for HIVST across public and private sectors.

4.1 Commodity Management

This represents the set of practices that must be coordinated to ensure that appropriate, high quality supplies are available whenever and wherever they are needed. It entails proper coordination and management of commodities in order to ensure the six rights in supply chain, i.e. the right commodities in the right quantities, in the right condition delivered to the right place at the right time and for the right cost.

4.2 Kit Selection

The selection of the kits to be procured nationally will be guided by the HIVST selection criteria. (See Chapter 6 Table 2). In-country validations must be conducted by authorized government laboratories.

4.3 Quantification And Procurement

For the public sector, quantification will be done through the annual national forecasting and quantification process, while in the private sector; this will be done based on demand. Procurement will be done by KEMSA for the public sector while for private sector it will be done through the mechanisms established for commercial procurement.

4.4 Allocation and test kits distribution plan to service delivery points

For the public sector, the current commodity management system will be adopted. Kits will be allocated initially based on estimates and subsequently on consumption reports. Data on the number of test kits issued will be generated through the county reporting and allocation mechanisms. Rationalization of kits allocated will be done by the national commodity TWG prior to distribution. The allocation and distribution plan in the private sector will be based on the demand generation and distribution mechanisms in place.

4.5 Inventory Management

The management of the kits will be aligned to the existing inventory management system. This will include receipt of kits, storage according to the manufacturer's instructions or in adherence to the recommended storage guidelines and distribution to service delivery points (SDPs). Proper record keeping shall be ensured by use of the existing tools (stock cards) and commodity management reporting systems.

5

CHAPTER FIVE: **Coordination**

This section outlines the various players and their roles in the coordination of HIVST.

5.1: Roles and Responsibilities

The coordination of HIV self-testing services will be done in line with the coordination mechanism as described in the Kenya HIV Testing Guidelines (Chapter 10). In addition other key actors that include the regulatory bodies, professional associations and test kit manufacturers, distributors and vendors will also be involved and specifically to coordinate the private sector.

This is a multi-faceted and multi-level activity that spans the national, county and lower level structures. At each level, various bodies are responsible for various functions as indicated below.

Table 1: Roles and Responsibilities

| NATIONAL: | |
|--|--|
| Institution | Roles and Responsibilities |
| National AID and STI Control Programme (NASCOP) | NASCOP is responsible for the development and dissemination of HIVST policy, strategic documents, guidelines and implementation support tools, provision of technical assistance on the implementation and capacity building of the County Health Management Teams (CHMTs).It also coordinates the implementing partners who provide HIVST services at all levels. Development of HIVST M & E tools and indicators as well as quality assurance is part of NASCOPs roles and responsibilities through the leadership of the national HTS technical working group |
| National AIDS Control Council (NACC) | At the national level, NACC will provide strategic guidance on the HIV response, coordinates all stakeholders and promote utilization of HIVST services. It will also be responsible for the coordination of the Civil Society (CSOs) and Community-based Organizations (CBOs). |



