

# **HIV SELF TESTING**



**Standard Operating Procedures for the delivery of  
HIV Self - testing Services in Sri Lanka**

**2022**

**NATIONAL STD/AIDS CONTROL PROGRAMME**

---

# **HIV SELF TESTING**

**Standard Operating Procedures for the delivery of  
HIV Self-testing Services in Sri Lanka**

**2022**

**NATIONAL STD/AIDS CONTROL PROGRAMME**

---

# **HIV self-testing Standard Operating Procedures for the delivery of HIV Self-testing Services in Sri Lanka**

Compiled by HIV testing Unit, National STD/AIDS Control Programme

## **Coordinated by**

Dr. Nimali Jayasuriya, Consultant Venereologist

## **Contributor**

Dr. Jayanthi Elwitigala, Consultant Microbiologist

Dr. Sathya Herath, Consultant Community Physician

Dr. Geethani Samaraweera, Consultant Venereologist

Dr. Champika Gunawardana, Acting Consultant Venereologist

## **Published by**

National STD/AIDS Control Programme,

Ministry of Health, Sri Lanka.

2022

## **Funded By**

GFATM

## **1<sup>st</sup> Edition**

**November 2022**

## CONTENTS

1. Introduction .....	6
2. Goal and objectives .....	7
3. Guiding principles .....	8
4. Implementation of HIV self-testing.....	10
5. <b>Placing</b> an order, specification and distribution of HIV self-test kits .....	12
6. Inventory management / Monitoring and evaluation.....	14
7. Annexures .....	15
7.1 Locally printed leaflet .....	16
7.2 HIV self-test request form.....	17
7.3 HIV Self-Test Receipt Book.....	18
7.4 STD clinic - HIV Self-Test stock management register.....	19
7.5 HIV Self-Test stock management form – NGO/CBO.....	20
7.6 HIV Self-Test component in clinic quarterly return (Table 12 & 13) .....	21
7.7 HIV Self-Test quarterly return by CBO/NGO.....	22



## ACRONYMS

<b>ARV</b>	Anti-Retro Viral
<b>CBO</b>	Community Based Organization
<b>HIV</b>	Human Immunodeficiency Virus
<b>HIV ST</b>	HIV self-testing
<b>HTS</b>	HIV testing services
<b>LTFU</b>	Lost To Follow UP
<b>NGO</b>	Non-Governmental Organization
<b>OTC</b>	Over the counter
<b>PLHIV</b>	People Living with HIV
<b>PrEP</b>	Pre-Exposure Prophylaxis
<b>RDT</b>	Rapid Diagnostic Test
<b>SIM</b>	Strategic Information Management
<b>STI</b>	Sexually Transmitted Infections
<b>WHO</b>	World Health Organization

## DEFINITION OF TERMS

### **HIV Self-Testing (HIV ST):**

An individual collects their own specimen, performs an HIV test, and interprets the results, often in a private setting either alone or with someone they trust.

### **Assisted HIV Self-Testing:**

**Trained providers or Peers giving individuals an in-person demonstration before or during HIV ST of how to perform the test and interpret the results.**

### **Unassisted HIV Self-Testing:**

An individual obtaining a kit for HIV ST and performing the HIV test following the instructions on their own without assistance.

### **Reactive results:**

This indicates that HIV antibodies are present in the specimen. Anyone whose result is reactive to a self-test must be followed by additional HIV testing in the STD clinic according to the National HIV testing algorithm.

### **Non-reactive results:**

This indicates that HIV antibodies are not found in the specimen. Anyone whose result is non-reactive may undergo further testing or repeat testing in interval as per their risk. Those who are negative need to be supported by preventive services.

---

# 1. INTRODUCTION

## 1.1 Background

HIV self-testing has been recommended by WHO as an innovative strategy to reach the unreached and people who do not attend HIV testing services. The evidence shows that HIV st is safe , accurate, highly acceptable, increase access and increase the uptake among those who are at high risk and who may not test otherwise.

