



Ministry of Health
ESWATINI

HIV SELF-TESTING

STANDARD
OPERATING PROCEDURE FOR THE
DELIVERY OF HIV SELF-TESTING
SERVICES IN SWAZILAND



Swaziland National AIDS Program

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 HIV testing services (HTS) provision in this Swaziland. The development of this HIVST standard operations procedure was therefore necessitated by the need to increase the uptake of HIV testing in the country.

HIVST 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 counselling services with information about their HIV status. Thus, HIVST has the capacity to significantly contribute to the national objective of universal knowledge of HIV status.

This SOP presents information on the approaches, procedures, self-testing standards, potential benefits, risks, education materials, policies and regulatory considerations. The SOP targets both private and public health care providers, NGOs, individual researchers and any other relevant healthcare workers providing HIV services within the community and clinical settings to ensure a wider reach.

I strongly encourage Swazis to advocate for the utilization of the HIVST in the country but within the framework of relevant national policies and the constitution. The development of the HIVST standard operational procedure is a result of the efforts by the National HIVST task team, the HTS technical working group and coordinated by SNAP. I thank the SNAP HTS Team for spearheading this process and working tirelessly with the partner organizations to develop this HIVST guideline. Special and sincere appreciation also goes to all technical personnel and individuals who participated in meetings and workshops to share useful ideas towards the development of this document.

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ACRONYMS

ARV	Antiretroviral therapy
CBOs	Community Based Organization
CME	Continuous Medical Education
CSO	Civil Society Organization
EC	Expert Clients
F/U	Follow Up
HIV	Human Immunodeficiency Virus
HIVST	HIV Self-Testing
HMIS	Health Management Information System
HTS	HIV Testing Services
HCW	Health Care Workers
IEC	Information Education Communication Material
KPs	Key Population
NGO	Non-Government Organization
M&E	Monitoring and Evaluation
MOH	Ministry of Health
PEP	Post Exposure Prophylaxis
PrEP	Pre-Exposure Prophylaxis
PMTCT	Prevention of Mother to Child Transmission
QA	Quality Assurance
RHMT	Regional Health Management Teams
SHIMS	Swaziland HIV Incidence Measurement Survey
SNAP	Swaziland National AIDS Programme
SOP	Standard Operating Procedures
UNAIDS	United Nations Programme on HIV/AIDS
VMMC	Voluntary Medical Male Circumcision

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 unassisted

Directly Assisted HIV self-testing: Refers to when an individual who is performing a self-test for HIV receives an in-person demonstration from a trained provider or peer before and/or during HIVST. This assistance is provided in addition to the manufacturer supplied instructions for use and other materials found inside HIVST kits.

Unassisted HIV self-testing: Refers to an individual obtaining a kit for HIVST and performing the HIV test following the instructions on the insert on their own without assistance.

Reactive results: This means that the test indicates that HIV antibodies are present in the oral fluid sample. Anyone whose result is reactive to 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 oral fluid sample. Anyone whose result is nonreactive to 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 or trained health care worker that offers HIVST services.

HIV testing services (HTS): Indicates the full range of services that a client is offered together with HIV testing. This includes counselling (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.

EXECUTIVE SUMMARY

Low 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) 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 supervised by an HTS counsellor or unsupervised. The HIVST strategy is guided by the principles of HIV Testing Services (HTS) as outlined in Chapter 2 of the Swaziland Integrated HIV Management guidelines of 2015. It has similar requirements with current HIV testing and counselling approaches including commodity management, quality assurance and linkage to care.

The coordination of HIVST services will be a multi-faceted and multi-level activity that spans the national, regional and lower level structures of the health system and needs to be done in line with the coordination mechanism as described in the Swaziland Integrated HIV management Guidelines 2015 (Chapter 2).

These standard operating procedures outline the programmatic approaches to HIVST, describe the package of support services required under HIVS, describe commodity management system requirements and outline coordination mechanisms for HIVST. They also outline quality assurance strategies, and monitoring and evaluation for HIVST.

