

National Guideline on HIV Self-Screening Test Service in Thailand



กรมควบคุมโรค
Department of Disease Control

**Division of AIDS and STIs
Department of Disease Control
Ministry of Public Health**

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Executive Summary

This document aims to introduce guidance on using HIV self-screening test (HIVSST) kits, which have been approved by the Food and Drug Administration (FDA) so that anyone wanting to know their HIV status will have open access to one. HIVSST should be easily accessed by purchasing from a vendor or requesting public health services. Suppose HIVSST users are concerned about performing the screening test by themselves. In that case, they will have access to guidance on the use of the test kit and counselling or be linked to information channels that will instruct them on how to collect their own specimen, collect their own specimen, oral fluid or blood, perform an HIV rapid diagnostic test and interpret the result. Although rare, personal or social hazards related to HIVSST should be considered and have links to mental health and psychosocial assistance when needed,

Thailand's National Strategy on Ending AIDS, together with the ministerial regulation on HIVSST, are measures that will expedite overcoming barriers to HIV testing. HIVSST will assist the country in meeting the 95-95-95 goals by allowing individuals to obtain and use the screening test kits at their convenience and be linked to prevention and treatment services. Thailand already has a wealth of understanding and experience using HIVSST through various projects and research studies. Currently, the Food and Drug Administration (FDA) has approved the use of two HIVSST kits, one that uses oral fluid and one that uses whole blood,

Models for HIVSST focus on the normalisation of HIV testing by allowing the general public to purchase and use HIVSST kits easily and unsupervised. However, if there is any doubt about using the self-screening test kit, supervision is available, including a demonstration of HIVSST kit use and pre- and post-test counselling, if desired. Whether the individual uses the HIVSST kit unsupervised or supervised, they will have links to comprehensive HIV prevention and treatment services as well as options for the secondary distribution of HIVSST kits to their partners.

At present, the availability of HIVSST is not widely known. Therefore, awareness and understanding of HIVSST need to be conveyed through multiple communication channels. An important objective of this communication is to provide linkages to comprehensive HIV services after the screening test result is known. Messages communicated must be suitable and appropriate for each target population, i.e., health care providers, the general population, and key populations, to create demand for HIVSST.

HIVSST is a new service that requires coordination between stakeholders to draw upon the knowledge, understanding, experience, and potential to work together and reinforce each other. However, HIVSST is different from other measures because of the appearance of unapproved screening-test kits in the market, primarily through online sales, before government sanction of HIVSST. Therefore, it is essential to build the understanding and the capacity of government, private sector and civil society stakeholders and establish a Public-Private Partnership that will create a cooperative environment for efficient delivery of services and distribution of HIVSST that meet the required standards.

Monitoring and evaluation indicators of HIVSST will focus on the country's primary objectives of increasing HIV testing and access to prevention and treatment services. Therefore, only a few key indicators will be adopted not to overburden health care providers or the national HIV database. Indicators will be linked to HIVSST use and attendance at health facilities to receive confirmatory testing and pre-exposure prophylaxis (PrEP) or antiretroviral therapy (ART).

HIVSST should be considered for use in times when regular HIV testing services (HTS) are inaccessible or in emergencies. During the COVID-19 outbreak and lockdown, for instance, access to HIV-related services was limited, which affected newly infected persons accessing

testing and treatment and at risk, non-infected persons from accessing or continuing PrEP. Thailand should consider conducting studies that will contribute to guidance currently being drafted by the World Health Organization (WHO).

The key recommendations to strengthen the national HIV response with HIVSST include:

1. Develop an operations manual with clear and appropriate strategies for implementing HIVSST services among different populations.
2. Create opportunities for cooperation and collaboration among stakeholders listed in the table for roles and responsibilities in HIVSST coordination and capacity building (in Chapter 5) so that everyone is moving in the same direction to build a more robust HIV response.
3. Establish a mechanism that will link clients to comprehensive HIV services that are efficient, fluid, and client centred in both public and private health care settings.
4. Discuss with existing screening test kit distributors in the country to reduce the price of the kits. At the same time, encourage distributors of other various brands of test kits available to apply for approval to distribute their kits in Thailand to create price competition that will reduce screening-test kit prices and generate more demand.
5. Work with the Department of Medical Sciences, the Food and Drug Administration, and relevant organizations to establish a more convenient and practical process in approving new generations of HIVSST kits.
6. Study the potential of periodic use of HIVSST in ongoing PrEP services so that clients do not have to attend services in health care facilities for follow-up HIV testing during emergencies.
7. Apply the lessons learned from COVID-19 self-testing and data collection in response to the COVID-19 outbreak to explore ways to link HIVSST with the country's central HIV database appropriately.
8. Establish a new comprehensive HIV service monitoring and evaluation approach by considering additional indicators on the use of HIVSST, PrEP, and index testing to find the link between services and reduce the burden of service providers.

Definition of terms

Assisted partner notification services: Refers to when a trained provider assists consenting HIV-positive clients to disclose their status or anonymously notify their sexual and drug-injecting partner(s) of their potential exposure to HIV infection. The provider then offers HIV testing to these partner(s). Assisted partner notification is done using contract referral, provider referral or dual referral approaches.

Client referral: The index client takes responsibility for disclosing their HIV status to partner(s) and encouraging partner(s) to seek HTS. This is often done using an invitation letter or referral slip.

Contract referral: An assisted partner notification service approach in which HIV-positive clients enter a contract with a trained provider and agree to disclose their status and the potential HIV exposure to their partners by themselves and refer their partners to HIV testing services (HTS) within a specific time period. Suppose the partner(s) of the HIV-positive individual does not access HTS or contact the health provider within that period. In that case, the provider will contact the partner(s) directly and offer voluntary HTS. Counsellors/providers offer voluntary HTS to partner(s) while maintaining the confidentiality of the index client.

Dual referral: An assisted partner notification service approach in which a trained provider accompanies and supports HIV-positive clients when they disclose their status and the potential exposure to HIV infection to their partners. The provider also offers voluntary HTS to the partner(s).

Directly assisted HIV self-testing (HIVSST): Refers to when individuals who are self-testing for HIV receive an in-person or telehealth demonstration from a trained provider or peer before or during HIVSST, with instructions on how to perform a self-screening test and how to interpret the self-screening test result. This assistance is provided in addition to the manufacturer-supplied instructions for use (IFU) and other materials found inside HIVSST kits. Because “assisted” self-testing in some projects indicates that the service provider helps collect the specimen and then processes the test, the term “supervised” is used in this document.

Harm or social harm: Any intended or unintended cause of physical, economic, emotional, or psychosocial injury or hurt from one person to another, a person to themselves, or an institution to a person, occurring before, during or after testing for HIV.

HIV self-screening (HIVSS): A process in which a person performs a preliminary screening test by collecting their own sample (oral fluid or blood) and then performs a screening test and interprets the result, often in a private setting, either alone or with someone they trust.

HIV self-screening test/testing (HIVSST):

HIV status: Summary of blood test results obtained from the confirmation test for the diagnosis of HIV infection by means of a set of diagnostic tests that have accepted standards. The HIV status of the client can be concluded as negative, positive or inconclusive.

HIV screening-test result: The result from a single screening test on a given assay. Possible results may be reactive, non-reactive, or invalid.

Index case testing (ICT): Index case testing refers to a process in which HIV testing is offered to everyone exposed to HIV by the index client (an individual newly diagnosed as HIV-positive or an HIV-positive individual). There are four types of Index case testing, all of which are defined separately in this list: (1) client referral, (2) contract referral, (3) provider referral, and (4) dual referral. All four ICT processes can be enhanced with HIVST.

Intimate partner violence: Behaviour within an intimate relationship that causes physical, psychological, or sexual harm to those in the relationship, including acts of physical violence, sexual violence, emotional or psychological abuse and controlling behaviours.

Key populations: Groups at increased risk of HIV infection irrespective of the epidemic type or local context due to specific higher-risk behaviours. These guidelines refer to the following groups as key populations: men who have sex with men, people who inject drugs, people in prisons and other closed settings, migrants, sex workers and transgender people.

Lay provider: Any person who performs functions related to health-care delivery and has been trained to deliver these services but has no formal professional or para-professional certification, nor a tertiary education degree.

Non-reactive test result: A screening test result that does not show a reaction indicating the presence of HIV-1/2 antibodies.

Partner notification services: Also known as disclosure or contact tracing, is defined as a voluntary process whereby a trained provider asks people diagnosed with HIV about their sexual partners and drug-injecting partners, and then, if the HIV-positive client agrees, offers this partner(s) HTS. Partner notification is provided using passive or assisted approaches.

Passive referral: A partner notification service in which HIV-positive clients are encouraged by a trained provider to disclose their status to their sexual and drug-injecting partners by themselves and suggest HTS to the partner(s) given their potential exposure to HIV infection.

Pre-test information: A dialogue and the provision of accurate information to a client by a lay provider or a health worker before an HIV test is performed.

Provider referral: An assisted partner notification service approach in which, with the consent of the HIV-positive client, a trained provider confidentially contacts the person's partner(s) directly, informs them that they have been exposed to HIV, and offers the partner(s) voluntary HTS while maintaining the confidentiality of the index client.

Quality assurance: Part of quality management focused on providing confidence among stakeholders that quality requirements will be fulfilled.

Quality control: The set of procedures designed to monitor the test method and results to ensure appropriate test system performance. It includes testing control materials, charting the results and analysing them to identify the source of error, and evaluating and documenting any remedial action taken as a result of this analysis.

Quality improvement: An element of quality management focused on increasing the ability to fulfil quality requirements.

Rapid diagnostic test: In vitro diagnostic medical device of immunochromatographic or immunofiltration format for the detection of HIV-1/2 antibodies and HIV p24-1 antigen in the context of HIV. Reactive test result: a test result that shows a reaction indicating the presence of the analyte, which in the context of HIV includes HIV-1 p24 antigen or HIV-1/2 antibodies.

Reactive test result: A screening test result indicates that the test has reacted to something in the blood or oral fluid, which should be investigated further.

Repeat testing: A situation in which additional testing is performed for an individual immediately following the first test, during the same testing visit, due to HIV-inconclusive status or discordant test results. The same assay(s) is used and, where possible, the same specimen.

Retesting: Refers to specific situations in which individuals should be retested after a defined period: (1) HIV-negative people with recent or ongoing risk of exposure; (2) people with an HIV-inconclusive status; and (3) HIV-positive people before they enrol in care or initiate treatment. Reasons for retesting before initiation of care or treatment include ruling out laboratory or transcription errors and ruling in or ruling out seroconversion.

Sensitivity: Denotes the probability that an HIV assay/algorithm will correctly identify all specimens that contain HIV-1/2 antibodies and/or HIV-1 p24 antigen. Seroconversion happens when an individual's immune system produces a quantity of HIV-1/2 antibodies sufficient to be detectable on a given HIV serology assay.

Sero-discordant couple: A couple in which one partner is HIV-positive, and one partner is HIV-negative.

Specificity: The probability that the assay/algorithm will correctly identify specimens that do not contain HIV-1/2 antibodies and/or HIV-1 p24 antigen.

Supervised HIV self-screening: Involves support from a health worker or volunteer before or after individuals screen themselves for HIV. Supervision may include a demonstration of how to use the screening test, how to interpret the result, the provision of pre-test information on where and how to seek additional support, confirmation testing, and HIV prevention, care, and treatment services, as well as providing a link to index testing. This post-test support may include face-to-face or telephone, or telehealth counselling, peer support and referrals for additional HIV prevention,

Testing algorithm: The combination and sequence of specific assays used within HIV testing strategies.

Undetectable = Untransmittable (U=U): People living with HIV who are taking effective antiretroviral therapy and whose level of HIV is suppressed to undetectable levels will not transmit HIV sexually.

Unassisted HIV self-screening testing: Refers to when individuals self-test for HIV using only a self-test kit that includes manufacturer-provided instructions for use. As with all self-testing, users may be provided with links or contact details to access additional support, such as telephone hotlines or instructional videos. Projects in Thailand have used the term "unassisted" to reflect client self-sample collection, followed by test kit processing by a medical technologist or another trained service provider. Therefore, the term "unsupervised" is used in this document.

Unsupervised HIV self-screening testing: Refers to independent or open access to HIV self-screening. Support may or may not be indirectly provided, based on the user's initiative, such as links to video instructions on how to use the test, telephone hotlines, telehealth services, leaflets, referral information on confirmation testing, HIV treatment, care and prevention services.