HIV self-testing allows people to get an HIV test and find out their result in their own home or other private location. The availability of HIV self-tests in Sri Lanka may help increase awareness of HIV infection. HIV ST has the potential of being a high-impact, low-cost intervention to reach high-risk individuals that are not seeking testing through other HIV testing delivery systems and to increase the number of people with undiagnosed HIV infection who are identified and linked to care services. HIV ST also presents an opportunity to provide linkages to HIV prevention services for those who are test negative.

## 1.2 Overview of HIV Self-Testing

HIV self testing involves collecting own specimen ( oral fluid or blood )using a rapid HIV testing

This approved tests uses oral fluid or blood to check for antibodies to HIV Type 1 and HIV Type 2. The kit is designed to allow to take the HIV test anonymously in private location and to wait 20 minutes for results. Majority of HIV self tests are based on second and third generation technology. These tests accurately detects chronic ( long standing ) HIV inflection. But ability to detect recently acquired HIV is more variable. Their window periods are little longer than fourth generation test. A positive result with this test does not mean that an individual is infected with HIV, but it must be confirmed by some other test or tests. Rather than additional testing, it should be done in a medical setting to confirm the test result. Additionally, a negative test result does not mean that an individual is not infected with HIV, particularly when there is a recent exposure.

## 2. GOAL AND OBJECTIVES

### 2.1 Overall goal

The overall goal is to improve HIV testing among individuals not currently being reached by existing HIV testing services (HTS).

### 2.2 Objectives

- To implement HIVST as an additional HIV testing approach in Sri Lanka.
- Improve couples testing to reach untested male or female partners.
- Provide an option for regular repeat HIV testing in key populations, such as sex workers, MSM, transgender people, people who inject drugs and mobile populations (truck drivers, miners, and farm workers)

**HIVST should not be utilized to replace conventional HTS for maximum impact and cost-effectiveness, but rather to:**

1. Increase access to people with high HIV risk and vulnerability, including people living with HIV who have gone missing (PLHIV LTFU), people who do not already utilize HTS, adolescents, and other hard-to-reach key populations.
2. Encourage partner and index testing by supplying kits to those living with HIV or at high risk of acquiring the virus so they can test their partners or others in their social networks.
3. Expand testing coverage by incorporating it into clinical services where testing is required but not frequently offered or poorly implemented.
4. Increase demand for HIV prevention services and uptake. Those who have a nonreactive self-test result will not need confirmatory testing, but HIVST is an opportunity to refer them to preventative programs (such as PrEP, condoms, and STI screening/treatment).

### 3. GUIDING PRINCIPLES

#### 3.1 Right Based approach

HIV Self-testing should always be voluntary. It is essential to empower vulnerable and socially marginalized populations through a human rights-based approach that prioritizes universal health coverage, gender equality, and health-related rights such as accessibility, availability, acceptability, appropriateness, and quality of services.

#### 3.2 The 5 Cs

**The 5Cs can be used in all types of HIV testing, including self-screening.**

**Consent, Confidentiality, Counseling, Correct results, and Connection**

**Consent:**

The age of consent for HIV self-screening is based on the age of consent for routine HIV testing.

**USE OF RAPID HIV-1/2 SALIVA-BASED ANTIBODY TESTS IN CHILDREN AND YOUNG ADOLESCENTS**

Children and adolescents aged 12 to 18 years are advised to select the directly assisted HIV self-screening option.

**USE OF RAPID HIV-1/2 SALIVA-BASED ANTIBODY TESTS IN CHILDREN 2–11 YEARS**

Rapid HIV-1/2 saliva-based antibody tests have been shown in studies to have high sensitivity and specificity in children older than 2 years. They have been recommended by WHO for use in children aged 2 to 11 with the support of a skilled healthcare professional.

**Confidentiality:**

it is important to maintain confidentiality in directly assisted HIVST.

**Counseling:**

The product package will include adequate pre-test and post-test information. Those who present to a healthcare provider for confirmatory testing following a reactive self-screening test can receive detailed counseling.

**Correct:**

HIVSS kits that have been pre-qualified by the WHO are purchased and distributed to ensure accurate and reliable HIVSS results. Reactive self-screen result must be confirmed by a trained

provider, starting with the screening test within the national testing algorithm. Ongoing risk of HIV and recent exposure should be taken into consideration when interpreting a negative (non-reactive) self-screening result.

