

National Standard Operating Procedures for Implementation of **HIV** Self-testing in Nepal

April 2023



Government of Nepal
Ministry of Health and Population
National Center for AIDS and STD Control
Teku, Kathmandu

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Preface

It gives me immense pleasure to present the National Standard Operating Procedures (SOP) for Implementation of HIV Self-Testing in Nepal." This document is the result of the hard work and dedication of a team of experts who worked tirelessly to create a standardized and evidence-based approach to HIV self-testing in Nepal.

The development of this SOP was made possible through the joint efforts of various stakeholders from the Ministry of Health and Population, National Centre for AIDS and STD Control (NCASC), and other implementing partners. Their contributions and support have been invaluable in shaping this document and ensuring its relevance and applicability to the Nepalese context.

I would like to express my gratitude to United States President Emergency Plan for AIDS Relief (PEPFAR) and the United States Agency for International Development (USAID)-supported Meeting Targets and Maintaining Epidemic Control (EpiC) Nepal project for their crucial role in providing technical assistance in the development of this SOP.

I would also like to thank the members of the technical working group, who tirelessly dedicated their time and expertise to develop this SOP. Their contributions and insights have been invaluable in shaping this document into a comprehensive and practical guide for HIV self-testing implementation in Nepal.

Lastly, I would like to express my gratitude to all those who have contributed to the development of this SOP, directly or indirectly. Your commitment to improving the quality of HIV self-testing services in Nepal is deeply appreciated, and I believe this SOP will serve as an important resource for healthcare providers and policymakers in the years to come."

Thanking you,

Dr. Sudha Devkota
Director
National Center for AIDS and STD Control



Abbreviations

°C	Degree Celsius
°F	Degree Fahrenheit
ARV	Antiretroviral
ART	Antiretroviral Therapy
CBS plus	Community-based supporter plus
CW	Community workers
CLT	Community-led testing
DIC	Drop-in centers
GF	The Global Fund
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HIV	Human immunodeficiency virus
HIVST	HIV self-testing
HMIS	Health Management Information System
HTC	HIV testing and counseling
HTLV	Human t-lymphocyte virus
KP	Key Population
ONHIS	One National HIV Information System
NCASC	National Centre for AIDS and STD Control
PEPFAR	The United States President's Emergency Plan for AIDS Relief
PN	Peer Navigator
PrEP	Pre-exposure prophylaxis
USAID	The United States Agency for International Development
WHO	World Health Organization

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1. Introduction

HIV self-testing (HIVST) is “a specific process by which a person collects his/her specimen (oral fluid or finger stick blood), performs a test and interprets the result for their HIV status—often in private or with someone they trust” (World Health Organization (WHO), 2021). HIVST can be a complementary approach to reach those who are not reached by existing HIV testing and services (HTS). The self-test kits can be offered to any person who considers him/herself at risk of HIV. HIVST can also be used for index testing by providing test kits to sexual partners, friends, or an adult family member, encouraging them to use the test and helping them learn their HIV status on their own, and for follow-up of screening pre-exposure prophylaxis (PrEP) use. HIVST is a simple and convenient test for HIV testing. The test procedure does not provide a definite HIV-positive diagnosis, and individuals with a reactive (positive) test result must undergo further testing performed by a trained service provider according to the national testing algorithm. The further test confirms the HIV diagnosis.

HIVST kits are single-use, qualitative immunoassays to detect antibodies to Human Immunodeficiency Virus Type 1 (HIV-1) and Type 2 (HIV-2) in oral fluid or blood. HIVST is intended for use by lay users as a self-test to aid in the diagnosis of infection with HIV-1 and HIV-2. As per the test kit manufacturers, the HIVST kit may use oral fluid or capillary blood as a sample.

There are two ways of conducting HIVST: Supervised HIVST and Unsupervised HIVST. Supervised HIVST refers to HIV self-testing when an individual conducts self-test with the support of a service provider. The service provider guides the individual to perform the test and interpret the test result. Unsupervised HIVST refers to HIV self-testing when an individual conducts self-test independently following the instruction provided by the manufacturer without taking support from the service provider. Clients performing unsupervised HIVST are encouraged to inform the nearest HIV testing center if the test result is “Reactive” to get confirmation of HIV status and further treatment and care support.

a. Types of HIV self-test

Oral fluid-based HIVST detects antibodies to HIV-1 and HIV-2 in oral fluid. For

this test, a person swipes a mouth swab across the outer gum line to collect oral fluids, puts the swab into a test tube, and sees the result after some minutes.