Abbreviations

ART	Antiretroviral therapy
CRS	Crisis Response System
CSO	Community Service Organisation
DAS	Division of AIDS and STIs
DDC	Department of Disease Control
DEpi	Department of Epidemiology
FDA	Food and Drug Administration
HITAP	Health Intervention and Technology Assessment Program
HIV	Human immunodeficiency virus
HIVSST	HIV self-screening test/testing
HIVST	HIV self-testing
IBBS	Integrated bio-behavioural surveillance
IFU	Instructions for use
M&E	Monitoring and evaluation
MSM	Men who have sex with men
MSW	Male service worker/sex worker
NAPAC	National AIDS Prevention and Alleviation Committee
NHSO	National Health Security Office
OPS MOPH	Office of the Permanent Secretary, Ministry of Public Health
PLHIV	People living with HIV
PEP	Post-exposure prophylaxis
PrEP	Pre-exposure prophylaxis
QA	Quality assurance
RDT	Rapid diagnostic test
SSO	Social Security Office
STI	Sexually transmitted infection
TG	Transgender
TGW	Transgender woman
TGSW	Transgender service worker/sex worker
U=U	Undetectable = Untransmittable
UNAIDS	Joint United Nations Programme on HIV/AIDS
WHO	World Health Organization

Chapter 1: Introduction

Purpose of this document

This document aims to introduce guidance on using HIV self-screening test (HIVSST) kits, which have been approved by the Food and Drug Administration (FDA) so that anyone wanting to know their HIV status will have open access to one. HIVSST should be easily accessed similarly to pregnancy, and COVID-19 screening test kits may be purchased from a vendor or requested from health centres, both public and private, or civil society organizations (CSO). Moreover, suppose HIVSST users are concerned about performing the screening test by themselves. In that case, they will have access to credible information or may request guidance from specially trained individuals, such as outreach workers or comprehensive HIV services in the public, private, and civil society sectors.

Definition and characteristics

HIVSST is a process whereby an individual who wants to know their HIV status collects their 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 they trust.¹ HIVSST may be performed unsupervised, by oneself, or supervised, under the guidance of a health care worker or a trained civil society volunteer. The screening test is not sufficient to make an HIV-positive diagnosis. Therefore, a reactive HIVSST result should be confirmed using the validated national testing algorithm. A person who tests negative is advised to re-test if they have had any possible exposure to HIV within the window period. There are two types of HIVSST, oral fluid and whole blood. Most HIVSST are second- or third-generation HIV tests that can only detect HIV-1/2 antibodies, whereas a fourth generation HIVSST can also detect p24 antigen.

The situation of HIV testing in Thailand

Currently, Thailand has an average HIV testing rate close to the target of 95-95-95. The country's progress is at 94.3-83.5-97.2 (MOPH, 2021), but during 2017-2020, the key populations in Thailand's HIV strategy still had test rates in those groups that were reasonably below targets. The national average rate of HIV testing among men who have sex with men (MSM) is 53% (2020), down from 69% (2018), transgender women (TGW) 68% (2020), 45.5% female sex workers (2018), and the lowest rate was in people who inject drugs (PWID) at 38% (2020).²

Thailand National Strategy on Ending AIDS³

The joint end to AIDS problem by 2030, which takes into account the principles of human rights and gender equality, has three main goals:

1. Reduce new HIV infections to fewer than 1 000 cases per year.
2. Reduce AIDS-related deaths to fewer than 4 000 cases per year.
3. Reduce HIV and gender-related discrimination by 90%.

Moreover, in the implementation of the Strategy, the following key principles shall be observed:

1. Promote fairness, reduce inequality, and address all sectors of the population.
2. Respect, prevent and protect human rights and gender equality.
3. Promote ownership and accountability of networks and related partners of government agencies, civil societies, and private sectors.

To achieve these three goals by 2030, six strategies have been identified, namely:

Strategy 1: Focus and expedite an effective and inclusive package of services to locations and populations with high HIV transmission.

Strategy 2: Strengthen and integrate effective prevention efforts into the existing system to ensure quality and sustainability.

Strategy 3: Develop and enhance differentiated treatment, care and social support, ensuring quality, comprehensiveness and sustainability.

Strategy 4: Adjust HIV perceptions and build the capacity of individuals, families, and communities and strengthen a rights protection mechanism.

Strategy 5: Enhance joint accountability, investment and efficiency of administrative efforts in all sectors at the international, national, provincial and local levels.

Strategy 6: Support and improve accessibility and utilization of strategic information and research that are inclusive and efficient.

The use of HIVSST kits addresses Strategy 1 as an additional, highly effective service. HIVSST can provide quick and easy access to HIV testing for people at risk of HIV and thereby increase testing coverage. Studies in many countries have shown that HIVSST encourages key populations and individuals at high risk of infection and transmission to others to access HIV testing.⁴

In addition, a Ministerial Regulation on HIVSST in Thailand, No. 1/2015, was approved by the National Council for Peace and Order to promote people knowing their HIV status by increasing access to HIV testing with HIVSST kits. The regulation was promulgated in the Government Gazette, Notification by the Ministry of Public Health, Re: Test kits related to self-screening for HIV infection, on April 9, 2019,⁵ HIVSST kits were also listed in the Food and Drug Administration's Notification regarding Criteria for Approval for Test Kits Related to HIV Screening in individuals, announced 17 Sep. 2019.⁶

Benefits of HIVSST

HIVSST is widely accepted, safe and has relatively high accuracy. HIVSST provides opportunities to increase coverage and frequency of testing, especially for individuals that have difficulty accessing standard testing services. These individuals may include people who live far away from testing services, sexually active young people that have difficulty accessing friendly services, and key populations.

HIVSST is a convenient and confidential option for HIV testing. WHO has recommended HIVSST as a safe, accurate and effective way to reach people who may not test otherwise, including people from key populations.⁷ Lay users can perform HIVSST in the privacy of their own homes easily, reliably and accurately and achieve performance comparable to that of trained healthcare workers. HIVSST can also reduce the barriers to accessing HIV testing in healthcare settings due to stigma and discrimination, reduce the hospital's waiting time, and provide an opportunity to cope with a confirmed test result in a safe place. Thus, HIVSST can contribute to increased demand for HIV testing.

Benefits of HIVSST

- Encourages access to HIV testing.
- Provides the freedom to make decisions (autonomy)
- Provides confidence that confidentiality is maintained
- Builds empowerment and the ability to define one's path in life.
- Is convenient
- Reduces time burden for user and service provider.

Thailand's Experience in HIVSST

Several studies on the use of HIVSST have been conducted in Thailand in recent years. During 2017-2018, FHI360, through LINKAGES, conducted a cross-sectional study among men who have sex with men (MSM) and transgender women (TGW). Participants were recruited during outreach and online activities and were offered unassisted or assisted HIVSST,⁸ discussed in the next chapter or referral to HIV testing services. The *Access to HIV Self-Testing Demonstration Project*, supported by the Centre for Thailand MOPH – U.S.CDC Collaboration in Public Health and the Division of AIDS and STIs, was launched on 12 August 2020. The project aims to study the feasibility of distributing HIV self-test kits to MSM and TGW through pharmacies.⁹ The *StandUp-Teen* study was conducted by the Institute of HIV Research and Innovation (IHRI) and Mahidol University. It explored the role of HIVSST in accelerating PrEP uptake and improving retention in PrEP care among young MSM and TGW aged 15-19.¹⁰ A similar project was conducted at the Buddy CU Clinic at the King Chulalongkorn Memorial Hospital from January 2020 to January 2021, which offered HIVSST for PrEP continuation for youth aged 15-24 years. From the experiences of this project, HIV self-testing was included in the 2021 Thailand National Guidelines for Pre-Exposure Prophylaxis (PrEP) as a non-invasive and easy method of specimen collection that can reduce the anxiety that comes with blood-based rapid testing.¹¹

These studies found that HIVSST is widely accepted among MSM and TGW. The acceptance level from the FHI360-LINKAGES study was as high as 99.7%.¹² In addition to HIVSST kits approved by the Thai Food and Drug Administration (FDA) for study purposes, preliminary data has shown that there has been a lot of interest in HIVSST through the purchase of test kits online, even though the FDA has not yet approved the kits.

Components of this document

HIVSST is still new to Thailand and its users. Therefore, this document is considered a living or dynamic document that can evolve contextually through updates and be expanded as needed as HIVSST develops and changes.

This HIVSST Guideline consists of the following sections:

1. A description of the approaches to HIVSST and the required support packages.
2. An overview of demand creation and communication strategies for HIVSST.
3. A description of the commodity management and distribution systems needed for HIVSST.
4. An outline of roles and responsibilities and the coordination mechanisms for HIVSST.
5. An overview of quality assurance strategies in HIVSST.
6. A description of the monitoring and evaluation strategy for HIVSST.
7. Discussion on the use of HIVSST under challenging situations, such as the COVID-19 outbreak.
8. References

Chapter 2: Approaches for HIV self-screening

HIV self-screening is a strategy for increasing the rate of HIV testing. Therefore, the approaches to HIV self-screening should consider the target populations and the operational areas of the national strategy to end AIDS in Thailand by 2030. HIV self-screening falls under the umbrella of the comprehensive HIV service principles by adhering to the HIV status-neutral approach to reduce stigma and discrimination to assist individuals, regardless of their screening-test result, have access to confirmatory testing, prevention, and care and treatment services.

The essence of the approaches to HIV self-screening services

HIVSST is not intended to replace conventional HIV testing but rather to complement HIV testing and counselling and enable more people to know their HIV status, particularly those not reached by existing services. It is important to carefully position this service to be highly efficient and effective at reaching the undiagnosed and people with ongoing risk. It should be noted that anyone who requests to self-test should not be denied the opportunity to do so. However, HIVSST may not be for everyone. Individuals and communities must know how and where to access facility and community-based testing where diagnostic testing can be provided.

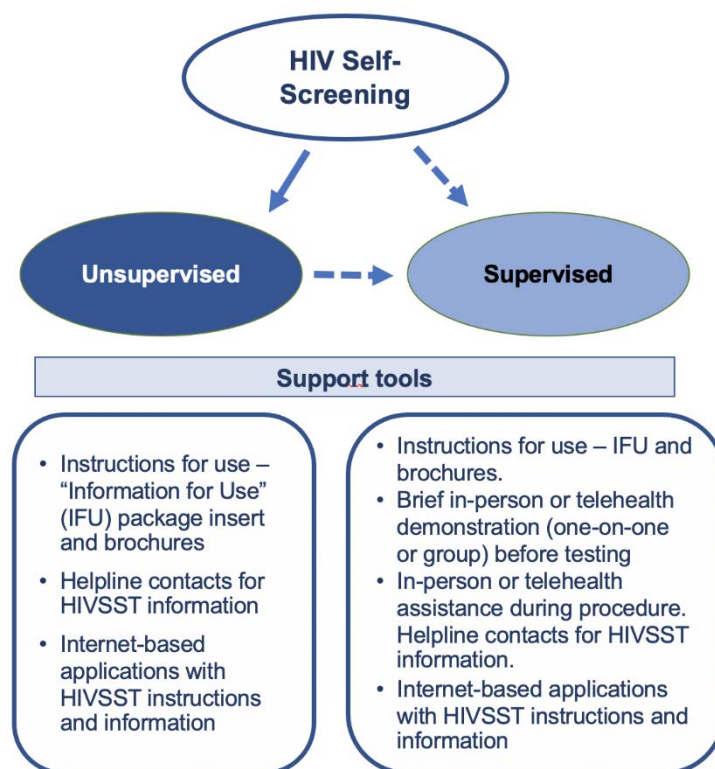
Target populations

The populations targeted for HIVSST are members of the general population, who think that they have behaviours that place them at risk of HIV infection, have never tested for HIV or test infrequently, and key populations that have been identified in the Thailand National Strategy for Ending AIDS. Each target population needs access to HIVSST and a linked package of appropriate services to their context and understanding.

Approaches to HIVSST

There are two approaches to HIV self-screening, “unsupervised” and “supervised” (also called “unassisted” and “assisted”). Regardless of the approach, users can obtain HIVSST kits through easily accessible channels, such as a point-of-sale vendor or a health facility, pending the user’s discretion. If the user desires supervision, it will be available through public, private, and civil society information and service channels. Whether the user chooses one-way communication, face-to-face or online interaction, the user remains responsible for sample collection, performing the screening test, and interpreting the result. The difference between unsupervised and supervised HIVSST will depend on the level of assistance needed by the user and from where the HIVSST kit was obtained.

Figure 1. HIVSST Approaches¹



Unassisted HIVSST refers to when an individual uses a HIVSST kit with instructions for use provided by the manufacturer without the help of a trained provider or peer. Indirect support, such as an instructional video on how to perform the screening test and telephone helpline services, may be accessed through links in the instructions, which also provides links to confirmatory testing and prevention or treatment services.