CHAPTER 1: INTRODUCTION

Globally, 36.7 million people are estimated to be living with HIV in 2015. Swaziland 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 years¹. Swaziland has adopted the ambitious United Nations 95-95-95 global targets with the expected results of ensuring that 95% of people living with HIV know their status, 95% of people diagnosed are put on antiretroviral drugs, and 95% of those on ARVs achieve viral suppression by 2030².

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 an empowering and innovative way to help achieve the first of the United Nations 95–95–95 treatment targets (1) – for 95% of all people with HIV to know their status by 2030. HIVST is a process whereby an individual conducts his or her own HIV test using a simple oral 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. Considerable efforts have been made in Swaziland to respond to the HIV testing gap of 5% of the first 90 of the UNAIDS 90-90-90 goal as recently highlighted by the SHIMS 2 results for HIV positive adults knowing 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.³ HIVST also

¹ UNAIDS, Global AIDS updates 2016, Available:

http://www.unaids.org/sites/default/files/media_asset/global-AIDS-update-2016_en.pdf

² UNAIDS, Fast track ; ending the AIDS epidemic by 2013, Available:

http://www.unaids.org/sites/default/files/media_asset/JC2686_WAD2014report_en.pdf

³ Rooyen v H, Tulloch O, Mukoma W, Makusha T, Chepuka L, Knight LC, Peck RB, Lim JM, Muturi N, Chirwa E, Taegtmeier M. What are the constraints and opportunities for HIVST scale-up in Africa? Evidence from Kenya, Malawi and South Africa. *J. Int AIDS Soc*, 2015; 18(1):19445.

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 or unassisted.

This Standard Operating Procedure (SOP) defines the delivery of HIV Self-Testing services in Swaziland.

1.1 Overview of HIV Self-Testing

HIVST is a process whereby an individual collects his or her own specimen, performs an HIV rapid diagnostic test and interprets the result, often in a private setting, either alone or with someone he or she trusts and or a health worker. HIVST is a screening test and is not sufficient to make an HIV-positive diagnosis. A reactive self-test result should **always** be confirmed using the national testing algorithm by an HTS-trained service provider. A non-reactive self-test result does not need to be confirmed by a HTS-trained service provider. A person will be advised to re-test as per National HIV Integrated Guidelines, Chapter 3.

1.2 Potential benefits of HIVST

HIVST has several benefits which include:

- Promoting access to HIV testing services
- Increasing clients autonomy
- Assuring confidentiality
- Empowering individuals
- Convenience

HIVST is intended as a HIV screening tool that has the potential to meet the needs and address challenges in people knowing their 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 settings⁴. It is generally accurate when performed with regulated and quality rapid diagnostic tests⁵. When provided in conjunction with adequate instructions for use and

⁴ WHO HIV testing Policy Brief, December 2016. Available: <http://apps.who.int/iris/bitstream/handle/10665/251549/WHO-HIV-2016.21-eng.pdf;jsessionid=80027CBD9F172EFEEDA2F8C65704F32A?sequence=1>

⁵ UNITAID, WHO and PSI. Market and technology landscape. HIV rapid diagnostic test for self-testing, 3rd edition, 2017. Available: https://unitaid.eu/assets/HIV-Rapid-Diagnostic-Tests-for-Self-Testing_Landscape-Report_3rd-edition_July-2017.pdf

post-test support information, 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 who do not attend other health approaches offering HTS.

Evidence from various research and pilot projects has shown high acceptability and feasibility for HIV self- testing as well as high consumer-demand. Although evidence shows that these tests have high sensitivity (99.6%) and specificity (100%) it is important to note that HIVST does not provide a confirmed HIV positive result⁶. All reactive self-test results must be confirmed using the recommended national HIV testing algorithm. Studies have shown evidence that those who self-test can access additional testing for confirming the HIV positive results and post-test counselling⁷.

HIVST has been reported to be less costly than provider based screening in resource limited settings.⁸ 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 need 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.