| | |
|---|---|
| National HIV Reference Laboratory (NHRL) | NHRL will be responsible for <ul style="list-style-type: none"> • Overall quality assurance in HIVST services • Test Kit validation and new lot verification • Conduct post market surveillance HIVST test kit |
| Kenya Medical Supplies Agency (KEMSA) | <ul style="list-style-type: none"> • Procurement, warehousing and distribution of HIVST kits |
| Health Information System (HIS) | Registration of HIVST M&E tools as developed under the leadership of NASCOP |
| Regulatory Authorities | These includes Kenya Pharmacy and Poisons Board, Kenya Medical Laboratory Technologist Board (KMLTB). NASCOP shall work with these bodies in ensuring adherence to HIVST protocols. |
| Professional Associations | These includes but is not limited to Kenya Medical Practitioners and Dentists Board (MPDB), Pharmaceutical Society of Kenya (PSK), Kenya Pharmaceutical Association, , Kenya Medical Association (KMA), Nursing Council of Kenya (NCK), Kenya Medical Laboratory Technologist Board (KMLTB), Clinical Officers Council(COC) and Kenya Private Hospitals Association. NASCOP shall work with these bodies in the coordination of HIVST services within the private sector. This will include distribution of the HIVST kits, training and accreditation of private sector service providers and service delivery points as well as ensuring adherence to HIVST protocols. |
| Manufacturers and Suppliers of Test kits | <ul style="list-style-type: none"> • Ensure HIVST kits brought in the country conform to the national guidelines • Provision of patient education information in the inserts • Provision of training to their distributors |
| COUNTY LEVEL | |
| County Health Management Teams (CHMT) | <ul style="list-style-type: none"> • Management of HIVST service delivery including human resource management and training • Ware housing and distribution of HIVST commodities • Printing and distributions of M&E tools and the nationally recommended IEC materials • Development of infrastructure for HIVST services • Provision of supervision of HIVST services • Conduct monitoring and evaluation • Ensures the provision of quality HIVST services • Distribution and utilization of data collection and reporting tools • Coordination of data reporting at service delivery points |
| Service Delivery Points | <ul style="list-style-type: none"> • Provision of quality HIV Self testing services • Performance monitoring and reporting • Commodity management and reporting • Human resource management • Provision of follow up confirmatory HIV testing <p style="text-align: center;">Community level organizations</p> <ul style="list-style-type: none"> • Community mobilization and advocacy • Provision of quality HIV services • Provision of or referral for follow up confirmatory HIV testing • Data collection and reporting ¹ |

¹ NB: Promotion of HIVST services will be done at all levels



5.2 Private-public partnerships (PPP)

The PPP initiative aims to link the private health providers to the national HTS program. The PPP will assist the country in achieving the gaps in the 1st go. This will include and are not limited to:

- i) Coordination of the private sector in providing HTS services
- ii) Dissemination of national policy and guideline to the private sector
- iii) Management of data which includes collection and reporting to the national and county level
- iv) Analysis and use of data for decision making at various levels
- v) Quantification and monitoring of HIVST kits
- vi) Incorporation of national QA schemes in private sector
- vii) Facilitating linkage;
 - a. For additional HIV testing by a trained HTS provider.
 - b. Into care and treatment

The coordination of the PPP will be led at the national level by NASCOP, and by the County Director of Health at county level. The PPP should include representation from organizations listed in Table 1.



6

CHAPTER SIX: **Quality Assurance**

This section aims to provide guidance on:

- Ensuring the quality of HIVST test kits
- Ensuring quality of the HIVST process

6.1 Benefits of Quality Assurance in HIVST

Quality Assurance is a systematic planned approach to monitor, assess and improve quality of services on a continuous basis. Quality assurance is an integral part of all HIV Testing Services (HTS) and should be implemented through simple and practical approaches at all levels.

For HIVST, a focus on quality assurance will:

- Ensure that the client gets correct test result
- Ensure the need and expectations of clients and communities are met in terms of HIV testing.
- Outline how the HIVST process and supporting service delivery mechanisms can be improved.
- Ensure standardization to facilitate access to quality services

6.2 Components of quality assurance for HIVST

Quality assurance for HIV self-testing can be considered in terms of quality assurance of the test product and of the HIV self-testing process.

6.2.1 QUALITY ASSURANCE OF HIV SELF-TEST KITS

WHO Prequalification

All test kits for national procurement MUST attain WHO pre-qualification of the HIV self-test kit



In-country laboratory validation

All test kits must undergo in-country laboratory validation to ensure that they meet the minimum inclusion criteria.

Registration by regulatory bodies

All HIVST test kits must be validated, certified and registered by relevant national regulatory authorities before being dispatched into the market

Lot to lot validation

All procuring entities must ensure that any new lots of HIVST test kits coming into the country are evaluated to ensure that products delivered meet criteria for quality and performance. Only lots with satisfactory results should be distributed.