Supervised HIVSST means that health care providers may be called upon to assist screening-test users before, during and after the screening test. Supervision may include pre-screening test information, or pre-test counselling may be provided before the screening test. A demonstration on collecting the screening-test sample, performing the screening test, and interpreting the result may be provided during the screening test. Post-test counselling with referral to comprehensive services may occur after the screening test. The HIVSST user will determine when they wish to have supervision during the screening-test process. Supervision may be provided in person or through telehealth/telephone video call services. It provides a direct link to the health service system.

¹ Adapted from “HIVST Approaches and Support Tools” in National AIDS and STI Control Programme, Ministry of Health, Kenya. (2017) HIV self-testing: An operational manual for the delivery of HIV self-testing services in Kenya.

Supervision in HIVSST may include:

- Pre-test information or pre-test counselling
- A demonstration of how to use the HIV self-screening kit.
- Information on possible screening test results and their meaning and how to interpret the screening test result
- Post-screening test information – How to access HIV confirmatory testing and prevention, care and treatment services
- Post-test counselling – risk assessment and risk reduction, psychosocial support
- Referral of sexual and needle-sharing partners for HIV screening or diagnostic testing with a reactive or confirmed positive result (Index testing).

In-person supervised HIVSST may be provided through:

1. Its integration in various clinical services, using a provider-initiated testing and counselling (PITC) approach. Health clinics for tuberculosis, sexually transmitted infections, antenatal services, or adolescent sexual health may recommend and distribute HIV screening as part of their service packages.
2. Prison/correctional facility/detention centre health units
3. Community outreach activities
4. Mobile clinic
5. Drop-in centres and key population-led health centres (KPLHS).

Remote and virtual supervised HIVSST may be provided through:

1. Telephone helpline or hotline services
2. Telehealth or video calls

Secondary Distribution

Secondary distribution is the distribution of HIVSST kits among partners (including sexual and drug-injecting partners) and within social networks by individuals who have used HIVSST or have received diagnostic testing. One or more self-screening kits are given to these individuals, not for personal use but to distribute to their partners or others in their social networks. This approach can increase testing uptake among people who would otherwise not test and are at high risk of HIV infection (e.g., sexual or drug-injecting partners of HIV-positive index clients) and potentially help facilitate linkages to care and treatment.

For secondary distribution to be effective, the initial HIVSST kit distribution must include:

- Information on how to self-test
- Information on how to offer and demonstrate a self-test
- Information on linkage into confirmatory testing and HIV prevention, treatment, and care services.
- If indicated: consent for provider follow up with the self-tester directly

Essential requirements for all channels of secondary distribution:

- Screening for risk of intimate partner violence (IPV).
- The voluntary consent of the partner.
- The partner is not required to disclose their screening test result.

Secondary distribution channels for HIV self-screening

Facilities-based channels: HIVSST can promote couple or partner testing by offering individuals to give to their sexual partners, especially serodiscordant, using the secondary distribution method. Potential settings include antenatal clinics (ANC), postnatal care (PNC), STI, TB, and family planning services.

Community-based channels: HIVSST kits can be distributed through community outreach workers, drop-in centres, or key population-led health services. HIVSST kits are provided to individuals who have already been screened or tested and are willing to be secondary distributors to their sexual or drug-injecting partners.

Index testing: The distribution of the HIVSST kits may be considered for use in index testing by providing kits to people with HIV or at high risk of HIV to offer HIVSST to their partners or other people in their social and sexual networks. More information on Index Testing may be found in the Thailand index partner testing guideline 2021.¹³

Access to HIV self-screening tests

HIV self-screening tests may be accessed in the following ways:

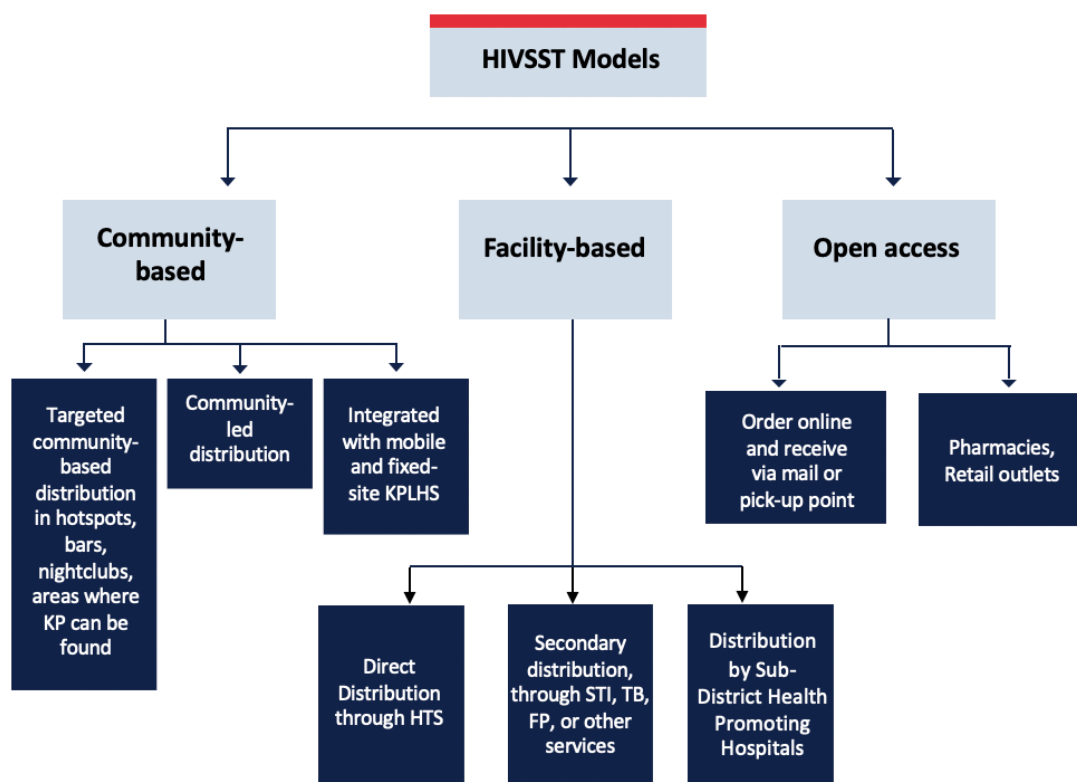
Open access: HIV self-screening tests are publicly available and distributed through many types of services and locations, such as pharmacies, clinics, convenience stores and vending machines.

Community Access: Key population-led health services (KPLHS) and community health workers provide HIV self-screening tests to members of key populations through outreach activities, community mobile health services, or KPLHS telehealth services.

Facility Access: Facility-based health professionals may offer HIV self-screening tests to clients waiting for other services, such as TB, STI, viral hepatitis or other sexual health services, or be provided with a self-screening kit to take home to use on themselves.

Facility access includes populations with limited access to HIV self-screening test kits, such as prisoners. Responsible agencies can provide inmates with HIV self-screening tests through nursing staff who have been trained in counselling and can provide referrals to confirmatory services.¹⁴

Figure 2. HIVSST distribution models²



What do the test results mean?

There are three possible HIV self-screening test results:

1. **Reactive** (often incorrectly referred to as “positive”) result. This means that the reagent in the screening-test kit reacts with the substance in the blood sample or substances from the user’s saliva. This does not imply that screeners are HIV positive but means that the user should be referred to confirmatory testing at a health facility.
2. **Non-reactive result.** Suppose the result of the test kit is non-reactive. This means that the screening kit cannot detect antibodies to HIV 1/2 in the substances tested. If the test result is non-reactive outside the window period, it may be considered a **negative** screening test result. However, the user should still be referred to HTS for HIV prevention and diagnostic services for STI and viral hepatitis.
3. **Invalid.** An unclear result that may be due to either human error or screening-test kit failure.

² Adapted from “HIVST distribution models” in United States Agency for International Development. (2021). HIV self-testing operational guide for the planning, implementation, monitoring and reporting of HIV self-testing.

The user should repeat the test with a new HIVSST kit with an invalid result. They should understand that the HIVSST may be inaccurate in cases where:

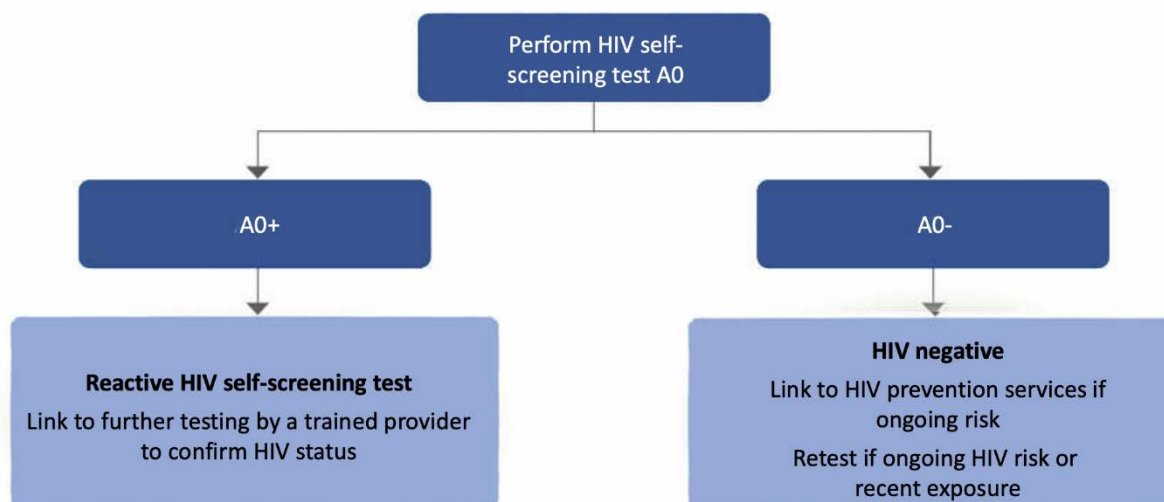
- HIVSST kits are not up to quality standards
- Incorrect testing procedures, e.g., insufficient sample collection (oral fluid or blood).

If screening-test kit failure is suspected, the user should do the following:

1. Repeat the screening test with a new HIVSST kit or get re-tested at a facility-based service.
2. Report the problem to the dealer. Inform them of the problem and provide the HIVSST kit lot number.

HIVSST is for screening purposes only. An HIV diagnosis cannot be based on a single test result. Therefore, a trained service provider should confirm a reactive self-screening test result using tests identified in the validated national testing algorithm. A person testing non-reactive (negative) is advised to re-test if they have been exposed to HIV within the window period or are at ongoing risk of HIV exposure.

Figure 4. HIVSST triage³



³ Adapted from: WHO Consolidated guidelines on HIV prevention, testing, treatment service delivery and monitoring, July 2021.

The HIV self-screening test as an entry point to HIV prevention and treatment

An HIV test should be followed by a status-neutral approach to active engagement of the client regardless of their HIV status. Those who tested HIV-positive are engaged in treatment right away, while those who tested HIV-negative are also immediately engaged in PrEP or PEP. Both HIV-positive and HIV-negative individuals end at a common final stage of continuously engaging in clinical care with zero risk of transmitting and negligible risk of acquiring HIV. Condoms are available to prevent STIs and pregnancy regardless of HIV status.

The HIVSST can be an entry point into HIV testing, prevention and treatment, as shown in the diagram below.

1. Provides an opportunity for individuals who are reluctant to test for HIV to test in the privacy of their own home and adjust to the result before accessing confirmatory testing for prevention or treatment purposes.
2. Provides an opportunity for others who may have never tested or may be at risk of HIV infection to receive a HIVSST kit through secondary distribution or index testing as an entry point to HIV testing, prevention, and treatment.
3. Provides an opportunity for remote monitoring of individuals taking PrEP when access to facility-based services is limited, such as during COVID-19 lockdowns.