**Connection:**

For those with reactive HIVSS results, should be referred to confirmatory testing. Those who are negative should be linked to preventive services.

### **3.3 Key considerations for HIV self-testing**

- HIVST is not meant to be a replacement for conventional HIV testing methods
- Appropriate, validated, clear, and concise instructions are provided in the instruction leaflet. Low literacy people can be supported by picture demonstration or in-person demonstrations.
- A reactive (positive) self-screening result must be confirmed using the recommended Sri Lanka HIV testing algorithm. HIV ST positive patient enter to national algorithm through HIV RDT -1/ELISA.
- **People living with HIV (PLWHIV)** on ARVs, and people in HIV-related clinical trials should not do HIVST test as this may result in a false non-reactive outcome.
- If a person is uncertain about how to correctly perform the self-screening test, or interpret the self-screening result, he or she should be encouraged to access the conventional facility- or community-based HIV testing.

## 4. IMPLEMENTATION OF HIV SELF-TESTING

### 4.1 Target audience

Program managers and staff responsible for HIV testing and prevention services.

### 4.2 Target population

- Main target population is people who are not reached by existing services
- It should be noted that anyone who requests self-screen should not be rejected.

### 4.3 HIV self - screening approaches

#### **Directly assisted HIV self-screening**

It is recommended for:

- Any individual who requests assistance during self-screening.
- A person who is using the HIV self-screening kit for the first time and is unsure of the procedure, or those with low literacy levels until they are confident to self-screen.
- Adolescents from 12 to 17 years old.

#### **Unassisted HIV self-screening**

- This approach refers to individuals who self-screen for HIV independently, without the help of a trained provider or peer.
- They can use manufacturer-provided instructions or may be provided with access to additional support such as telephone hotlines, brochures, or instructional videos.

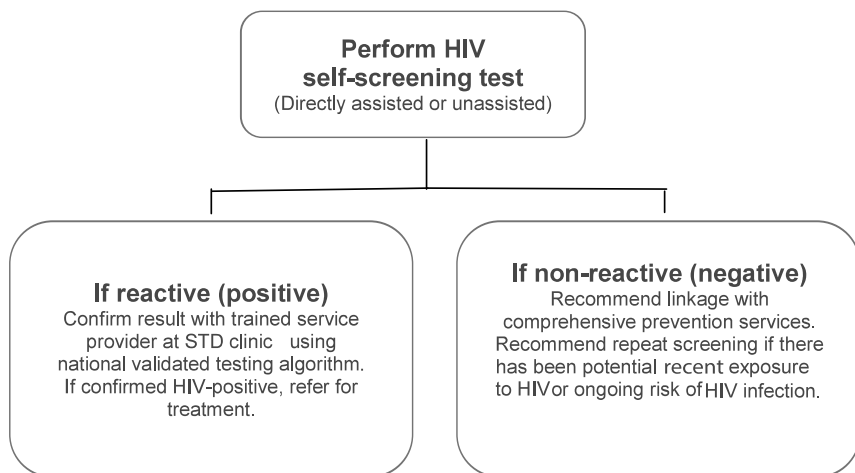
### 4.4 Requirements for HIV self-screening instructions for use

The manufacturer instructions are available with the test kit. Locally printed leaflet in sinhala and tamil languages will be made available with HIV ST kit to access additional support for unassisted testing.

The following introductions have to be included in the leaflet

- How to perform the self-screen
- How to handle and store the test kits before using the test
- How to interpret the test results
- What to do after reading the results.
- **How to contact services for HIV treatment and prevention.**
- How to safely dispose of the used test-kits

#### 4.5 Algorithm for HIV self- testing



#### 4.6 Referral and linkage to services

**For reactive HIV self-screening results:** Linkage to services (connection) includes linkage to confirmatory HIV testing by a trained healthcare provider.

**For non-reactive results:** Clients should be referred and linked to HIV prevention services such as Prep, treatment, for STIs, provision of condoms, Lubricants and PreP.