1.3 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

⁶ Choko AT, Desmond N, Web EL, Chavula K, Naierala-Mavedzenge S, Gaydos CA, Makombe SD, Chunda T, Squire SB, French N, Mwapasa V, Corbett EL. The Uptake and Accuracy of Oral Kits for HIV Self-Testing in High HIV Prevalence Setting: A Cross-Sectional Feasibility Study in Blantyre, Malawi. 2011. Available: <https://doi.org/10.1371/journal.pmed.1001102>

⁷ Pant Pai N, Sharma J, Shivkumar S, Pillay S, Vадnais C, Joseph L, et al. (2013) Supervised and Unsupervised Self-Testing for HIV in High- and Low-Risk Populations: A Systematic Review. *PLoS Med* 10(4): e1001414. <https://doi.org/10.1371/journal.pmed.1001414>

⁸ Potential Impact and Cost-effectiveness of Self-Testing for HIV in Low-Income Countries ,Benjamin P. Linas, *The Journal of Infectious Diseases*, Volume 212, Issue 4, 15 August 2015, Pages 513–515, <https://doi.org/10.1093/infdis/jiv041>

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 HIVST information line has been put in place for testing support and referral to additional support systems

1.4 SOP objectives and target audience

The HIVST SOP provides the framework within which HIVST can be implemented safely, effectively and accurately.

The specific objectives of this SOP are to:

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

The target audience for this guideline include:

- National and Regional Program managers responsible for the HIV response
- Service providers and program officers involved in HIV prevention, care and treatment services
- All HTS implementing partners public and private, national NGOs, civil society and community based organizations (CBO)
- The Laboratory service staff.

CHAPTER 2: HIVST APPROACHES DELIVERY MODELS

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

2.1 Directly Assisted HIVST

Refers to trained HTS provider 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 an in-person demonstrations and explanations before, during and/or after testing.

2.2 Unassisted HIVST

Unassisted HIVST refers to when an individual self-tests for HIV and uses an HIVST kit without the help of a trained HTS provider. Unassisted HIVST also includes clients receiving HIVST kits through secondary distribution, e.g. from a partner that attended HTS.

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

Table 1: HIVST distribution methods

DIRECT HIVST DISTRIBUTION TO CLIENT
<ul style="list-style-type: none">▪ Client given information on HIVST as an option for HIV testing <p>If a client opt to take the kit home:</p> <ul style="list-style-type: none">▪ Provide pre-test information on HIV transmission, prevention and treatment▪ Provide instructional video through 'WhatsApp' and 'Share it' (Optional)▪ Client encouraged to use the HIVST information line▪ Emphasis will be made on confirmation of HIV positive result within 1 week.

SECONDARY HIVST DISTRIBUTION TO CLIENT

For any client undergoing HIV testing, an HIVST kit can be given to be distributed to their partner(s). **Priority groups** to receive secondary distributed HIVST kits include:

- Partners of pregnant and lactating women
- Partners, family members and peers of KPs and index cases

HIVST kits can also be provided as a strategy for index testing to partner(s) of previously tested HIV positive clients.

- HIVST is kit given to client to take to the partner
- Instructional video shared with client through 'WhatsApp' and 'Share it' platforms
- Client gives partner information on HIVST and shares the video with partner
- Client gives partner kits to perform the HIV test
- If partner is negative, they are encouraged to retest as per ongoing risk.

→If the partner screens positive, partner is encouraged to go to any preferred facility for confirmation test within 1 week.

DIRECTLY ASSISTED DISTRIBUTION

- Client given information on HIVST as an option for HIV testing
- Client given an option between testing on site or taking the kit home

If a client opt to perform test on site:

- Client is given pre-test information
- Client has access to a private room, gazebo or cubicle on site to perform the test
- Instructional video or materials should be provided
- Additional information can be provided where needed.
- Client performs the test
- Clients are encouraged to discuss the test result with a provider.
- Reactive test results should be confirmed on site with the assistance of a counsellor using the national algorithm
- Referral and linkages for both negative and positive clients as indicated.

If a client opt to take the test off site:

- Client is given pre-test information including available services post HIVST.
- Instructional video or materials should be provided
- Additional information can be provided through the HIVST information line.