Entry points for HIVSST into status-neutral, comprehensive HIV services

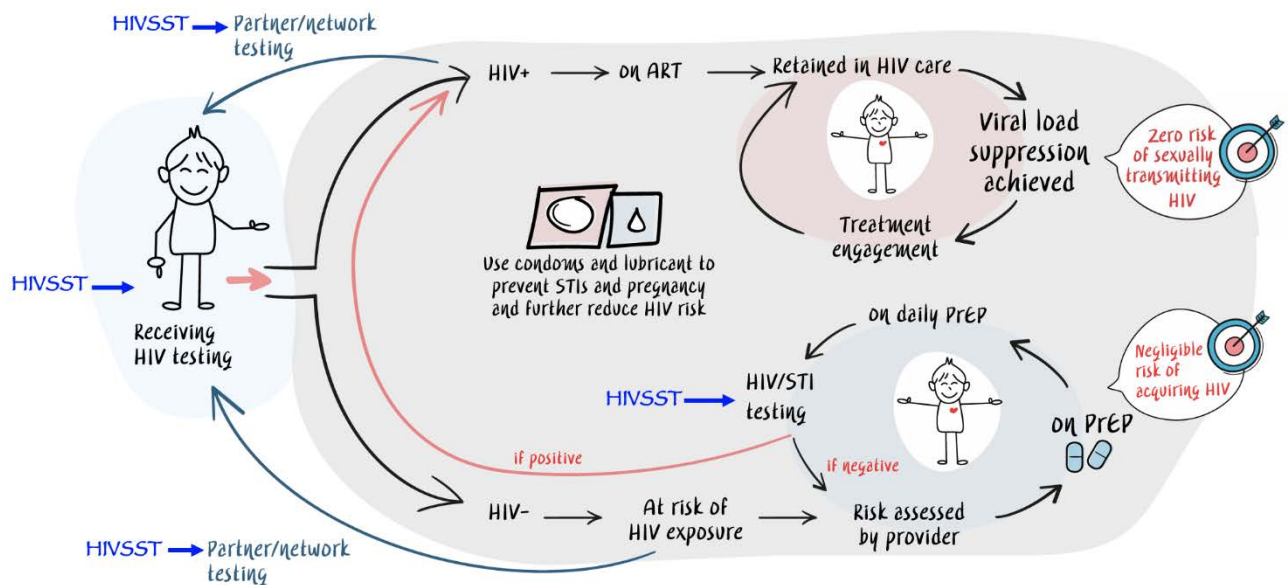


Figure 3. Adapted from “Status-neutral” approach to HIV as a way to shift the messaging and programming paradigms of HIV treatment and prevention in Phanuphak, N., Ramautarsing, R., Chinbunchorn, T., Janamnuaysook, R., Pengnonyang, S., Termvanich, K., . . . Phanuphak, P. (2020). Implementing a Status-Neutral Approach to HIV in the Asia-Pacific. *Current HIV/AIDS Reports*, 17(5), 422-430.

Referral and Linking into Comprehensive HIV Services

HIV self-screening is considered a strategy to increase the uptake of systematic HIV testing in populations that have difficulty accessing HIV testing and treatment services. Linking HIV self-screening test users to HIV services is critical for attaining the national 95-95-95 goals. Communication and demand creation are essential in creating efficient links between HIV self-testing and health services. Linkage to services includes linkage to confirmatory HIV testing by a trained healthcare provider in a stigma-free setting.

Services that should be linked before, during or after HIV self-screening:

- Counselling before and after HIV self-screening. (Pre-/post-test counselling)
- Supervision for conducting HIV self-screening test and interpretation of results.
- Confirmatory testing
- Referral to health facilities, both public, private and civil society
- HIV prevention services, condoms, lubricants, PrEP and PEP
- Early HIV treatment and care

HIV self-screening is considered a strategy to increase the uptake of systematic HIV testing in populations that have difficulty accessing HIV testing and treatment services. Regardless of the screening-test result, linking HIV self-screening test users to HIV services is critical for attaining the national 95-95-95 goals. Communication and demand creation are essential in creating efficient links between HIV self-testing and health services. Linkage to services includes linkage to confirmatory HIV testing by a trained healthcare provider in a stigma-free setting. For non-reactive results, clients should be referred and linked to HIV prevention services such as PrEP, treatment of STIs, provision of condoms and partner testing/notification.

Linkage channels after HIV self-screening

- Information material, such as manufacturer's instructions for use, brochures and flyers distributed with HIV self-screening kits should have information on linkages for all possible outcomes.
- A telephone hotline that self-screener can use before, during or after self-screening for psychosocial or technical support can help with referral and linkage information.
- Mobile phone text message (SMS) services or a smartphone application can provide information, reminders, videos and messages that encourage linkage following HIVSST
- Proactive, community-based follow-up by peer or outreach workers
- Community health workers can provide additional post-screen counselling where appropriate and support with referral to confirmatory testing services
- Couples and partner self-screening can promote linkage and should be encouraged, including partner delivered self-screen kits with information on linkage

Chapter 3: Communication and Demand Creation for HIVSST

HIV self-screening is a strategy for reaching people who have never been tested for HIV before (first-time testers), who do not know their status or have ongoing risk of infection, and to normalise HIV testing. A survey conducted in September 2021 found that knowledge about HIV self-screening among the general population of males and females is still relatively low (22% males and 38% females). However, in key populations, specifically, men who have sex with men and transgender women, awareness of HIV self-screening was much higher (>58-60%), and demand for self-screening was very high (99%)⁴ when compared to referral to facility-based HIV testing.

Principles of communicating HIVSST use

The content and communication channels should be tailored to the target audience's context. If planning to provide information through various social media channels, knowledge level, language used and understood, and the ability to access devices, such as smartphones, applications, or the Internet, should be considered. Various traditional media styles, such as leaflets, brochures, and billboards, may also be used.

Communication channels: It should be used for many purposes;

- Create awareness of HIV self-screening test kits available in Thailand approved by the Food and Drug Administration.
- Provide information on how to get an HIV screening test kit.
- Have links to comprehensive HIV services
- Collection of data on the use of the screening-test kits and screening-test results.

Access to HIV self-screening must take into consideration the decision-making capacity of every target population. Special care must be given when it comes to the issue of age and open access. The *Guidelines for the Implementation of the Ministerial Regulation Determining the Types of Services, Facilities and the Facility Operations for Preventing and Solving the Problem of Adolescent Pregnancy, 2019* conclude that children from the age of 10 have the right to HIV and STI testing without parental consent. However, before the introduction of HIV self-screening, testing would have occurred in health facilities. If children and youth have access to HIV self-screening, links to youth-friendly HIV services or appropriate KPLHS are required.

Communication

In raising awareness to increase the uptake of HIV self-screening, it is necessary to create campaigns and create messages focused on the use of the screening-test kits, the correct interpretation of the screening test results, and linkages to confirmatory testing, prevention, treatment and care services. Communication for screening-test demand creation should be based on the normalisation of HIV and promote a status neutral approach to reduce stigma and discrimination and the likelihood of intimate partner violence (IPV), self-harm and human rights violations from inappropriate use of HIV self-screening kits. Communication messages should also promote the use of the standardised test kits that have been approved by the Food and Drug Administration (FDA). Communication messages may target three main groups:

- Health service providers
- General population
- Key populations

⁴ Girault, P., Misa Wong, C., Jittjang, S., Fongkaew, K., Cassell, M. M., Lertpiriyasuwat, C., Phanuphak, P. (2021). Uptake of oral fluid-based HIV self-testing among men who have sex with men and transgender women in Thailand.

It is essential to adjust the communication content to the target audience's context. This adjustment can be accomplished through the following communication strategies.

Communication strategies for different targets

For health care providers

- Build awareness of the benefits of HIV self-screening, from knowing your status to the simplicity and convenience of the screening test kits.
- Build understanding and develop the capacity of health care providers for HIV self-screening as an innovation in HIV testing to increase access to HIV testing. Strategies:
 - Distribute guidelines for HIV self-screening
 - Create a manual on HIV self-screening
 - Provide Continuing Medical Education credits (CMEs) or Continuing Professional Education credits (CPEs) in the training of medical personnel, including medical technicians, nurses and pharmacists.
 - Provide on-the-job training (OJT)
 - Distribute Information Education Communication (IEC) materials
- Integrate into other health services, such as TB and family planning, among others, by inserting HIV self-screening into the service flow.

For general population

- Communicate, emphasising an understanding of HIV in treatment issues. For example, “Quick and treatable” can promote HIV self-screening while reducing stigma and discrimination for those with reactive test results.
- Build understanding and awareness among the general population that self-testing for HIV can be a means of knowing their HIV status. Regular media channels or media such as leaflets, brochures at screening-test kit sales points, such as pharmacies, are methods to do this. Digital platforms, such as the Internet and Google, and social media platforms, such as Facebook, LINE, Twitter, etc., are other options.
- Communicate that HIV testing is a regular part of personal health care. Include the use of HIV self-screening as part of the annual public health check-up package that can be conducted unsupervised at home or under supervision online or at medical facilities with links to comprehensive services.
- Communicate the need for confirmatory testing to both persons with reactive screening-test results or non-reactive screening-test results to reduce the stigmatisation and discrimination for those with reactive test results and provide access to comprehensive HIV services.

For key populations

In addition to the communication strategies used to reach the general population, communication strategies to reach key populations will be adapted to their specific contexts.

- Providing information about the steps in HIV self-screening by phone or video call via Internet or application and the next steps for reactive and non-reactive results.
- The government works together with civil society organisations, which work with key populations, children and youth groups, migrant workers, and the private sector to create key messages tailored to different groups' contexts.
- The government works with civil society organisations that work with the key populations, children and youth groups and migrant workers, including the private sector, to create

communication data sets with the same data structure but tailored content to the context of different groups.

- Provide key messages with important prevention issues, such as knowing your HIV status and access to PrEP.

Key communication messages:

- Ease of knowing your HIV status.
- Where to get confirmatory testing.
- How to access post-test counselling when needed.
- How to access prevention (PrEP) and treatment (ART) services.
- How to access psychological support services.

Communication Channels

One-way communication

- Develop media campaigns tailored to specific key populations or the general population. Methods may include publicity billboards, posters, newspaper advertisements, television and radio spots and programmes, etc.
- Government, civil society, and the private sector websites and social media channels, such as Facebook, LINE, Twitter, YouTube, and TikTok, can reach out to various key population groups and be searched through various search engines such as Google.
- Provide information documents, including pamphlets, and brochures, with both images and print information and easy-to-understand communication formats, such as a cartoon format suitable for the target group.
- Target various dating applications for key populations, such as Grindr, Hornet, BlueD, and the general population, including all gender groups, and applications accessible to adolescents and young people.
- Video clips to communicate and demonstrate the use of the HIV self-screening test kits and discuss the benefits of confirmatory testing and prevention and treatment services.
- Group messaging, such as SMS, LINE, and WhatsApp, provides information, alerts, and links to services.

Interactive communication

- Promote official communication channels, such as Moh Prom, which can access information, registration, and linkages to supportive services related to HIV self-screening.
- Web boards and chatbots such as Buddy Station of the Department of Disease Control to post questions for an informed response.
- Hotlines to guide HIV self-screening both before and after conducting the screening test. Possible hotlines may include:
 - 1663 AIDS and Pregnancy Consultation Hotline (AIDS ACCESS), Mental Health Hotline 1323 (Department of Mental Health, MOPH), and others for the general population.
 - Sai Sabai Jai (Rainbow Sky Association of Thailand) and other civil society hotlines for key populations.
- Access to specific social media channels such as LINE groups or Facebook groups.

Demand Creation

The principles that should be considered when creating demand for HIV self-screening are “easy access, easy linkages, and easy treatment.”

Methods for generating screening-test demand are grouped according to the characteristics of access described in the previous chapter. These are: Open access through the free market that is easily accessible to the general public; Assisted access through community health services and civil society organisations; and semi-restricted access through health care facilities such as hospitals or clinics

Open access demand creation

Open access demand creation means creating demand for commercially available HIV self-screening kits. This demand will be created by communication messages through the various channels mentioned above, targeting private sector enterprises, such as pharmacies, as both dealers and distributors. Demand creation among target groups requires systematic access to the kits and links to support services after purchasing the screening test kit. The use of HIV self-screening kits approved by the Food and Drug Administration should be emphasised.

Other demand creation strategies may include:

- Use celebrities or net idols who previously used HIV testing kits to promote HIV self-screening kits in each target group.
- Give out discount coupons or provide rebates to self-purchased screening kits.
- Provide fast-track access to confirmatory testing and other services, such as PrEP.