Blood-based HIVST detects antibodies to HIV-1 and HIV-2 in blood. The test kits come with simple lancets to collect blood samples from a finger prick. This test is not intended to be used as HIV screening test for blood donation.

Some people who want to self-test may prefer an oral fluid-based test, while others prefer a blood test. It is ideal to have the provision of both options to suit the preferences of potential users. The different types of HIV kits available globally and in Nepal are detailed in Annex 1.

b. HIVST in Nepal

Nepal introduced oral fluid-based HIVST in the country following a demonstration study in June –September 2018. Testing initiated by the United States President’s Emergency Plan for AIDS Relief (PEPFAR)/ the United States Agency for International Development (USAID) supported Linkages across the Continuum of HIV Services for Key Populations Affected by HIV (LINKAGES) Nepal Project in July 2019. The service is currently available in PEPFAR/USAID and Global Fund (GF)-supported districts in Nepal.

During Jan-Dec 2022, in PEPFAR/USAID implemented community sites, nearly 10,991 HIVST kits were distributed, nearly 99.7% (10,956 out of 10,991) of which had been utilized. Among these, nearly 3.4% (371 out of 10,956) were reactive. Out of the reactive tests, nearly 93.3% (346 out of 371) were confirmed as HIV positive by labs using the national testing algorithm. Among those confirmed, 97.1% (336 out of 346) were linked to care.

Most (98.8%) of the kits distributed and used were supervised compared to 1.2% that were distributed unsupervised.

2. Requirements and process for HIVST testing

The National Centre for AIDS and STD Control (NCASC) provides guidance for the overall program implementation and HIVST. HIV-related reports should be provided to the NCASC by reporting in One National HIV Information System (ONHIS) and to Health Management Information System (HMIS).

a. Guiding principles of providing HIVST testing services

This SOP manual is a live document and will be revised based on national and international recommendations and the decision of the NCASC. Providing HIVST services follows the following basic principles:

Consent: HIVST tests either supervised or unsupervised can only be provided with the informed consent of the HIVST user. Verbal consent is adequate to provide HIVST kit.

Confidentiality: All the information collected should be kept confidential and should not be shared with anyone without the consent of the client.

Counseling: HIVST testing service must be accompanied by appropriate and good quality information and counseling if sought by the clients. All clients should have the opportunity to ask questions in a private setting.

Correct: All the information provided to clients should be correct, scientifically proven and based on the standard national and international guidelines. The test kits used for the self-test should be approved for the use by government of Nepal.

Connections: All the HIVST users should have access to the facility to confirm their HIV status and there should be provisions of support to get the confirmatory HIV test. All confirmed HIV positive should have access to HIV treatment and care services and HIV non-reactive or HIV negative should have access to HIV

prevention services including HIV pre-exposure prophylaxis services and provisions of condoms and lubricants.

b. Recommended staff structure and facility for HIVST services

HIVST should be provided and distributed for self-testing and/or testing at the community level for primary screening. Recommended staff structure for providing HIVST testing distribution and supervision, are in Table 1 below.

Table 1: Recommended staff structure for HIVST testing

Staff	Training requirements	Role
<p>Outreach workers: Peer navigators (PNs), community-based supporters (CBSs), community home-based care (CHBC) workers, and other outreach and in-reach workers.</p>	<p>Community-led Testing (CLT) training with one-day orientation on HIV self-testing use.</p>	<ul style="list-style-type: none"> ■ Kit distribution to eligible clients at the community ■ Provide information as sought by the clients (supervised) ■ Provide counseling to the clients. ■ Link the clients to the HIV service sites when reactive
<p>Antiretroviral therapy (ART) counselors, Lab focal points at HIV screening and testing sites</p>	<p>Training on HIV testing and counseling</p>	<ul style="list-style-type: none"> ■ Provide information as sought by the clients (supervised) present at the facility. ■ Provide counseling to the clients present at the facility. ■ Provide kits to the community providers—PNs, and CBS plus., ■ Link client to diagnosis and treatment and support if reactive, and support community provider to do so as well. ■ Recording/reporting (R&R)

c. Setup for providing HIVST testing service

- **Community-based services:** No specific setup is needed. The only requirement is a safe bag for storing and carrying the HIVST test kits. Community lay providers (e.g., PN, CBS plus, CHBC workers, outreach/in-reach workers, etc). Can distribute test kit in the community as a part of the community-led testing.

d. HIVST service delivery package and eligibility

The HIVST testing is done for the purpose of screening only. This message should be made clear to the client and informed that they should reach out to HIV centers for confirmation or any assistance with the interpretation of results if needed. They can also reach out to the community providers (PNs, CBS Plus) if they want.