- Client performs the test at any preferred place.
Emphasis will be made on confirmation of HIV positive result within 1 week

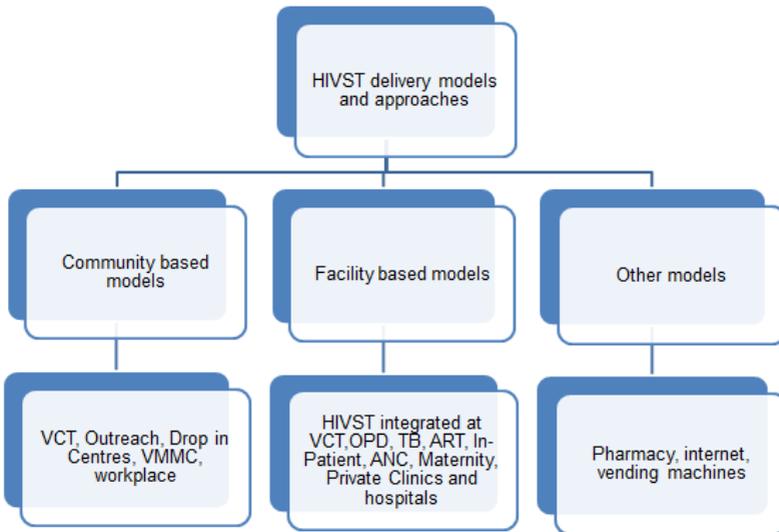
2.3 Access to HIVST Rapid Test Kits

HIVST kits will be availed for public health programs as well as for public consumption through different channels. 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 public use. The public will also access kits through other service delivery channels such as the pharmacy and vending machines soon.

2.4 HIVST Service Delivery models

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 Client Initiated HIV Testing Services (CIHTS), Provider Initiated HIV Testing Services (PIHTS) and address any gaps in HTS coverage. The channels can be facility based, community based or through other conduits as well. See the figure 1.

Figure 1: HIVST delivery models in Swaziland



Community based models: HIVST can be offered to community members and targeted populations such as key populations (KPs), youth and adolescents through existing community based structures such as VCT centres, Outreach drop in Centres, VMMC and workplace settings.

Facility based models: HIVST can be integrated 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 in Swaziland. Facility based approaches can include but not limited to the following;

HIVST kits can be distributed in different ways for both community based and facility based models. See table 1, HIVST distribution models.

Other channels: Alternative HIVST service delivery channels include provision of HIVST services through public-private channels or distribution at key points as per table 2.

Table 2: Alternative HIVST service delivery channels

Public-Private sector channels (Pharmacies, Internet, Vending Machines, Voucher Programs)	Distribution at key points (Tinkhundla, Institutions of higher learning, Youth centres)
<ul style="list-style-type: none"> ▪ Clients access kits at pharmacies at a fee and/ or free of charge ▪ Clients pick up kits or buy kits and take them home to self-test themselves at their own place ▪ Clients will perform unassisted HIVST as per table 1, page 13. 	<ul style="list-style-type: none"> ▪ Kits can be placed at strategic key points where anyone can access them. ▪ Clients pick up kits and take them home to self-test themselves at their own place ▪ Clients will perform unassisted HIVST as per table 1, page 13.

CHAPTER 3: HIV SELF-TESTING PACKAGE

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

- HIV self-testing promotion and communication (move to beginning)
- The guiding principles of HIVST
- The standards and procedures for HIVST
- HIVST information package
- Linkage and referral
- Partner disclosure

3.1 HIV Self-Testing Promotion and Communication

To create awareness and increase utilization of HIVST, advocacy and communication strategies should aim to inform health care workers (HCW) and the general population on the availability and the correct use of HIVST kits.

Healthcare workers

- Sensitization of HCW on HIVST as an additional strategy for increasing access for HTS. This can be done through guidelines and HIVST SOP dissemination, Continuous Medical Education (CME) sessions, On the Job Training, and clinical mentoring.
- Integration of HIVST into existing programs e.g. PMTCT, PrEP, PEP, HTS, VMMC, KP programs, care and treatment and other routine health services
- Encouraging HCW to advocate for use of HIVST to increase testing among PMTCT clients, partner testing and KPs.