Health service provider demand creation

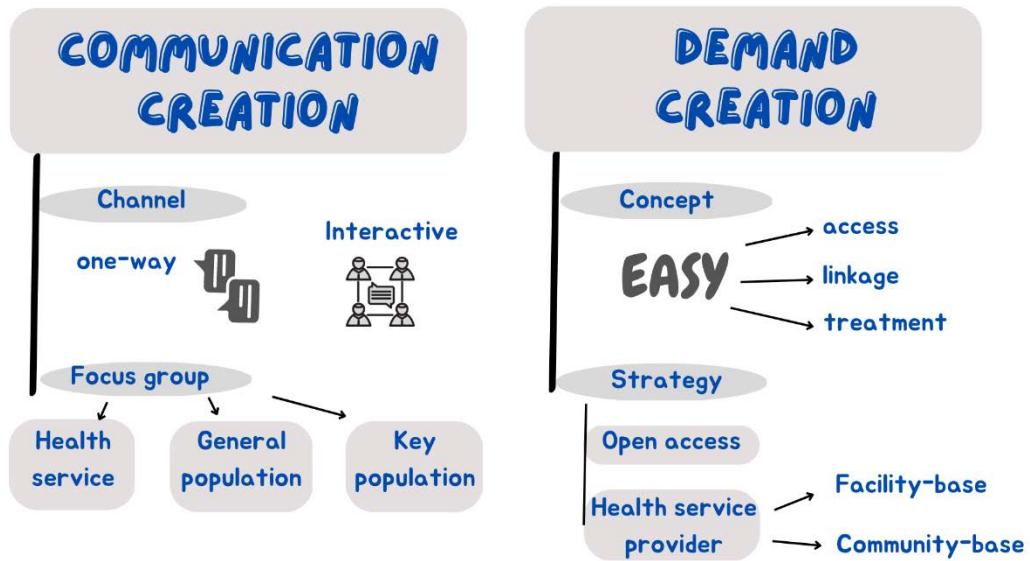
Facility-based demand creation

- HIVSST can be conducted at the hospital, or screening can take place at home.
- Integration into HIV testing services (HTS), such as HIV clinics, PrEP or PEP services, and treatment and care for discordant couples.
- Integrate HIV self-screening into regular public health services, such as antenatal care (ANC) and family planning, adolescent clinics, tuberculosis clinics, and sexual health clinics with services for sexually transmitted infections and Hepatitis B and C.
- Encourage health care providers to motivate patients in various clinics. Get yourself tested for HIV. Either in family planning clinics, tuberculosis clinics in the main population, or inviting couples for HIV testing.
- Advocate for the inclusion of HIV self-screening as a health benefit under the Universal Health Care scheme (UHC), Social Security scheme (SS), and the Civil Service Medical Benefits Scheme (CSMBS).

Community-based demand creation

- Increase the provision of HIV self-screening kits in community HIV services or key population-led health services (KPLHS).
- Provide mobile clinical services in the community or in drop-in centres that can recommend using HIV self-screening kits at the service or provide them for use at home. Information about the person receiving the screening kit would be collected to coordinate further linking into the system.
- Provide information through a social network approach in key population groups.

- Provide proactive service by the staff, both in-person and online, especially for hard-to-reach groups at very high risk, such as subgroups of men who have sex with men involved in Chemsex or swinging.



Chapter 4: Commodity Management

This chapter covers the management of commodities, i.e., HIVSST kits, and commodity data for HIVSST across the public and private sectors.

Commodity Management

Commodity management encompasses collaborative practices that ensure appropriate and high-quality supplies are available whenever and wherever needed. It entails proper coordination and management of commodities to ensure six of the seven “Rs” (rights) in the 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.

Pricing

A research study found that HIVSST users are willing to pay not more than 250-300 baht per kit.¹⁵ However, if efforts succeed in getting coverage for HIVSST under the Universal Health Care Scheme, more competition would be created, and more HIVSST options would be available in the future. The NHSO should consider expanding HIV testing benefits to include HIVSST free of charge. Management of HIVSST should be a collaboration between key agencies, namely the NHSO, the Social Security Office (SSO), and the Comptroller General's Department. Academic information can be provided by the Department of Medical Sciences, the FDA and the Division of AIDS and STIs.

HIVSST Kit Selection

Together with the Department of Disease Control and the Department of Medical Sciences, the Food and Drug Administration will review dossiers of HIVSST kits submitted for approval. The review is based on HIVSST selection criteria set by the collaborating agencies. In-country validation of kits under consideration is also required.

Quantification and Procurement

Procurement will be based on a national forecasting and quantification process for the public sector. The NHSO will be responsible for forecasting supplies and procurement of test kits for the public sector. Private-sector forecasting will be based on consumer demand, and procurement will be managed through the existing commercial procurement.

Allocation and test kits distribution plan to service delivery points

A HIVSST commodity management system is needed for the public sector. HIVSST kits will be initially allocated to service sites based on estimates and subsequently on consumption reports. The county reporting and allocation mechanisms will generate data on the number of test kits issued. The allocation and distribution plan in the private sector will be based on the demand generation and distribution mechanisms in place for other commodities.

Inventory Management

The management of the kits will be aligned with the existing inventory management system. This system will include receipt of kits, storage according to the manufacturer's instructions or adherence to the recommended storage guidelines, and distribution to service delivery points (SDPs). Existing tools, such as stock cards and the commodity management reporting system, will ensure proper record-keeping.

Screening test kits nearing their expiration date

Because HIVSST kits do not have a long shelf life, the stock should be regularly reviewed to manage the test kits purchased and distributed to different service points. Responsible agencies should establish an expiration date management plan, such as reallocating HIVSST to nearby service points with higher demand, for example, from government clinics to civil society services, which may reach potential users more easily or distribute HIVSST through promotional campaigns.

Expired HIVSST kits could be used to train service providers on how to demonstrate HIVSST to clients, or they may be used in the actual demonstrations since the sample collection and interpretation of the demonstration screening test result is not needed.



Chapter 5: Coordination and Capacity Building

Self-screening for HIV remains a new issue in Thailand. It requires coordination across sectors, from the policy level, issuing operational guidelines for health services in the public, private and civil society sectors to the universal health insurance system, which has experience in managing the COVID-19 outbreak, using self-test kits to detect SARS-CoV-2. In addition, Thailand has recently introduced PrEP into HIV prevention services, which provides a wealth of experiences to learn from and drive the use of HIV self-screening kits.

Roles and Responsibilities of public health services, civil society, and the private sector

The table below summarizes the roles and duties of service providers in government, civil society, and private sector services. This list of roles and responsibilities is not comprehensive but just a few examples of what can be done. The role and duties are listed by RRTTPR measures and deal with HIVSST only. Other roles and responsibilities in comprehensive HIV services are not included here.

In addition, self-testing for HIV is still new. HIV testing could only be provided by doctors, nurses, or medical technologists in the past. For HIV, self-screening, counselling, test kit demonstration, and supervision do not need to be provided by a medical service provider. Trained and certified civil society volunteers can provide counselling, demonstrate oral fluid and blood-based screening test kits, and interpret results. Responsibility for sample collection and interpreting results will lay with the user.

HIV program cascade	Description	Government Services/ KPLHS	Civil Society Organizations CSO/NGO	Private service access points
Reach/Recruit				
Awareness-raising & Demand creation for self-screening	HIVSST is offered in community/mobile services and online service channels	✓	✓	✓
Access to free test kits	HIVSST kits are provided through project sponsorship or by reimbursement by NHSO.	✓	✓	✓
Access to test kits for sale	- Selling in the retail shop - Social marketing - For fundraising	KPLHS only	✓	✓
Demonstration of how to use a test kit or pre- and post-screening test Counselling	Counselling before and after a demonstration of test kit use when needed. The range of services provided will depend on the needs of the user.	✓	✓	✓
Secondary distribution	Individuals reached are provided with HIVSST kits to distribute to sexual partners and others at risk.	✓	✓	✓
Referral for confirmatory HIV testing	HIVSST users are referred to KPLHS or other clinical facilities for confirmatory testing.	Sub-district community hospitals	✓	✓

Test				
Confirmatory testing	Confirmatory testing is provided through medical facilities and KPLHS and linked to prevention and treatment services.	Medical facilities & KPLHS (MOPH service unit)		
Follow-up of confirmatory testing	Follow up call/contact to ensure HIVSST users proceed to confirmatory testing.	Sub-district community hospitals	✓	✓
Pre- and post-test Counselling for confirmatory testing	HIVSST users receive standard pre- and post-test counselling through clinical facilities and mobile services equipped to provide confirmatory testing.	✓	✓	
Secondary distribution through Index testing	Index clients provided with HIVSST kits to distribute to sexual partners.	✓	✓	
*Prevention				
Counselling on PrEP and combination prevention**	Counselling provided for effective use of PrEP and the importance of condoms in preventing other STIs, including hepatitis B and C.	✓	✓	
Recommend HIVSST as an entry point for access to PrEP or PEP	HIVSST is provided as part of a PrEP and PEP promotional package.	✓	✓	
HIVSST for the continuation of PrEP during emergencies (see chapter 8)	Home HIVSST as an alternative to facility-based testing during emergencies	✓	✓	
Retain (Negative)				
HIVSST for follow up testing for individuals testing negative	KP-lay providers send reminders for retesting	✓	✓	

Note:

* Refer to the Thai PrEP guidelines document.

** The cascade for treatment is not included in this table because users must undergo confirmatory HIV testing first.

Different levels of service provision of government and civil society service providers.

Level	Services	Description	Service entities
1	RRR	Reach, Recruit, Retain	CSO/NGO
2	RRTR	Reach, Recruit, Test, Retain - referral to secondary hospitals for confirmatory testing	CSO (GF), Sub-district community hospitals
3	RRTTPR	Reach, Recruit, Test, Treat, Prevent, Retain – and for KPLHS – further service referral to secondary & tertiary level hospitals.	KPLHS and from secondary-level hospitals up.

Coordination

Thailand should establish a coordinating mechanism to bring HIV self-screening concretely to life. The relevant agencies to be invited to participate in the mechanism should include regulatory agencies for the use of test kits, professional councils, manufacturers and distributors of test kits, civil society organizations, representatives of different populations groups, and resellers of the test kit, including the seller of the test kits, such as pharmacies and convenience stores.

From the first national consultation on HIV self-screening, coordination was discussed, and the roles and responsibilities of various agencies related to HIV self-screening were identified.

Table 1: Coordination

Tasks	Key agencies	Support agencies
1. Preparation/review of policies and strategies	DDC, NHSO	CSO
2. Preparation/review Guidelines for using the test kit	DAS	HITAP CSO DOC
3. Estimate/review the number of test kits required for each population group and resource estimation	DAS, DEpi, CSO	Development partner, Product distributors
4. Preparation/review of measures to communicate and create demand for testing kits together with the reduction of stigma and discrimination	CSO, DAS	Business Sector (Distributors), Office of Risk Communication Development
5. Preparation/review continuous service arrangement and organize a support system	DAS, CSO	Office of Public Health Administration
6. Training and quality control of the use of the testing kit and organising a support system	DAS, CSO	Product distributors, Pharmacy Assoc
7. Prevention of adverse events (e.g., self-harm, coerced or compulsory examination)	DAS, CSO	Rights Protection Sub-Committee
8. Management of test kits (Supplies change) QA of test kits in case of inclusion in health benefits, Quality control of test kits	NHSO, SSO, Comptroller General's Dept.	Dept. Med. Sci., FDA

Tasks	Key agencies	Support agencies
9. Monitoring and Evaluation – logging, surveying, data usage	DAS, DEpi, NHSO, CSO	Subcommittee for Ending AIDS, National AIDS Committee
10. Implementation of HIVSST	Public Health facilities, CSO/KPLHS	DAS, NHSO

DDC, Department of Disease Control, NHSO, National Health Security Office, CSO, Civil Society Organizations, DAS, Division of AIDS and STIs, SSO, Social Security Office, DEpi, Department of Epidemiology, FDA, Food and Drug Administration, HITAP, Health Intervention and Technology Assessment Program

Private-public partnerships

Private-public partnerships (PPP) should link the private HIVSST kit distributors and private health providers to the national HTS program. The PPP will assist the country in achieving the gaps in the 1st 95. The PPP will include and are not limited to:

1. Coordination of the private sector in providing HIVSST services
2. Dissemination of national guidelines on HIVSST to the private sector
3. Management of data on HIVSST, which includes collection and reporting to the national and provincial levels (?)
4. Analysis and use of data for decision making at various levels
5. Forecasting demand / Quantification and monitoring of HIVSST kits
6. Encouraging quality assurance of HIVSST kits that distributors have not yet obtained approval from the Food and Drug Administration.
7. Facilitating linkages:
 - a. For confirmatory HIV testing.
 - b. Into prevention, treatment and care services

The coordination of the PPP will be led at the national level. The PPP should include representation from all organizations listed in Table 1 above.