Post-market surveillance

Post-market surveillance will be conducted periodically by authorized government agency to assess the quality and performance of the test kits in use, in compliance with the set standards.

Refer to Table 2: Factors to consider when selecting HIVST test kits.

6.2.2. Quality assurance of the hiv self-testing procedure

Capacity building and sensitization on HIVST

All HIVST service providers should be sensitized according to the HIVST training package (Appendix 1). This includes capacity building and knowledge on how to conduct the tests and where to refer clients to for linkage for additional testing and further support.

Availability of testing aids, Instructions for Use (IFU) and Standard Operating Procedures (SOPs) at the outlet,

Information on HIVST including but not limited to how to conduct a HIV self-test and results interpretation should be readily available to all clients. All clients must also be aware of the need to confirm any reactive test results as per the national HIV testing algorithm.

Infection, prevention and control

While the risk of HIV transmission through HIV self-tests has been demonstrated to be minimal, clients should be made aware of correct practices to minimize biosafety risks (See Appendix 2)

Referral and linkages

Information on referral and linkage to HIV appropriate services should be made available to all clients. In the event of a reactive HIV self-test result, clients must be made aware of where additional testing can be conducted. A referral directory should be available for HIV additional testing and other services.



Table 2: Factors to Consider When Selecting HIV Self-testing Kits

| Criteria | Desired Characteristics |
|---|--|
| Sensitivity | Above 99% |
| Specificity | Above 99% ¹ |
| Ease of Use | Should not require additional equipment to perform Should not require technical training to perform the test Stable end-reading points Results should not need interpretation with additional equipment |
| Rapidity of the test (time to result) | Should avail a result within 20 minutes |
| Storage Conditions | 2-30 degrees Celsius |
| Shelf-life | Above 6 months |
| Packaging | Single packing of complete set Retractable lancets (blood kits) |
| * Kit should be affordable to increase access to HIVST by most people | |

¹ From laboratory evaluation

7

CHAPTER SEVEN: **Monitoring & Evaluation**

This section outlines the monitoring and evaluation (M&E) requirements to inform uptake and utilization of HIVST.

7.1 Indicators for M&E In HIVST

National and institutional specific standard tools should be utilized by the HIVST service providers and programmers to collect and report data. Reports should be sent, to the relevant levels as specified in the national HTS guidelines and as per specific programs requirements. Refer to Appendix 3 for further information.

The following indicators will be reported to the national level:

1. HIVST service delivery points/outlets (Source: MFL code, accreditation number)
2. Total number of test kits issued / sold (Source: KEMSA/manufacturers sales records and individual vendors)
3. Total number of persons reporting having done self-testing (Source: Helpline, hits on the website, HIVST/HTS register)

Other indicators that can be collected at service delivery and program levels are;

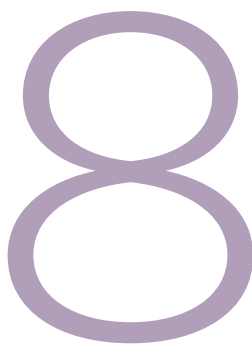
- Number of persons referred for HIVST by age and gender (source: HTS register / HIVST register)
- Number of persons offered HIVST by age and gender (source: HIVST register)
- Number of people accessing HIVST by age and gender (source: HIVST register)
- Number of people reporting results (Reactive and non-reactive outcomes) (source: HIVST register)
- Number of people reporting reactive results accessing HIV testing using the national algorithm (source: HIVST register)

Reporting tools and systems

There is need to develop HIVST tools to capture and report on data at service delivery points. These tools should include:

- i. The HTS register with HIVST incorporated or a HIVST register
- ii. Commodity tools (FCDRR/FMAPS)
- iii. Linkage register
- iv. To incorporate HIVST in the DHIS reporting tools (731)






APPENDICES

Appendix 1:

Table 1: Re-testing Recommendations

| Scenario/Population | Recommendation for Re-testing |
|--|--|
| General population | Re-test annually (for children, re-testing is only required if there is a new exposure) |
| Key populations | Re-test every 3 months in case of frequent instances of high risk exposure |
| Negative partner in discordant union | Re-test at the initiation of ART for the HIV positive partner, and every 3 months until HIV-positive partner achieves viral suppression. Once viral suppression is confirmed re-testing can be performed every 6 months. Other prevention services should still be recommended, including consistent and correct use of condoms. Assess for eligibility and willingness for PrEP |
| Pregnant women | Test in first trimester or first contact; re-test in the third trimester. All women who were not tested during the third trimester should be tested during labour and delivery |
| Breastfeeding mothers | Re-test after delivery at 6 weeks, at 6 months then follow testing recommendations as per their risk category |
| Persons who had a most recent (e.g. less than a month) specific exposure incidence | Test at initial presentation and re-test at 4 weeks, after which annual re- testing applies |
| Symptomatic STI patients | Test at initial presentation and re-test at 4 weeks, after which annual retesting applies |
| PWID | Re-test every 3 months |
| Individuals on -re-exposure Prophylaxis (PrEP) | Re-test every 3 months |
| All persons newly diagnosed as HIV positive | retest with a second specimen using the same testing algorithm at CCC, before enrollment into care initiation of ART (particularly pregnant or lactating women, children under 5, TB patients, KPs), to rule out potential misdiagnosis |

Table 2: Client Data Card

| | |
|---|--|
| <p>Thank you for taking this bold step to perform your own HIV testing. This information will remain anonymous and will assist in improving Self-testing services. Please do not include your name or your phone number</p> <p>Age (years): [____]</p> <p>Gender: Female [__] Male [__]</p> <p>Have you ever tested for HIV before?: Yes [__] No [__]</p> <p>How long ago did you have the HIV test Never [__] Last three months [__] Last one year [__] Longer than one year [__]</p> <p>What Type of HIV self-test kit have you purchased today: Oral [__] Blood [__]</p> | <div style="text-align: center;">  </div> <p style="text-align: center;">What is the main reason for testing? (select one only):</p> <ul style="list-style-type: none"> • To understand illness/ symptoms that I have/had • Advice from the pharmacist/ my doctor • I recently had a possible exposure to HIV • To plan the future/ take charge of my own health/ getting married • Encouraged by sex partner • It has been longer than 1 year since I last tested • Other reason (please indicate): _____ _____ _____ |
|---|--|





Key Messages

- Always obtain a HIV self-test kit from an authorized provider/outlet
- Always follow the instructions provided in the self-test kit or by provider when conducting a HIV self-test
- HIV reactive results are not conclusive and a person should seek further HIV testing from a HTS service delivery point at facility or community level
- Adhere to proper infection prevention and control measures



Safety

- Maintain proper mouth and hand hygiene
- In oral HIVST, the risk of HIV infection transmission is minimal.
- Where blood-based kits are used biosafety and infection prevention control measures should be adhered to as per manufacturers' instructions.
- Used kits should be disposed of as per manufacturers' instruction.



Referral and Linkage

- HIV self-testing is a screening test
- The vendor of HIVST kits should map and identify facilities that can provide further HIV testing
- Clients should be counselled on the importance of additional HIV testing in case of a reactive test.
- Clients on substantial risk of HIV acquisition should be counselled on how to stay negative and/or referred to facilities for additional preventive strategies e.g. PrEP

The test should not be done immediately after brushing or sterilize your mouth

The kit is for single use.

Do not share the kit. If you have to test as a couple/family, have individual kits

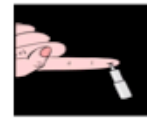
Do not test your partner or anyone without his/her will.

- 1 **OPEN** the HIVST kit package carefully and place the test kit pieces on a flat surface. Do not spill or drink the content.
- 2 **READ** the test kit insert carefully before using the test.
- 3 **PERFORM** sample collection as per the package insert.