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, campaigns, brochures and flyers, billboards, digital platforms such as the internet, social media platforms WhatsApp, Facebook, Twitter etc.
- Use of self-testing champions like peer educators, adherence counsellors 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.

3.2 Guiding Principles of HIVST

The HIVST strategy is guided by the principles of HIV testing services as is outlined in the 2018 Integrated HIV Management Guidelines. All forms of HTS, including HIVST, regardless of approach, are guided by core principles known as the 5 Cs i.e. Consent, Confidentiality, Counselling, Correct results and Connection - linkage to care and other appropriate post-test services. All HIV Testing services, 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:

Consent

Informed consent is important for persons who wish to undertake an HIV test in general. 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.

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

Counselling

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, brochures and flyers and audio or video counselling services.

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.

Connection/Linkage to Care

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 on-going 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.

3.3 Standards and procedure for HIV self-testing

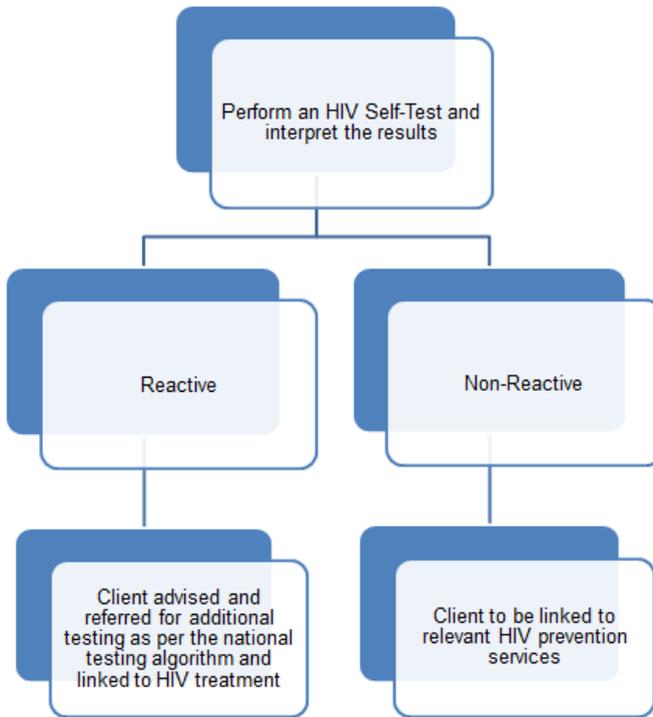
HIVST must be conducted using the nationally approved HIV rapid self-test kits. The kit will include instructions in English and SiSwati as well as pictorial diagrams to aid ease of use and correct interpretation of results. It is recommended that all HIVST kits distributed must also be accompanied with client education material such as e.g. IEC

All distribution points should display illustrations or instructions on HIVST procedures should a tester require further explanation or testing support. 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 guideline retesting recommendations. If the HIVST test result is reactive, the individual should be advised to seek further testing from a trained HTS provider within 7 days. This is shown in figure 2.

A reactive HIV self-test result always requires additional HIV testing per the national HIV testing algorithm as defined in the Swaziland Integrated HIV Management guidelines.

Figure 2: HIVST Flow Chart



3.4 HIVST information package

HTS counsellors dispensing HIVST kits should be able to provide all the necessary information on the use of the kits.

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 counselling, 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 should 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 low when people with HIV are on ART.

3.5 Referral and Linkage

In addition to delivery of effective HIVST service in Swaziland, 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 package. Individuals whose self-test results are reactive must seek confirmation from a qualified HTS provider within 7 days.

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 of health facilities as well as through making enquiries via the HIVST information line.

Linkage approaches for HIVST

- Community based follow up by health care workers, peer support officer or adherence officer and outreach workers through telephone or SMS. This is especially applicable where HIVST is offered at community level.
- Invitation slips, vouchers, coupons or rebates – applicable mostly to key populations
- Telephonic counselling services and step-by-step instructions on what to do following a reactive self-test may be provided, computer-based programs and applications (such as Facebook, WhatsApp, Twitter etc.)
- Information line where users call for pre-test and post-test counselling and technical support can still offer linkage to HTS
- Through community mobilisation where information on where to find HTS services and post-test services is given to the public.