Capacity Building

Health care providers and the staff of other facilities and national programmes are likely to need guidance and training on including HIV self-testing in existing HIV testing and counselling frameworks. Standardized training content and a standardized training framework should be identified to allow collaborating partners to build capacity in their respective sectors as needed. Two areas in which capacity building is necessary are:

1. Use of the self-screening test kit
2. Data collection.

HIV self-screening test kit

Health professionals, such as healthcare workers, pharmacists, and certified civil society volunteers, require additional orientation, training, and information about HIVSST to provide adequate support and facilitate linkage to further testing, prevention, and treatment. Lay providers, such as community health care workers, community outreach workers, and peer navigators, can be highly effective in mobilisation efforts, the distribution of HIVSST kits, and facilitating linkages to health facilities, mobile services, and community outreach activities. They also

need training. However, the standards in training will differ, depending on the roles and responsibilities of the provider. Therefore, two standard levels of training are recommended.

The table below lists contents for two levels of training, basic and advanced, while the contents in both courses are similar, the advanced course provides instruction in greater detail. Some additional topics, which service providers may encounter and troubleshoot, have been added.

Training topics for basic and advanced levels

2-Day Basic training

<u>Chapters</u>	<u>Topics covered</u>
Basic Information about HIV	Basic facts about HIV transmission and treatment Discordancy
Introduction to HIVSST kits	Antibody-based testing Promotion of HIV self-screening to clients Supervised and unsupervised HIVSST and secondary distribution Principles of consent and confidentiality
Skills for using HIVSST kits	Familiarisation with the HIVSST kits and teaching and demonstrating how to use them Interpretation of results
Links to health services	Linkages/referral to health facilities
Monitoring and evaluation	Data collection tools

4-Day Advanced training

<u>Chapters</u>	<u>Topics covered</u>
Same as the 2-day Basic training, but in greater detail and with the following additional modules	
Skills in HIVSST Counselling, online and offline	Pre- and post-screening test counselling and stand-alone post-screening test counselling, in-person and online Screening for Intimate partner violence
Partner screening/testing	Secondary distribution of HIVSST to partners Index testing

Regardless of the training standard, all trainees should undergo competency testing at the end of the HIVSST training course to assess training knowledge and skills. Once they have completed training and successful competency testing, they should be able to: provide clients with brief health information about HIV; information on the test; explain the benefits of using FDA approved self-screening kits; explain the contents of the “information for use” package inserts of the approved screening-test kits; perform the HIV self-screening tests; interpret the screening test results; demonstrate how to use the HIV self-screening test kits; make appropriate referrals for confirmatory testing.

Data collection

Staff should be trained on data quality to ensure that data integrity is maintained. Proper training will ensure that staff involved in data collection can identify barriers to data quality and make attempts to avoid them. Staff training should emphasise the importance of good quality data and how staff can contribute. It should include individual responsibility regarding data collection, analysis, and reporting, in addition to the implications of poor data quality, their accountability and policies related to data quality security and data protection.



Chapter 6: Quality Assurance

Evidence has shown that HIV self-screening has a high level of accuracy for both sensitivity and specificity when quality-assured products are used in the hands of untrained users (Figueroa, WHO, 2016). All HIVSST kits shall be subject to quality assurance according to defined national standards and should be monitored and evaluated. In addition, all providers should be trained to provide quality self-screening according to these guidelines

Benefits of Quality Assurance

Quality assurance (QA) is a systematic, planned approach to monitor, assess and improve the quality of services continuously. Quality assurance is an integral part of all HIV Testing and Counselling Services (HTC) and should be implemented through practical and straightforward approaches at all levels.

For HIVSST, a focus on quality assurance will:

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

Components of QA for HIVSST

Quality assurance for HIVSST can be considered in terms of quality assurance of the test product and the HIVSST process. Establishing quality assurance standards and systems

Quality Assurance of HIVSST test kits

WHO Prequalification

All test kits for national procurement MUST attain WHO pre-qualification of the HIVSST test kit.

In-country laboratory validation

All test kits must undergo in-country laboratory validation by the Department of Medical Science to meet minimum standards.

Registration by a regulatory body

All HIVSST kits must be validated, certified and registered by the Food and Drug Administration before being dispatched into the market.

Lot to lot validation

All procuring entities must ensure that any new lots of HIVSST test kits coming into the country are evaluated to ensure that products delivered meet the 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 agencies to assess whether the quality and performance of the test kits in use comply with the set standards.

Quality assurance of the HIVSST procedure

Capacity building and sensitization on HIVSST

All HIV self-screening test service providers should be sensitized according to the HIVSST training package. This sensitization includes capacity building and knowledge on conducting the tests, providing online counselling, and referring clients for additional testing and further support. Quality assurance assessments should be performed periodically to ensure that competencies in HIVSST service support are maintained.

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

Information on HIVSST, including but not limited to how to conduct HIVSST and results interpretation, should be readily available to all clients in various online and offline formats. All clients must also be aware of the need to confirm any reactive test results as per the national HIV testing algorithm. SOPs should be developed to guide supervised HIVSST, referral and follow-up.

Information on the HIV Self Screening Kit (IFU)

The information contained in the HIV self-screening kit requires an “information for use” (IFU) package insert. The IFU should include instructions for self-screening test use with easy-to-understand images of the screening process that will facilitate the correct use of the screening-test kit and accurate interpretation of the result. The instructions should include the following:

- Ethical and legal considerations. The user performs the HIV self-screening test with voluntary informed consent, absent of any form of coercion.
- How to manage test kits and proper storage before use.
- How to interpret the HIV self-screening test result.
- What you should do after reading the screening-test result. Information on post-examination services such as counselling, confirmatory testing, and access to prevention, treatment and care services.
- Safe disposal of used screening-test kits.

Infection, prevention and control

While the risk of HIV transmission through HIVSST using oral fluid is minimal, clients should be made aware of correct practices to minimize biosafety risks when using blood-based screening test kits. Biosafety and infection control measures should be adhered to when blood-based kits are used as per manufacturers’ instructions.

Referral and linkages

Information on referral and linkage to HIV appropriate services should be available to all clients. With a reactive HIVSST test result, users must know where confirmatory testing is available. An online referral directory of confirmatory testing services and other services should be available.

Approved HIV self-screening (HIVSST) kits

HIVSST kits have “unofficially” been on the market for some time. However, in 2019, the Ministry of Public Health announced the approval of the use of HIV self-screening tests that have been pre-qualified by the World Health Organization. As of August 2021, the Thai Food and Drug Administration (FDA) approved the blood-based INSTI HIV Self-Test (Bioanalytical, Canada), which entered the market in late 2021. An oral fluid-based self-screening kit, OraQuick HIV Self-Test (OraSure Technologies, USA), was approved and will enter the market in early 2022.

At the same time, HIV screening test kits that the FDA has not approved are available through online channels for personal consumption. Product dealers claim that these screening test kits have been certified abroad, but they have not yet been approved for use in Thailand. The responsible agencies should encourage the manufacturers or distributors to apply for test kit approval from the Food and Drug Administration. Greater competition in the free market between self-screening kits may help to reduce prices and create greater access to the kits.

Approved HIVSST kits in Thailand

Test name (manufacturer/ supplier)	Test generation	Specimen	Approval status	Distribution channel
INSTI® HIV Self-Test (bioLytical Lab., Canada)	3	Whole blood	Thai FDA approved	Online, Pharmacies
OraQuick® HIV Self-Test (OraSure Technologies, USA)	2	Oral fluid	Thai FDA approved	Online, Pharmacies
iCARE HIV 1&2 Self Test Rapid Diagnostic Kit (Nantong Egens Biotechnology, China)	3	Whole blood	Thai FDA approved	Online, Pharmacies

Chapter 7: Monitoring and Evaluation

This chapter outlines the monitoring and evaluation (M&E) requirements to inform uptake and utilization of HIVSST. Thailand needs to develop an M&E plan, indicators, tools, and equipment to monitor and assess HIV self-screening outcomes that can be measured through in-person and online services and include open access self-reporting. The country's current system for COVID-19 control may be used as an example.

Indicators for monitoring and evaluation

There are many indicators for monitoring and evaluating HIVSST. However, considering the main purpose of HIVSST, it is important to link the indicators directly to 95-95-95 targets. Therefore, the indicators presented in this document are high-level indicators that demonstrate the uptake of HIV testing in Thailand among various populations and an increase in access to antiretroviral drugs for treatment and to reduce the spread of infection. The data must be disaggregated by demographic group, gender, and age to be used as quantitative and qualitative data according to HIV standards.

Examples of indicators for HIVSST

Access to HIV testing services (HTS)	Data Source
1. Number of new HIV testers who have never been tested before, who test with a HIVSST	NAP
Access to HIVSST	
2. The number of people accessing HIVSST	Registration to get a HIVSST kit, IBBS
3. The number of people with a reactive HIVSST result who access confirmatory testing	Registration to get a HIVSST kit, NAP
Linked uptake of HIV treatment and access to PrEP	
4. The number of self-testers presenting for confirmatory testing and access care and treatment services.	NAP
5. The number of self-screening test users presenting for re-testing to access PrEP	NAP

Tools related to monitoring and evaluation of HIV self-screening should be developed and used nationally and at the level of implementation to record information that will be reported. Data collection may involve adding indicators related to HIVSST users seeking confirmatory testing and starting treatment in NHSO's NAP system and adding indicators in the IBBS on access to HIVSST in the general population.

Concerning reporting the use of HIV self-screening kits, additional tools need to be developed to retrieve data and facilitate reporting by various health care facilities at each level

These tools should include the following:

1. The addition of HIVSST to the HIV test registration system or set up a separate registration system for HIVSST.
2. The collection of data to show links to the NAP system
3. The addition of HIV HIVSST to the IBBS data collection

Chapter 8: Considerations for HIVSST in time when HTS are inaccessible

The Coronavirus Disease 2019 (COVID-19) is a significant health threat, which has caused countrywide disruptions, such as economic slowdown, travel restrictions, interruptions to the supply of medical, diagnostic and infection prevention commodities. It has severely affected access to public health services.

The 2020 – 2021 period is an example of the significant barriers to accessing public health services, including HIV testing, prevention, treatment and care. However, in the future, public health services, including HIV services, might be interrupted more often due to various natural disasters, including other epidemics. These interruptions are likely to be more severe and occur more frequently due to global climate change. The use of HIV self-screening kits is an option that still allows users to have access to HIV detection and access to related services

Advantages of using HIV self-screening kits during unusual situations

- Users can access HIV testing while adhering to social distancing disease prevention guidance.
- It reduces the number of people attending HTS in health facilities.
- It reduces persons with non-reactive results risk of exposure to infections during hospital visits.
- Provides an opportunity for a person to check their HIV status more frequently as part of their ongoing HIV prevention efforts to maintain their negative status

Using HIV Self-Screening Kits in Different Situations

The implementation of HIVSST can be easily adapted to the Covid-19 epidemic control period or other emergencies, including various disasters, such as flooding. It can be used in facilities and community settings, ordered online, or purchased close to home. HIV self-screening kits could even be considered for survival kits along with other medical supplies in the future.

HIV Self Screening Kit and PrEP Continuous Use

One issue to consider is whether it is possible to use HIV self-screening for the continuation of PrEP. PrEP clients need to have periodic HIV testing to receive their medication refills. During the COVID-19 crisis, many clients could not access PrEP because they could not attend clinical services for a blood test during the epidemic. HIV self-screening, combined with electronic-health initiatives (telehealth services), could provide access to PrEP during periods of lockdown. Blood-based HIVSST may be preferable over oral fluid-based HIVSST.¹⁶ Further studies are needed to explore this possibility.

Chapter 9: Social Precautions, Incident Reporting and Management of HIVSST Misuse

While ethical, legal, and human rights concerns have been raised about the licensing of HIV self-screening tests for private use, studies have shown that HIV self-home tests are not likely to be harmful in a way that justifies restricting people's access to them and have plausible benefits⁵. At the same time, it is vital that protections are in place to protect against coerced testing and that information about linkage to treatment and social and psychological and legal support is available.

HIVSST and human rights violations

Areas of particular concern are abusive relationships, employment, and education. The HIVSST could conceivably be purchased to bully partners (or family members), employees, or students. There is particularly some concern that HIV self-screening test kits could potentially be used to test sex partners before sexual intercourse. Testing sex partners in this manner could create situations where testing is coercive and puts individuals at risk of violence if they refuse¹⁷ or if the result is reactive.

Violations related to sexual intercourse

In the context of the HIV self-screening test, coercion is usually defined as being forced to test.¹⁸ Forced testing may be through physical means (with actual violence or threat of violence) or could involve threats to take away something if the person does not do the test (e.g., losing their job, breaking up a relationship, and not having sex)¹⁹.