## 5.PLACING AN ORDER (MAKE A REQUEST), SPECIFICATION AND DISTRIBUTION OF HIV SELF-KITS

### 5.1 Place an order

HIV self-kits must be requested from HIV testing unit by an authorized person using the HIV ST request form. Further HIV ST receipt books , stock management forms, request form books and leaflets can be requested.

### 5.2 HIV ST Distribution

NSACP HIV self-screening tests can be delivered through primary or secondary distribution methods:

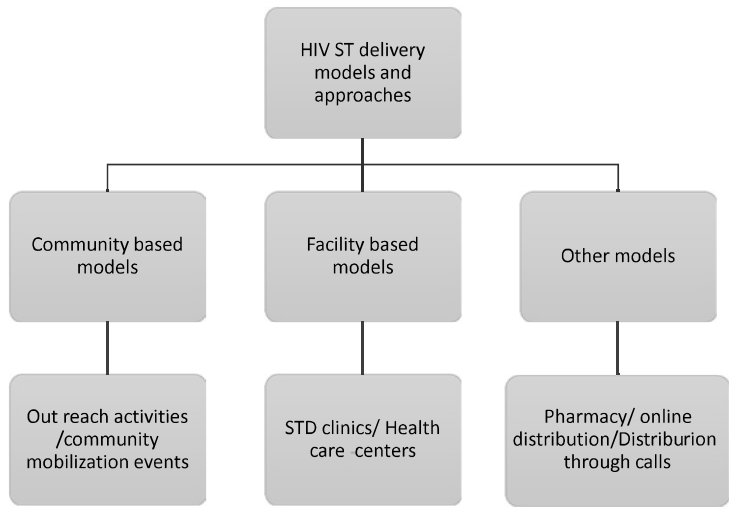
#### **The primary distribution method**

HIV self-screening kit is delivered directly to the end-user.

#### **Secondary distribution**

One or more self-screening kits are given to an individual, not for their own use, but to distribute to their sexual partner, family member or anyone in their network.

5.4 Distribution channels for HIV ST services.



---

## **6. INVENTORY MANAGEMENT / MONITORING AND EVALUATION**

### **6.1 Inventory management**

The management of the HIV ST test kits should be aligned with existing inventory management system. This will include receiving HIV kits, storage, and distribution to service delivery points. Stock management log should be maintained at the STD clinic and CBO /NGO office.

### **6.2 Monitoring and Evaluation**

HST registers should be maintained. Data must be reported through STD quarterly return to Strategic Information Management (SIM) unit. NGO/CBO should directly send data quarterly to SIM or HIV testing unit.

## 7. ANNEXEX

I.	Locally printed Leaflet
II.	HIV Self-Test request form
III.	HIV Self-Test Receipt Book
IV.	STD clinic - HIV Self-Test stock management register
V.	HIV Self-Test stock management form – NGO/CBO
VI.	Self-Test component in clinic quarterly return (Table 12 & 13)
VII.	HIV Self-Test quarterly return by CBO/NGO

# Annexure I: Locally printed Leaflet

ස්වයං HIV මුඛ තරල පරීක්ෂාව (Oraquick ) සිදුකිරීමට උපදෙස් පත්‍රිකාව

- පරීක්ෂණය ආරම්භ කිරීමට පෙර මෙම උපදෙස් පත්‍රිකාව හොඳින් කියවන්න. පරීක්ෂණයේ නිවැරදි ප්‍රතිඵල ලබා ගැනීම සඳහා දී ඇති උපදෙස් තරයේ පිළිපදින්න.
- පරීක්ෂණය ආරම්භ කිරීමට පෙර විනාඩි 15 ක කාලය තුල නිසිම ආහාරයක් නොගත යුතුයි.
- පරීක්ෂණය ආරම්භ කිරීමට පෙර විනාඩි 30 ක කාලය තුල දුන් මැදීම හෝ කට සේදීම නොකළ යුතුයි.