Eligibility is this site ?: All key populations (KPs) and priority populations (PPs) who intend to self-test and test their partner (as a part of index testing) who have not been previously diagnosed as HIV positive, are eligible to use the HIVST. The kits can either be received from a community provider (PN, CBS plus, outreach worker) or through facilities with test availability (e.g., ART center, city clinics, dispensing sites).

3. Recommended flow of HIVST services

HIVST services	Activities
Demand generation	Clients made aware of the availability of HIVST services through community health workers, posters, pamphlets, social media campaigns, and through online applications
Selection of eligible clients for HIVST	All KPs, PPs who intend to self-test, and test their partner (as part of index testing) who have not been previously diagnosed as HIV positive, are eligible to use the HIVST.
Counseling and providing information	<p>Provide information about the availability of HIVST kits for those eligible to use them. Upon interest, provide them with the following information:</p> <ul style="list-style-type: none">■ Option of supervised and unsupervised following the instruction provided with the kit or by the provider.■ Explain in brief, information about HIV, especially focusing on the mode of transmission, prevention measures, and other available HIV testing methods and screening in the community. Explain the difference between oral fluid and blood-based HIV self-test kits.■ Explain that mouthwash should not be used, teeth should not be brushed, and food and drink should not be consumed for at least 30 minutes prior to HIVST. This includes cases where bleeding gums are present where HIVST should not be performed.■ Offer to explain each step to the client and if requested, explain the procedure step-by-step showing the kit insert or the electronic flip chart.

- Re-explain that the result should be read at exactly 20 minutes, neither earlier nor later, and that there should be two lines in the result window of the test kit near “C” and “T”, to consider the result reactive.
- Discuss prevention measures, use of condoms and lubricants, possibilities of testing their partners, availability of treatment for HIV, and places where treatment is available in the district.
- The test kit—if taken for an unsupervised test—can only be stored in a cool and dry area, and cannot be stored in a freezer compartment of a refrigerator. The test should be performed in an area with a temperature of 15-37 degrees Celsius, which is warm temperature.
- Used test kit is not infectious and cannot transmit HIV. However, it needs to be disposed privately and in a safe place.
- A reactive result does not mean that they have HIV, this is just for primary screening, and they need to go to the HIV Center for laboratory confirmation. If the test is non-reactive, it means that the client is found not infected with HIV, using this test kit.
- Confidentiality will be maintained regarding individual information.

Providing the kit

- **Supervised:** Client receives an in-person demonstration from a trained provider or peer before or during HIVST, with instructions on how to perform a self-test and how to interpret the self-test result. This assistance is provided in addition to the manufacturer-supplied instructions for use and other materials found inside the HIVST kits.

- **Unsupervised:** Client self-tests for HIV using an HIVST kit with manufacturer-provided instructions, with no assistance. 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.
- **Index testing:** During index testing approach, which is focused HIV testing approach in which providers work with individuals living with HIV (index clients) to elicit their sexual or injecting partners, their biological children (not suitable for children <18 months), or biological parents (if a child is the index client), if client or partners chose to be tested with HIVST then can be offered.
- **Secondary distribution:** Individuals who have been provided with the HIVST kit plan to distribute the test kit to other individuals, which could be a part of index testing, testing of other peers (who may or may not be their sexual partner) or others, etc.
- **Takeaway:** Where kits are available at the HIV center and clients can simply take them, without the need to provide any information for their intended use.

Recording/
reporting

When the result is obtained, they should reach out to the HIV service centers (ART, city clinics, dispensing sites) where the reports should be recorded in HIVST forms (Annex 1 and Annex 2) as detailed in section 5.

4. Kits used for HIVST services in Nepal

- a. **The OraQuick® HIV self-test kit** is an oral fluid-based HIVST kit. It is a single-use qualitative immunoassay to detect antibodies for HIV-1 and HIV-2 in oral gum fluid. OraQuick® one-pouch kit contains a single-use test device, preservative, a developer solution vial, test Stand, and instructions (materials required but not provided are clock/watch, or timing devices). This in-vitro diagnostic medical device is intended for lay users to aid in the diagnosis of HIV infection.