Examples of coercion related to HIVSST

- Partner insisting on HIVSST before sexual intercourse.
- Pressure to have unprotected sex with a non-reactive HIVSST result.
- Commercial sex venues require supervised HIVSST for both workers and clients.
- Supervised HIVSST required for employment or education.
- Insurance companies requiring supervised HIVSST before providing coverage.

Violations related to health services

The 2016 World Health Organization (WHO) Guidelines on HIV Self-Testing state that “coerced or mandatory testing is never appropriate, whether that coercion comes from a health-care provider or a partner, family member, or any other person.” The guidelines emphasize that although reported misuse and social harm are rare, efforts to prevent, monitor, and further mitigate related risks are essential²⁰. While evidence from studies indicates that there are many benefits and that the risk of harm is minimal, coercion remains possible²¹.

Violations related to education and employment

The use of HIV self-screening tests for employment or education to screen applicants for HIV as part of the application process is a misuse of the screening-test kit. It would counter national policies on labour and education and violate human rights.

HIVSST, stigma and discrimination and self-harm

HIVSST is an entry point to confirmatory HIV testing, which serves as the gateway to HIV treatment and prevention. However, stigma and discrimination remain a barrier to the uptake of HIVSST. One study conducted in Chiang Mai in 2021 found that having a discriminatory stigma toward HIV was significantly related to having negative attitudes towards HIVSST.²² Participants in focus group discussions on MSM and TGW awareness and interest in HIVSST in Thailand in August 2021 expressed concerns about how targeted messaging on HIVSST

could contribute to greater stigmatization of MSM and TGW communities. They suggested that messaging take a risk behaviour rather than a risk group approach in promoting HIVSST. Increasing public education on HIV transmission, prevention, including PrEP and PEP, and treatment, especially U=U, and HIVSST, can help reduce the stigma associated with self-testing.

Findings from studies conducted in several countries have found that chances of self-harm resulting from the use of HIV self-screening and self-are very low. However, HIVSST should be provided within the human rights framework by providing sufficient information and links to support services, such as counselling and confirmatory testing, to reduce any chance of self-harm. HIV self-screening kits must be of high quality, be approved by the Food and Drug Administration and meet the needs of communities and key populations.

Misuse of HIVSST

According to the survey on awareness and interest in HISST in Thailand, conducted in August – September 2021, some participants revealed that they would like to use the kits to test their sexual partners before having sex. Therefore, risks related to coerced testing between sex partners, at home or an entertainment venue associated with sex, such as a sauna, and possible disclosure of personal information, need to be considered. Others were concerned about the use of HIVSST for education and employment.

Response to misuse

With any form of HIV testing, it is vital to provide safe and ethical services and have the user's consent. It is necessary to review policies and laws relevant to self-screening and build awareness of the appropriate use of the kits. In addition, the prevention of social harm and the establishment of an updated, real-time monitoring and reporting system are essential. Whether for assistance with HIV screening or referral to various HIV-related services, Helplines and hotlines are vital and should operate at appropriate times, including at night, when it may be most convenient to use them.

Potential barriers to HIVSST among the general population included concerns about the risk of violence, self-harm, or suicide; misuse of HIVSST kits; accuracy; lack of support; and potentially high costs. Educating the communities about HIVSST is critical to increase the uptake of self-testing and minimize the risks of misuse. HIV self-screening test kits must be of high quality, be approved by the Food and Drug Administration and meet the needs of communities and key populations.

Thailand has already developed a system for reporting and managing AIDS and gender rights violations among populations vulnerable to discrimination. The Crisis Response System (CRS) is the collaborative effort of DAS, the Foundation for AIDS Rights (FAR), the Subcommittee on the Promotion and Protection of AIDS Rights under the National AIDS Prevention and Alleviation Committee (NAPAC) and partners. The CRS is also a database that can be exploited to support efforts to reduce stigma and discrimination. (<https://crs.ddc.moph.go.th/crisis/public/>)

Measures to prevent misuse, incident reporting and management

Most of the measures, channels and services listed in the table below are actions that Thailand has already implemented to mitigate other problems and are proposed as a system to prevent, monitor, and resolve incidents related to the misuse of HIVSST. The health and legal sectors and civil society, together with other relevant agencies, are working in a multidisciplinary manner to prevent and redress personal, human, children's, labour, and educational rights violations. Civil society is proposing a law to outlaw all forms of discrimination as a tool to support work in all sectors in the future.

Table 1: Tools in the form of measures, channels and services for stakeholders

Tools	By whom	Note
Prevention of misuse		
Educate on HIV	Health care providers/CSO/NGO	
Educate communities about HIVSST	Health care providers/CSO/NGO	
Counselling before self-test	Health care providers/CSO/NGO	
Awareness of Human and AIDS rights, and stigma and discrimination	User/Health care providers/CSO/NGO/Law enforcers	
Reporting		
1663 hotline counselling for AIDS and unplanned pregnancy.	User	Initial contact and referral to appropriate services
<p>Crisis Response System</p> <p>- Incident reporting system: "Hello Pokpong."</p>	<p>A public health network, together with other relevant sectors, civil society, and related interdisciplinary agencies, on incident-related issues.</p> <p>User</p>	<p>A system for reporting human rights violations related to AIDS, gender, and being a member of a group that is vulnerable to discrimination</p> <p>Manual: https://crs.ddc.moph.go.th/crisis/public/contents/CRSmannual.pdf</p> <p>An online system for reporting rights violations, including coerced testing. https://crs.ddc.moph.go.th/crisis/public/case_inputs</p>
<p>One-Stop Crisis Centres (OSCC)</p> <p>- 1300 hotline</p>	<p>Health care providers/responsible line agencies</p> <p>User</p>	<p>Physical, mental health and legal support</p> <p>Hotline: 1300</p>
Lawyers Council Hotline	User	<p>Legal assistance</p> <p>Hotline 1167</p> <p>or call 02-522-7124 to 27 ext. 215-217, 02-522-7137 Fax : 02-522-7138</p>
Office of the National Human Rights Commission of Thailand	User	<p>Hotline: 1377</p> <p>Tel: 0-2141-3978-83</p> <p>Website: https://www.nhrc.or.th/Complaints/Online-complaints.aspx?lang=th-TH</p>
Civil Rights Protection and Legal Aid Office, Attorney General's Office	User	<p>Providing legal services to target groups in AIDS rights violations, gender, and demographic groups vulnerable to discrimination. under the Ministry of Justice</p> <p>Helpline: 1157</p>

Tools	By whom	Note
Support		
1663 hotline counselling for AIDS and unplanned pregnancy.	User	Hotline: 1663
1323 Mental health hotline, Department of Mental Health	User	Hotline: 1323
The Samaritans of Thailand	User	Helpline: 02-713-6793 02-713-6791 (English)
Referral to OSCC (One-Stop Crisis Centre)	Health care providers/CSO/NGO	The OSCC provide physical and mental treatment, legal assistance, and recovery and rehabilitation, with multidisciplinary teams to help victims of all forms of violence.
HIV testing	User	District hospitals, Provincial hospitals http://testmenow.net http://love2test.org
Sai Sabai Jai, Rainbow Sky Association of Thailand	User	Tel. 090-648-7407

* The measures, channels and services provided here are not exhaustive. Therefore, this information should be updated regularly

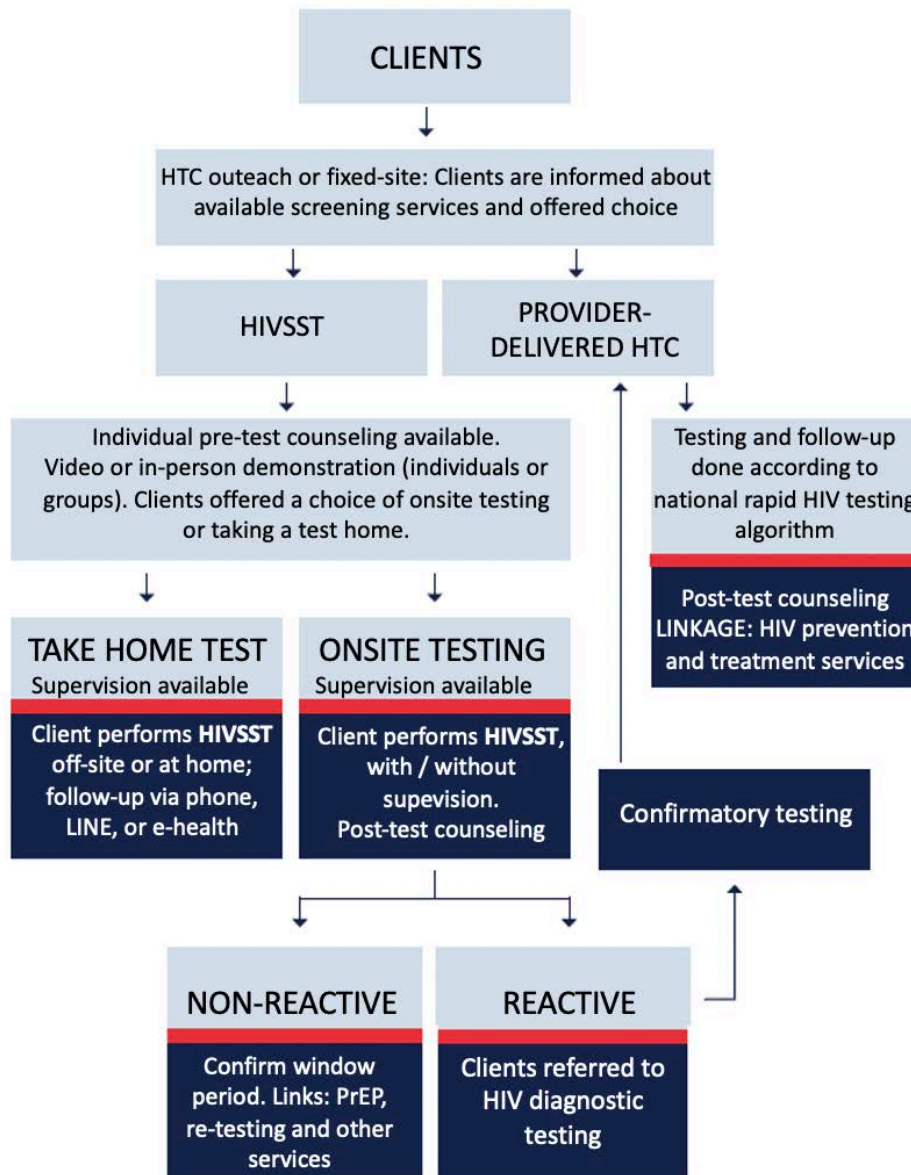
Recommendations

The development of this guideline has revealed opportunities to strengthen the national HIV response through HIVSST. Some key recommendations for doing this include the following:

1. Develop an operations manual with clear and appropriate strategies for implementing HIVSST services among different populations.
2. Create opportunities for cooperation and collaboration among stakeholders listed in the table for roles and responsibilities in HIVSST coordination and capacity building (in Chapter 5) so that everyone is moving in the same direction to build a more robust HIV response.
3. Establish a mechanism that will link clients to comprehensive HIV services that are efficient, fluid, and client centred in public and private health care settings.
4. Discuss with existing screening test kit distributors in the country to reduce the price of the kits. At the same time, encourage distributors of other various brands of test kits available to apply for approval to distribute their kits in Thailand to create price competition, reduce screening-test kit price and generate more demand.
5. Work with the Department of Medical Sciences, Food and Drug Administration, and relevant organizations to establish a more convenient and practical process to approve new generations of HIVSST kits.
6. Study the potential of periodic use of HIVSST in ongoing PrEP services so that clients do not have to attend services in health care facilities for follow-up HIV testing during emergencies.
7. Apply the lessons learned from COVID-19 self-testing and data collection in response to the COVID-19 outbreak to explore ways to link HIVSST with the country's central HIV database appropriately.
8. Establish a new comprehensive HIV service monitoring and evaluation approach by considering additional indicators on the use of HIVSST, PrEP, and index testing to find the link between services and reduce the burden of service providers.
9. Update the National AIDS Committee about HIVSST and its possible misuse to direct appropriate ministries and departments to mitigate the risk of misuse.