Perform **ORAL** fluid sample collection



OR



- 4 **Interpret or Read** test results after the recommended time as indicated in the kit insert. Reading results after the recommended time may give wrong results.



- 5 **INTERPRET** test results using the instructions from the test kit



- 6 **DISPOSE** off the used test kit following the instructions provided



- 7 **SEEK** follow up services based on your test results

If your test turns **reactive** (POSITIVE)

Either **CALL** the Help Line provided



OR

VISIT online Help Site (<http://www.nascop.or.ke/index.php/hiv-prevention/>)



THEN

SEEK additional testing (HTS) at health facility or community VCT by a trained HTS provider



If your test turns **non-reactive** (NEGATIVE)

READ the manufacturers insert about HIV prevention options

SEEK prevention services at a health facility or community setting, as required



Appendix 2:

Biosafety Recommendations

Standard Precautions

The following steps should be taken to ensure personal and environmental safety.

- ***Hand hygiene***

Testers should wash their hands with soap and clean running water before and after the HIV self-test procedure

- ***Good housekeeping***

Testers should ensure the testing area has been left clean after testing has been completed.

- ***Safe waste disposal***

The contents of the test kits should be disposed of as per the manufacturer's instructions. In case of assisted HIVST, the provider should follow the standard operation procedures for infection control.



List of Contributors

| | |
|----------------------|-------------|
| Betty Chepkwony | NASCOP |
| Charles Mutie | KDF |
| Daniel Koma | AFYA JIJINI |
| Dr.Christine Kisia | WHO |
| Dr.David Bukusi | KNH |
| Dr Joyce Wamicwe | NASCOP |
| Dr.Mohammed A.Sheikh | NASCOP |
| Dr.Samson Ndege | MTRH/MU |
| Dr.Sarah Masyuko | NASCOP |
| Edward Musau | NASCOP |
| Jane Kanga | KDF |
| Jones Mutiso | CHS |
| Joseph Gatimu | LVCT Health |
| Kennedy Muthoka | CHS |
| Moses Baraza | NHRL |
| Olivia Njathi | CHAI |
| Judi Lusike | CHAI |
| Patricia Oluoch | CDC |
| Muthoni Junghae | CDC |
| Pauline Mwololo | NASCOP |
| Peter Maingi | KNH |
| Roseline Warutere | NASCOP |
| Rosemary Njogu | JHPIEGO |
| Sarah Wanyonyi | NASCOP |
| Susan Kimani | PS Kenya |
| Peter Mogere | AVAC |
| Timothy Nzomo | NHRL |
| Franklin Kitheka | NPHLS |
| Tom Marwa | JHPIEGO |
| George Nchebere | DoD |

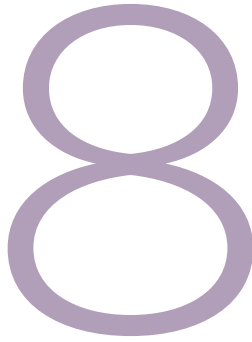
Editorial Team

| | |
|--------------------|-------------|
| Betty Chepkwony | NASCOP |
| Dr.Christine Kisia | WHO |
| Dr.Samson Ndege | MTRH/MU |
| Dr Joyce Wamicwe | NASCOP |
| Dr.Sarah Masyuko | NASCOP |
| Edward Musau | NASCOP |
| Jones Mutiso | CHS |
| Joseph Gatimu | LVCT Health |
| Kennedy Muthoka | CHS |
| Olivia Njathi | CHAI |
| Pauline Mwololo | NASCOP |
| Roseline Warutere | NASCOP |
| Sarah Wanyonyi | NASCOP |
| Susan Kimani | PS Kenya |
| Peter Mogere | AVAC |

External Reviewers

| |
|-------------|
| LVCT Health |
| CHAI |
| WHO |





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