- b. **The CheckNOW HIV self-test kit*** is a blood-based HIVST kit. It is a single-use rapid immunoassay that uses a blood sample from a finger puncture for the qualitative detection of antibodies to HIV-1 and HIV-2 in blood. CheckNOW one-pouch kit contains 2 sterile alcohol pads, 1 sterile plaster, 1 specimen dropper, 1 buffer, 1 sterile lancet, and instructions (materials required but not provided are clock/watch, or timing devices and tissues). This in-vitro diagnostic medical device is intended for lay users to aid in the diagnosis of HIV infection.

*(*in the process of being introduced)*

5. HIV testing procedures.

a. Oral fluid-based test using the OraQuick® HIV self-test kit

Box 1: Details of the oral fluid-based test using the OraQuick® HIV self-test kit

Sample collection, mechanism of the test, and storage of the test kit

The test device, which has a flat pad at one end, is placed into the mouth in such a way that the flat pad is between the cheek and the outer gums. It is then swabbed across the outer gum line. The device is then placed into a tube containing a premeasured amount of solution. Fluid from the surface of the gums enters the device through the flat pad and then flows onto a test strip. As it flows across the strip, a colored line forms in the 'T' (test) area of the result window if HIV antibodies are detected. If no HIV antibodies are detected, no line forms there. If the test is performed correctly, a line forms in the 'C' area of the result window. This is called the control line.

It is recommended to store the test kit and to conduct the testing in a cool area. The test kit should not be used if it has been stored outside the acceptable temperature of 2°-30° C (36°-86° F). This test should be performed at temperatures in the range of 15°-37° C (59°-99° F).

Testing procedure

A client can choose a supervised or unsupervised self-testing approach:

To conduct a supervised HIVST:

- Explain the test procedure to the client step-by-step showing the kit insert or electronic flip chart. Client needs to provide consent before testing— if they have understood everything explained—they can ask questions if they have any.
- Thank the client for choosing the supervised approach. Tell them that you will be with them during the whole testing procedure and will guide them in every step. Be present all the time, from handing over of test kit to interpreting the result and disposing of it.

- Explain in brief—information about HIV, especially focusing on the mode of transmission, prevention measures, and other available HIV testing methods and screening in the community. Explain the difference between oral fluid-based and blood-based HIV self-test kits.
- Ask the client to keep a device ready, to read the time (mobile, watch/clock), and then provide a sealed HIVST test kit package to them.
- Ask the client to open the test kit packet, keeping the content of the packet separate. Then, ask the client to open the client instruction leaflet and read the steps given in the leaflet, as well as to look at the photo and read the instruction. To answer the questions, explain using the flipchart provided.
- Ask the client to hold the pouch with the test kit and a test tube and then open the pouch at the side of the test tube and take out the test tube. Ask the client to open the test tube in an upright position as directed in the kit insert. Explain that there is liquid in the test tube, which is needed for testing. Ask the client not to spill the liquid. The client should not drink the liquid.
- Ask the client to put the test tube in an upright position on the stand provided and then open the pouch with the test kit by tearing the area marked. That side should be the broader side of the test kit. The broader side contains the result window. Ask to pull the test kit by holding the broader portion of the test kit and keep the test kit upright. The thinner side of test kits contains a spoon-like pad. Ask the client not to touch the spoon-like pad with their hand.
- Ask the client to put the pad between the gum bed and upper lip and move one time only—from one end of the mouth to another gently. Then, move the same pad in between the lower gum bed and lower lip.
- Inform the client that the test kit does not detect HIV from saliva. It detects HIV from the secretion between the gum and the inner side of the lip, so the test kit needs to swab the place between the gum bed and the inner side of the lip.

- Ask the client to dip the test pad in the test tube containing the liquid and note the time or start the timer. Ask the client to wait exactly 20 minutes for the result. In the meantime, discuss prevention measures, use of condoms and lubricants, possibilities of testing their partners, availability of treatment for HIV, and places where treatment is available in the district.
- Read the result exactly at 20 minutes—neither earlier nor later.