1. හොඳින් ආලේකය ඇති නිදහස් නැතැක් නොරාගන්න



2. කාලය මැනීමට උපකරණයක් ලෙස නාවාගන්න



3. සිමහේ පරීක්ෂණ කට්ටලයක් පැකට්ටු කොටස් දෙකක් ඇස



4. ඉන් පරීක්ෂණ තලය සහිත කොටස ඉරා විවෘත කර තලය පිටතට ගන්න



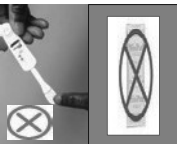
5. එතුල ඇති දියය සිටකට නොසාන ලෙස තලය විවෘත කරන්න



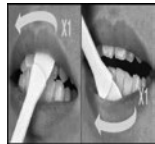
6. තලය, ලබාදී ඇති රළුතාය මත සිටුවන්න



7. ඇත්, ඉතිරි පැකට්ටුව ඉරා විවෘත කර, මුඛ සාම්පල ලබාගන්නා පරීක්ෂණ උපකරණය සිටකට ගන්න



8. උපකරණයේ පැතලි කොටස අනෙක් ස්වයං පොර්ට්ටු වලටම ගන්න. කල්පයා ගැනීමේ ද්‍රව්‍ය සහිත කුඩා පැකට්ටුවක්ද එතුල ඇත. එය ඉවත දමන්න. එය කැමට නොකන යුතුයි



9. ඇත් උපකරණයේ පැතලි කොටස සිමහේ මුඛය ඉහල විදුරුමය දිගේ රවන් තදින් ගෙනයන්න. පහල විදුරුමය මතද එළලවීම කරන්න



10. උපකරණයේ පැතලි කොටස තලයේ සතුලේ ගැටෙන සේ උපකරණය සම්පූර්ණයෙන්ම තලය තුලට ඇතුළු කරන්න. එතැන් සිට විනාඩි 20 ක් පරීක්ෂණ උපකරණය තලය තුළ තබන්න

විනාඩි 20 කින් ඔබේ පරීක්ෂණයේ ප්‍රතිඵල සුදානම්.....



11. විනාඩි 20 කින් ප්‍රතිඵල කියවීමට හැකියි. (විනාඩි 40 ක් හතළු පසු ප්‍රතිඵල කියවීමෙන් වැළකින්න)



12. C අකුර ඉදිරියෙන් රතු පාට ඉරන් පෙන්වන නමුත් T අකුර ඉදිරියෙන් කිසිම ඉරන් මතු වී ඇත්නම් එය සෘණ ප්‍රතිඵලයක් වේ. එනම් ඔබට HIV ආසාදනය වී නොමැත. \* නමුත් ඔබ පසුගිය මාස 3 තුල HIV ආසාදනයට නිරාවරණය වී ඇතැයි පැයකත් ඇත නම් මාස 3 කට පසු නැවත පරීක්ෂණය සිදු කරන්න.



13. C අකුර ඉදිරියෙන් රතු පාට ඉරන් සහ T අකුර ඉදිරියෙන් රතු පාට ඉරන් මතු වී ඇත්නම් එය ධන ප්‍රතිඵලයක් වේ. එනම්, ඔබට HIV ආසාදනය වී තිබීමට ඉඩ ඇත. එවැනි අවස්ථාවලදී ළඟම ඇති ලිංගාශ්‍රිත රෝග සායනයට වහාම පැමිණෙන්න. නැතහොත් ක්ෂණික දුරකථන අංක 071 637 9192 අමතා උපදෙස් ලබා ගන්න.



14. C අකුර ඉදිරියෙන් රතු පාට ඉරන් නොමැතිවීම හෝ පැහැදිලිව කියවිය නොහැකි රතු පාට පටියක් මතු වී ඇත්නම් හෝ රතු පාට පටි මතු වී ඇත්නම් C අකුර සහ T අකුර ඉදිරියෙන් නොපෙනීම හෝ හෝ අවිනිශ්චිත ප්‍රතිඵලයක් වේ. එවැනි අවස්ථාවක අලුත් පරීක්ෂණ කට්ටලයක් ගෙන පරීක්ෂණය නැවත සිදු කරන්න.