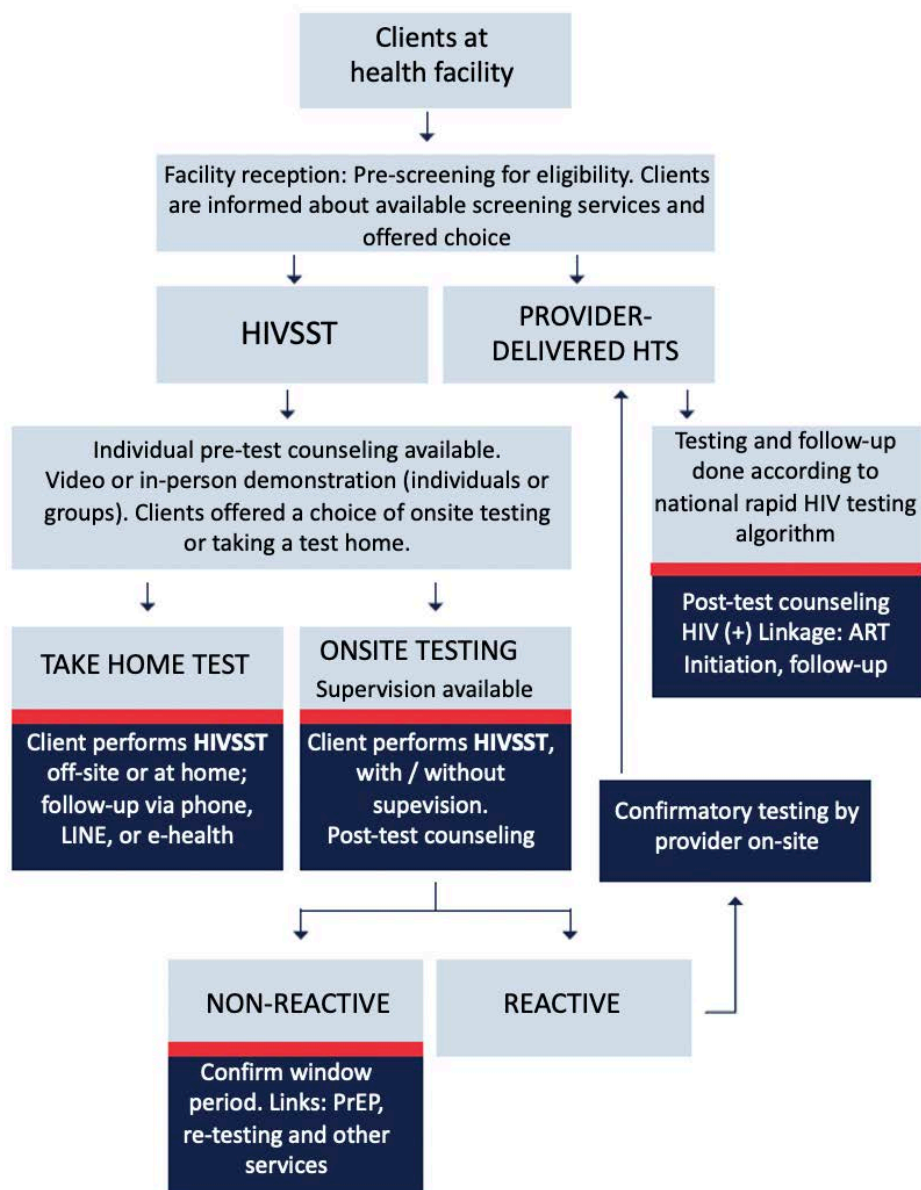
Annexes

Annex 1: Community-based distribution of HIVSST



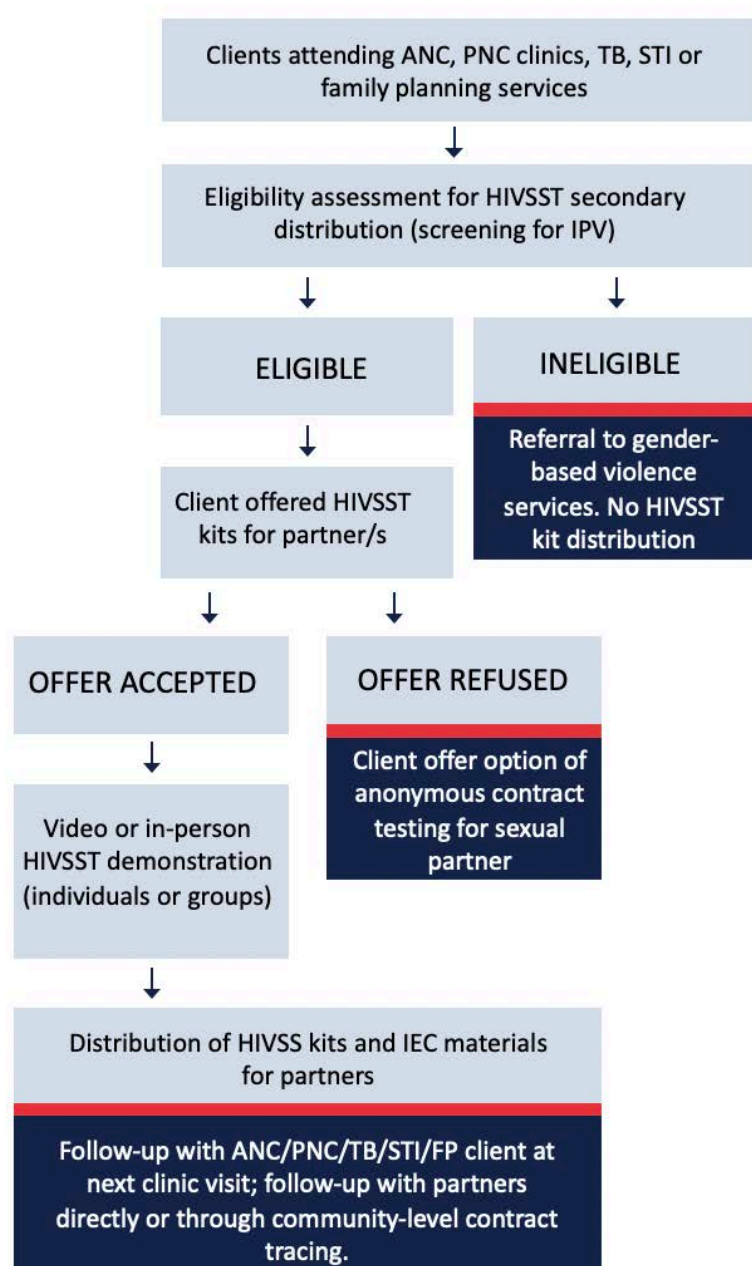
Adapted from: United States Agency for International Development. (2021). HIV self-testing operational guide for the planning, implementation, monitoring and reporting of HIV self-testing.

Annex 2: Facility-based distribution of HIVSST



Adapted from: United States Agency for International Development. (2021). HIV self-testing operational guide for the planning, implementation, monitoring and reporting of HIV self-testing.

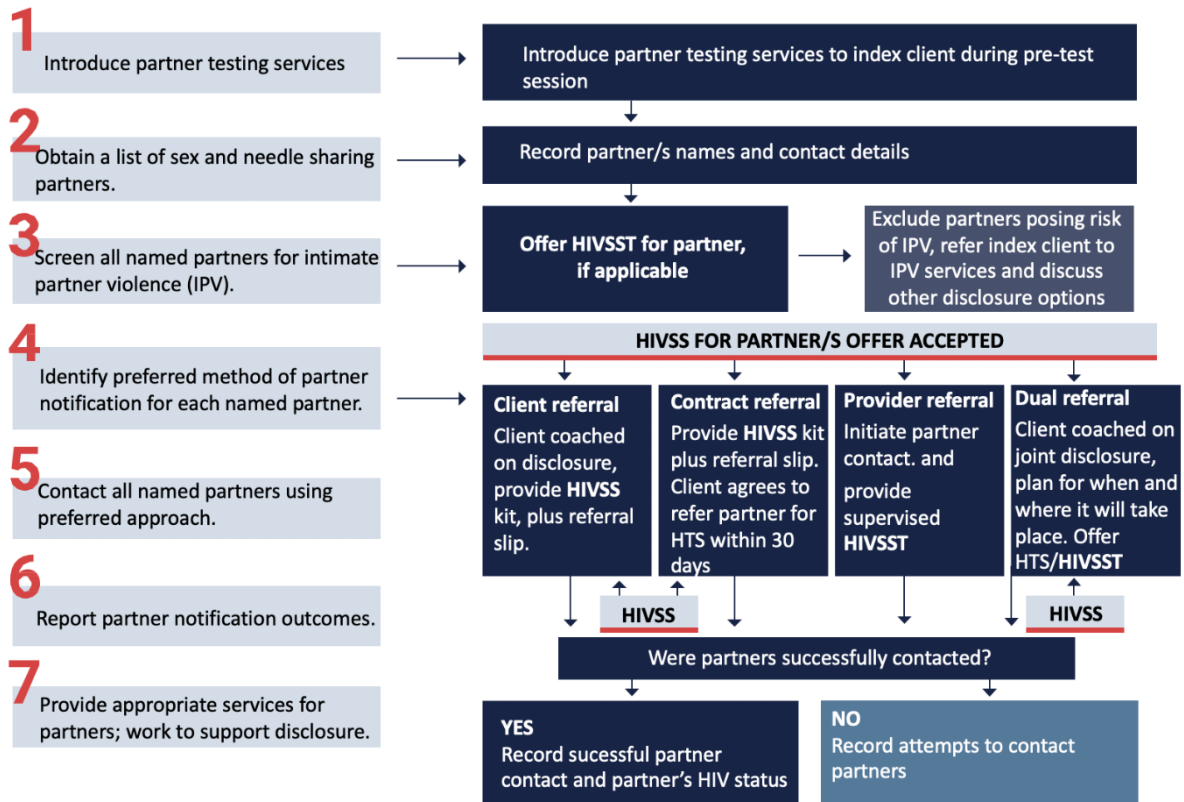
Annex 3: Facility-based secondary distribution



Adapted from: United States Agency for International Development. (2021). HIV self-testing operational guide for the planning, implementation, monitoring and reporting of HIV self-testing.

Annex 4: HIV self-screening and index testing

Steps for index partner testing services demonstrating opportunities where HIVSST could enhance each method of partner notification



Adapted from: United States Agency for International Development. (2021). HIV self-testing operational guide for the planning, implementation, monitoring and reporting of HIV self-testing.

Annex 5: Standards for HIV Self-Screening Test Kits in Thailand

Table 1: Criteria for testing or analysing antibodies for antibody-only and antibody-antigen-only assays.

Purpose of use	Requirements	Test samples	Number 1 (not less)		Acceptance criteria for assessment 2
			Assessment 1 2	Assessment 2 3	
Individual screening diagnostic type	Diagnostic sensitivity	Infected blood	500 samples	400 samples (200) ⁴	Not less than 99.5%
		Blood of newly infected person, intermittent blood draws	20 sets	8 sets	Number of sample sets that are slower to detect than existing methods does not exceed 25% of all sample sets
		First-stage infected blood	30 samples	30 samples	Error not more than 2 samples
	Diagnostic specificity	Uninfected blood	2,000 samples	2,000 samples (1000) ⁴	Not less than 99.0%
	Non-specificity	Blood likely to cause a false-positive result	30 samples	20 samples	Not more than 10%
	Repeatability 5	Diluted serum	50 times	50 times	Coefficient of variance less than 15%

Notes:

1. Applicants must submit the results of the assessment in both cases.
2. Test kit study data conducted domestically or abroad does not include assessment 2.
3. Assessment by Thai laboratories approved by the Food and Drug Administration
4. In the case of a single rapid assay (Rapid/Simple Test), use the number in parentheses instead.
5. No test is required in the case of a single rapid assay (Rapid/Simple Test).

Source: Ministry of Public Health. (2019). *Declaration of the Ministry of Public Health regarding HIV self-screening test kits*. B.E. 2562. Bangkok.

Table 3: Criteria for testing or analyzing HIV self-screening test kits that detect antibodies from oral fluid

What is tested Purpose of use	Antibodies				
	Requirements	Test samples	Number 1 (not less)		Acceptance criteria for assessment 2
Individual screening diagnostic type			Assessment 1 2	Assessment 2 3	
	Diagnostic sensitivity	Oral fluid of infected	500 samples	100 samples	Not less than 99.0 %
	Specificity	Oral fluid of uninfected	1000 samples	200 samples	Not less than 98.0 %
	Non-specificity	Oral fluid likely to cause a false-positive result	30 samples	20 samples	Not more than 10%

Notes:

1. Applicants must submit the results of the assessment in both cases.
2. Whether made in the country or abroad, the study data of the test kits from the manufacturers do not include assessment 2.
3. The Food and Drug Administration approves assessment by laboratories in Thailand.

Source: Ministry of Public Health. (2019). *Declaration of the Ministry of Public Health regarding HIV self-screening test kits*. B.E. 2562. Bangkok.

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