To conduct an unsupervised HIVST: Client self-tests for HIV using an HIVST kit with manufacturer-provided instructions only. Test kits taken for the unsupervised test should be stored in a cool and dry area. It cannot be stored in the freezer compartment of the refrigerator. Tests should be performed in areas with temperatures of 15-37 degrees Celsius. Ask the client to dispose the used test kit in a private area, not reached by children. The used test kits and components should be packed in the same test kit bag (zip-lock) and should be handed over to the nearest health facility in a red color waste bin.

Warning and precautions

- If an individual feels nervous about taking an HIV self-test, they should wait until they are calmer to take it or get tested by a which doctor in Nepal does test trained service provider.
- Only oral fluid should be used while testing with oral fluid-based HIVST. The test is not for use with blood, serum, breast milk, plasma, semen, urine, vaginal fluid, or sweat.
- All dental products that cover the gums, such as dentures, should be removed before collecting the oral fluid.
- The test result should be read in the presence of adequate lighting. If two lines are present at areas marked “T” and “C” on the Test Device at any visible intensity, the test result should be interpreted as positive.
- The self-test is not recommended for persons living with HIV. It is also not recommended for individuals who have participated in an HIV vaccine clinical trial. A positive test result is likely in this situation, even though the individual may not be infected with HIV.

- Oral HIVST is not recommended for anyone who is 11 years or younger.
- The kit should not be used if it has been exposed to household cleaning products such as bleach; if the “Use By” day mentioned on the outside of the pouch is crossed; if the tamper-evident seal is broken; or if any of the package contents are missing, broken or opened.
- Individuals should refrain from eating or drinking for at least 15 minutes before starting the test. Additionally, mouth-cleaning products such as mouthwash should not be used 30 minutes before using the test kit.
- The kit pouches should not be opened until they are ready to be used.

b. Blood-based test using CheckNOW HIV self-test kit

Box 2: Details of blood-based test using CheckNOW HIV self-test kit

Sample collection, mechanism of the test, and storage of the test kit

Two drops of the blood sample are collected from the finger stick in the basin of the plastic cover. A specimen dropper transfers one drop of blood to the well. After that, one drop of buffer is applied. When the test is completed, two lines can appear on the device. The red line in the Control Line (C) area will only become visible if the added blood sample and/or buffer have moved over the T/C Line areas of the reading window. The T-line area is pre-coated with HIV-1 antigen glycoprotein 41 and HIV-2 antigen glycoprotein 36. The red line in the Test Line (T) area will only become visible if the applied sample contains antibodies to HIV-1 or HIV-2.

Store the test kit at 2-30°C (36-86° F) until the expiry date (printed on the test pouch). The test kit should not be stored in freezing temperatures. The test device should be used within one hour after the pouch has been opened. The buffer is for single use and should be used within one hour after the cap opens.

Testing procedure

A client can choose a supervised or unsupervised self-testing approach:

To conduct a supervised HIVST:

- Explain the test procedure to the client step-by-step showing the kit insert or electronic flip chart. Client needs to provide consent before testing—if they have understood everything explained—they can ask questions if they have any.
- Thank the client for choosing the supervised approach. Tell them that you will be with them during the whole testing procedure and will guide them in every step. Be present all the time, from handing over of test kit to interpreting the result and disposing of it.
- Explain in brief—information about HIV, especially focusing on the mode of transmission, prevention measures, and other available HIV testing methods and screening in the community. Explain the difference between oral fluid and blood-based HIV self-test kits.
- Ask the client to keep a device ready, to read the time (mobile, watch/clock), and then provide a sealed HIVST test kit package to the client.
- Ask the client to open the test kit packet, keeping the content of the packet separate. Then, ask the client to open the client instruction leaflet and read the steps given in the leaflet, as well as to look at the photo and read the instruction. To answer the questions, explain using the flipchart provided.
- Prepare a timer and tissue, then open and place all materials on a brightly lit, flat, and clean surface. Ask the client to rub their hands together to make the fingers warm. Choose the ring finger and middle finger. Massage and rub the fingers to increase circulation.
- Ask the clients to clean the finger with an alcohol pad and let it dry for 10 seconds. Remove the lancet cover (Note: The lancet will prick only once, hence ask the client to be careful). Press the lancet against the finger until it clicks, then press the finger base to tip and let two drops of blood in the basin of the kit. Wipe the finger with another alcohol pad and apply plaster.
- Squeeze the top of the specimen dropper down and hold it while dipping in

the blood sample. Dip the dropper into the blood in the basin and release slowly to draw blood into the dropper (Note: Avoid air bubbles). Place the dropper over the well-labeled "S" and squeeze the top of the dropper to apply one drop of blood into the well-labeled "S."