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.

CHAPTER 4: COMMODITY MANAGEMENT

This section covers the management of commodities and commodity data for HIVST across public and private sectors. It represents the set of practices that must be coordinated to ensure that appropriate, high quality supplies are available wherever they are needed. It entails proper coordination and management of commodities 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.

4.1 Kit Selection

The selection of the kits to be procured nationally will be guided by the HIVST task team and in-country validations must be conducted by the National Referral Laboratory (NRL)

4.2 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.

4.3 Inventory Management

The management of the kits will be aligned to the existing inventory management system. This will include receipt of kits, storage per 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.

CHAPTER 5: 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 by the National HTS coordinator through the HIVST task team comprising of key actors that include the MOH/SNAP representatives, the laboratory, implementing partners directly involved in implementation of HIVST, CBO representatives, Civic society groups, regional partners and WHO representatives specifically to coordinate the HIVST program.

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

National	
Institution	Roles and Responsibility
The Swaziland National AIDS program (SNAP)	<ul style="list-style-type: none">▪ 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 Regional Health Management Teams (RHMTs)▪ Coordination of implementing partners providing HIVST services at all levels.▪ Development of HIVST M&E tools, indicators and quality assurance (QA) processes.▪ Providing strategic guidance on the HIV response and coordinating all stakeholders.▪ Coordination of the Civil Society (CSOs) and Community-based Organizations (CBOs).

National Laboratory	<ul style="list-style-type: none"> ▪ Ensuring QA in HIVST services ▪ National quantification of HIVST kits ▪ Distribution of HIVST kits ▪ Test Kit validation and new lot verification ▪ Conduct post market surveillance HIVST test kit
Health Management Information System (HMIS)	<ul style="list-style-type: none"> ▪ Guidance on development of National HIVST M&E tools and integration n CMIS.
HIVST Distributors	<ul style="list-style-type: none"> ▪ Provide pre-test information on HIV ▪ Distributes HIVST kits ▪ Ensures kits are kept at recommended temperatures (2-30 degrees) ▪ Explains the HIVST process ▪ Responds to questions and concerns of clients doing self-testing ▪ Ensures clients have access to linkage information and direction to care and treatment facilities ▪ Collects client’s information into the HIVST register and or distribution form ▪ Ensures follow up for clients consenting to follow up

CHAPTER 6: 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 HTS and should be implemented through simple and practical approaches at all levels.

6.2 Components of quality assurance for HIVST

Quality assurance for HIV self-testing can be considered in terms of:

- QA of the test product
- QA of the HIV self-testing process as per National SOP

6.2.1 Quality assurance of HIVST kits

WHO Prequalification

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

Laboratory validation

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

Table 3: Specification of Ora-Quick HIVST in Swaziland

Criteria	Desired Characteristics
Sensitivity	Above 99%
Specificity	Above 99%
Ease of Use	<ul style="list-style-type: none">▪ Should not require additional equipment to perform▪ Should not require technical training to perform the test▪ Stable end-reading points

	<ul style="list-style-type: none"> ▪ Results should not need interpretation with additional equipment
Rapidity of Test (Time of result)	Should avail a result within 20 minutes
Storage Condition	2-30 degrees Celsius
Shelf-Life	Above 6 months
Packaging	Single packing of complete set

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.

6.2.2. Quality assurance of the HIVST procedure

Capacity building and sensitization on HIVST

All HIVST service providers should be sensitized per the HIVST training package. 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), IEC 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.

CHAPTER 7: MONITORING AND 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.

The following indicators will be reported to the national level:

- Number of HIVST kits distributed desegregated by age and gender
- Number of first time testers using HIVST segregated by age and gender
- Number of people screened HIV positive that reported back to the facility
- Number of people confirmed HIV positive using the national algorithm
- Number of people linked into HIV care and treatment services
- Number of people linked to prevention services

7.2 Reporting tools and systems

There is need to develop new HIVST tools. HIVST should be integrated in the different HTS and laboratory tools. These tools should include:

1. HTS Register
2. HTS Monthly Reporting form
3. Stock Control Cards
4. National Referral forms