ඔබේ ලගම ඇති ලිංගාශ්‍රිත රෝග සායනයේ දුරකථන අංක

අනුරාධපුර	025 2236461	මහනුවර	081 2203622	බලුපිටිය	091 2256822	කර්මාන්ත	0112 763893
වෙසලානපොල	027 2225787	මාතලේ	066 2224202	නම්බන්කොට	047 2222247	පානුපිටිය	033 2280261
මඩකලපුව	065 2222261		066 2053746	නංගල්ල	047 2240261	යාපනය	038 2232261
අම්පාර	0652057078	ත්‍රිවර්ධනපුර	052 2223210	මීගමුව	031 2239016	යාපනය	021 2217756
කල්ලණිය	063 2224239		052 2222261	මේපහ	033 2234383	මුලතිව්	021 2061414
ත්‍රිකුණාමලය	067 2223660			දිල	046 245345	විවර්ධනපුර	024 2224575
තලාවත	026 2222563	රත්නපුර	045 2226561	දරණ	034 2236937	මහනුවර	021 2283709
තලාවත	032 2220750	කලුතල	035 2231222	ලක්ෂ්‍යපොල	036 2220303	මහනුවර	023 2250573
තුරුමාල	037 2281261 415	ඇම්ලිපිටිය	047 2260261	පොතුව	0112 667163	මුලතිව්	055 2222578
තුලියාපිටිය	037 2224339	මාතලේ	041 2223302		0112 667029	මහනුවර	055 2276826
පුත්තලම	070 1941313	මහ මෝදර	091 2245998	Hot lines	0112 695420 (කාන්තා සායනය)	මහනුවර	055 4936779
					0112 695433 (විරිම සායනය)		

Annexure II: HIV Self-Test Request form

HIV ST Request form

Item	Number requested	Number Issued
HIV self -test		
Receipt Book		
Stock management Form		
Request form book		
Leaflets		
	.....	.....
	Signature	Signature
	Requesting Officer	Issuing Officer

Received by: Name

.....

Designation

.....

### Annexure III: HIV Self-Test Receipt

## HIV Self -Test Receipt

Name of NGO/CBO:

Date:

Receipt No:

Number of Kits		
Received from (Name & Position)		Signature
Received By (Name & NIC No/ License No:		Signature

Age: ..... (years)

Sex: ..... (male/female/Other)

Contact No: .....

#### Annexure IV: STD clinic - HIV Self-Test stock management register

## HIV Self -Test Stock Management Form

[illegible]



## Annexure V: HIV Self-Test stock management form – NGO/CBO

**HIV Self -Test Stock Management Form – NGO/CBO**[illegible]

## Annexure VI: HIV Self-Test component in clinic quarterly return (Table 12 & 13)

Table 12: Number of HIV RDT (1,2,3), HIV ST condom and lubricants utilized or distributed by the STD clinic and KP unit during the quarter

		RDT -1	RDT -2	RDT -3	HIVST	Male condoms	Female condoms	Lubricants
12.1	FSW							
12.2	MSM							
12.3	TG							
12.4	Beach boys							
12.5	PWID- Male							
12.6	PWID – Female							
12.7	Prisoners – Male							
12.8	Prisoners -Female							
12.9	Others							

Table 12: Number of HIV RDT / HIV ST utilized or distributed by place of testing

		RDT -1	RDT -2	RDT -3	HIV ST	Number confirmed positive
13.1	STD clinic attendees					
13.2	ANC in STD clinic					
13.3	Pre -employment					
13.4	MOH					
13.5	Hospital Based testing					
13.6	GPs					
13.7	Migrant returnees					
13.8	Others					

Annexure VII: HIV Self-Test quarterly return by CBO/NGO

HIV Self-Test quarterly return by CBO/NGO

Name of the NGO:
District:

	Number utilized or distributed during quarter	Number positive	Number referred to STD clinic
FSW			
MSM			
TG			
PWID - Male			
PWID - Female			
Others			

Date:  
.....

Name:  
.....

Signature: .....



**National STD/AIDS  
Control Programme**  
**SRI LANKA**



**Ministry Of Health  
Sri LANKA**