- Ask the client to wait 15 minutes for the result. In the meantime, discuss prevention measures, use of condoms and lubricants, possibilities of testing his/her partners, availability of treatment for HIV, and places where treatment is available in the district.
- Read the result exactly at 15 minutes—not earlier than that, and no later than 20 minutes.

To conduct an unsupervised HIVST:

Client self-tests for HIV using an HIVST kit with manufacturer-provided instructions only. Test kits taken for unsupervised tests should be stored in a cool and dry area. It cannot be stored in the freezer compartment of a refrigerator. Tests should be performed in areas with temperatures of 15-37 degrees Celsius. Ask the client to dispose the used test kit in a private area, not reached by children. The used test kits and components should be packed in the same test kit bag (zip-lock) and should be handed over to the nearest health facility in a red color waste bin.

Warning and precautions

- If an individual feels nervous about taking an HIV self-test, they should wait until they are calmer to take it or get tested by a doctor or any other trained service provider.
- Only finger puncture blood samples should be used while testing with blood-based HIVST. The test is not for use with any other body fluids.
- The test result should be read in the presence of adequate lighting. If two lines are present at areas marked "T" and "C" on the test device at any visible intensity, the test result should be interpreted as positive.
- The self-test is not recommended for persons living with HIV. It is also not recommended for individuals who have participated in an HIV vaccine clinical trial. A positive test result is likely in this situation, even though the individual may not be infected with HIV.

- Not suitable for testing infants younger than 18 months.
- The kit should not be used if it has been exposed to household cleaning products such as bleach; if the “Use By” day mentioned on the outside of the pouch is crossed; if the tamper-evident seal is broken; or if any of the package contents are missing, broken or opened.
- Extra precautions are needed if the client has bleeding disorders and/or is needle-phobic.

c. Test validation criteria and result interpretation

Band reactivity: All visible bands. Even a faint band must be considered reactive.

Valid: A test is valid only if a reddish-purple line appears in the control (C) area, whether the T line gives a reactive or non-reactive result.

Invalid: If a reddish-purple line does not appear in the control (C) area, the test is invalid. An invalid test cannot be interpreted. It is necessary to repeat sample testing with a new device.

Upon validation, the interpretation of the test results is detailed below in Table 2

Table 2: Test result interpretation for OraQuick® HIV self-test kit and CheckNOW HIV self-test kit

Test Result	OraQuick® HIV Self-Test kit	CheckNOW HIV Self-test kit
<p>Reactive test result:</p> <p>Two complete lines, even if the line is faint</p>		
<p>Non-reactive test result:</p> <p>ONE LINE next to the "C" and NO line next to the "T"</p>		
<p>Invalid test results:</p> <p>No line next to the "C" (even when there is a line next to the "T")</p>		

d. Post-test following results:

NON-REACTIVE means that the client is found not infected with HIV using this test kit. In this case, repeating the test is not recommended. Clients with non-reactive results should always use condoms and lubricant during sexual contact or use only new sterilized syringes for injection.

All clients with REACTIVE results require a confirmatory test in a facility using other different types of test kits.

In case the test kit does not show any lines, the test result is INVALID. The test needs to be repeated if the result is invalid.

Used test kit is not infectious and cannot transmit HIV. However, it needs to be disposed privately, in a safe place. Therefore, collect the used test kit and bring it to your facility for disposal.

e. Limitations of HIVST tests

The limitations of available HIVST tests in Nepal are detailed below in Table 2.

Table 3: Limitation of HIVST tests (the OraQuick® HIV self-test kit and the CheckNOW HIV self-test kit)

The OraQuick® HIV self-test kit	The CheckNOW HIV self-test kit
<ul style="list-style-type: none"> ■ Designed to be used with oral fluid only. Other body fluids must not be used. ■ A NON-REACTIVE (Negative) result does not rule out the possibility of HIV infection. ■ Health care provider must confirm REACTIVE (Positive) result using appropriate confirmatory testing. ■ The intensity of the test Line for a REACTIVE (Positive) result does not reflect how much HIV antibody is present in the specimen. ■ The test may not detect HIV infections that have occurred within the last three months. ■ Clinical data has not been collected to demonstrate the performance of the test in individuals that are undergoing pre-exposure prophylaxis (PrEP). ■ Oral bleeding may result in an INVALID result. If the test result is invalid, visit your nearest testing center or healthcare facility. ■ If you are on antiretroviral medicines (ARVs) for HIV treatment, you may get a false, result. ■ If you have tested positive for hepatitis B virus (HBV), hepatitis C virus (HCV), or human T-cell lymphotropic virus (HTLV) I/II, you may get a false result. 	<ul style="list-style-type: none"> ■ Designed to be used with a finger puncture blood sample. Other body fluids must not be used. ■ Not suitable for testing infants younger than 18 months. ■ A NON-REACTIVE (Negative) result does not rule out the possibility of HIV infection. ■ Health care provider must confirm REACTIVE (Positive) result using appropriate confirmatory testing. ■ The intensity of the Test Line for a REACTIVE (Positive) result does not reflect how much HIV antibody is present in the blood sample. ■ Although it is rare, false results may occur. If you have concerns that your result may be false, please contact your healthcare provider. ■ An incorrect or “false” NON-REACTIVE (Negative) result can occur for any of the following reasons: incorrectly reading test results; not following the Instructions for Use carefully; if you are on HIV treatment (ARV); if you were very recently infected; the presence of bubbles during sample application, in low positive samples. ■ An incorrect or “false” REACTIVE (Positive) result can occur for any of the following reasons: incorrectly reading test results; not following the Instructions for Use carefully; having received an HIV vaccine; in cases of infection with cytomegalovirus.

f. Key messages for providers, self-testers, and communities

Box 3: Key messages for providers, self-testers, and communities

A person should never be coerced or forced to self-test. Coercive or mandatory use of an HIVST kit should never be supported or encouraged and is not considered self-testing.

HIVST is a triage test for screening and does not provide a definitive HIV-positive diagnosis.

A reactive (positive) HIVST result is not equivalent to an HIV-positive diagnosis. All reactive HIVST results need to be followed by further testing by a trained service provider to confirm HIV status, starting with the first test in the national testing algorithm.

Non-reactive HIVST results should be considered HIV negative, with no need for immediate further testing except for those starting pre-exposure prophylaxis (PrEP). Retesting following a negative self-test result is necessary only for those at ongoing risks, such as people from KPs and those reporting potential HIV exposure in the preceding 12 weeks.

An invalid HIVST result requires the test to be repeated, using another HIVST kit. Any person uncertain about their HIVST result should be encouraged to seek testing from a trained provider.

HIVST is not recommended for people living with HIV who are receiving ART, since false-negative HIV results can occur. Those who have been diagnosed with HIV but are not receiving ART should be encouraged and supported to initiate ART.

It is also not recommended that parents or guardians use HIVST kits to test their babies or children. HIVST will not provide a correct result for children younger than 18 months old and breastfeeding because the mother's antibodies may still be present in the infant.

Most people can perform HIVST correctly with minimal or no support. However, some may need and want support, and it should be provided (video instructions, virtual support, or in-person demonstration or training) and should be tailored locally.

6. Recording and reporting

The suggested key indicators for HIVST recording and reporting of HIVST are as follows:

No.	Indicators	Definition	Numerator	Denominator
1	Number of HIV self-test kits distributed	Number of HIV self-test kits distributed	Number of HIV self-test kits distributed assisted	Number of HIV self-test kits distributed
1.1	HTS Self Testing-assisted	Percentage of HIV self-test kits distributed assisted among total HIVST kits distributed	Number of HIV self-test kits distributed unassisted	Number of HIV self-test kits distributed
1.2	HTS Self Testing_unassisted	Percentage of HIV self-test kits distributed unassisted among total HIVST kits distributed	Number of HIVST kits taken by clients under the provision of HIVST kit takeaway services	Number of HIV self-test kits distributed
2	HIV self-testing kits taken away from dispensing sites	Percentage of HIVST kits taken by clients under the provision of HIVST kit takeaway services among HTS_SELF among total HIVST kits distributed		
3	HIV Self-test kits used	Number of individuals who reported the result of their self-testing		

4	HTS self-testing reactive	Number of individuals provided with self-testing who received a reactive result		
5	HTS self-testing confirmed	Number of individuals provided with self-testing who had reactive results confirmed using a national testing algorithm		
6	HTS self-testing linked to ART	Percentage of individuals provided with self-testing who had reactive results confirmed using a national testing algorithm and have initiated ART among the confirmed cases using HIV self-test kit	Number of individuals provided with self-testing who had reactive results confirmed using a national testing algorithm and have initiated ART	Number of individuals provided with self-testing who had reactive results confirmed using a national testing algorithm

7. Frequently asked questions (FAQs)

Table 4: FAQs on oral and blood based HIVST

FAQs	Oral fluid-based HIVST	Blood-based HIVST
What does the test do?	It is an in-vitro diagnostic self-test for HIV (HIV-1 and HIV-2) in oral fluid. The test works by detecting your body's natural antibodies that help you fight infection. A positive result is preliminary and additional testing at a health facility is required to confirm the result as true.	It is an in-vitro diagnostic self-test for HIV (HIV-1 and HIV-2) in blood. The test works by detecting your body's natural antibodies that help you fight infection. A positive result is preliminary and additional testing at a health facility is required to confirm the result as true.
What is a 'risk event' for HIV?	<p>A risk event is defined by any of the activities listed below:</p> <ul style="list-style-type: none"> ■ Sex (vaginal, oral, or anal) with multiple sex partners ■ Sex with person who is living with HIV or whose HIV status you do not know ■ Unprotected sex between a man and another man ■ Use of contaminated or used syringes and needles for injected drugs or steroids ■ Shared needles or syringes 	
How soon after a risk event can I test myself?	You can test any time—if you are using this test earlier than three months after a risk event and your test is negative, your result may not be accurate. You should test again three months after the risk event to be sure. You can also be tested at a health facility.	
Why should I not use this test right after a risk event?	When you have been infected with HIV, your body tries to fight the HIV by producing natural antibodies. These antibodies can be found in your oral fluid. It takes your body up to three months to make these antibodies at levels that can be detected by this test.	

FAQs	Oral fluid-based HIVST	Blood-based HIVST
Can I get HIV by using this test?	This test does not contain any materials or HIV that can cause HIV infection.	
How often should someone test for HIV?	If you have never been tested for HIV, you should be tested at least once. If you do things (risk events) that can result in HIV infection, you should be tested at least once per year (WHO recommendation). If you feel you are at an increased risk of being infected with HIV, you should test regularly.	
What does a non-reactive result mean?	A non-reactive result means that the test has not detected any antibodies. However, it may take up to three months from a risk event for the test to detect HIV. If it has been at least three months since you had a risk event and you followed the instructions for use carefully, you likely do not have HIV. If it has been less than three months since you had a risk event, wait the full three months since the risk event to take the test or go to your health facility.	
What should I do if I get a non-reactive result?	If you have not had any risk events within the past three months, and you followed the Instructions for use carefully, then you are most likely HIV negative. If you did not follow the instructions carefully, you should take the test again to be sure your result is correct. If you had any risk events in the past three months, you could be in the 'window period.'The window period is when a person has been infected with HIV, but their body has not made antibodies yet. If you think you may have been exposed to HIV within the past three months, you should retest for HIV three months following any risk event. If you continue to engage in risk events that could put you at risk for HIV, you should test regularly.	
What does a positive result mean?	A reactive result means that you may have HIV. Additional testing must be conducted at a health facility to confirm the result.	

<p>What should I do if I get a reactive result?</p>	<p>You need to follow up with a health facility to get additional testing to confirm the result. During the visit, your local clinic, doctor, or healthcare professional will discuss the next steps that need to be taken.</p>	
<p>Can I get an incorrect 'false' negative result with this test?</p>	<p>An incorrect 'false' negative result can occur for any of the following reasons:</p> <ul style="list-style-type: none"> ■ If you had a risk event less than 3 months before taking the test ■ Incorrectly reading test results as negative ■ Not following the instructions for use carefully ■ If you wore dental products such as dentures or any other products that covered your gums while swabbing your gums ■ If you are taking an oral PrEP regimen or if you are on HIV treatment (ARV) 	<p>An incorrect 'false' negative result can occur for any of the following reasons:</p> <ul style="list-style-type: none"> ■ If you had a risk event less than 3 months before taking the test ■ Incorrectly reading test results as negative ■ Not following the instructions for use carefully
<p>Can I get an incorrect 'false' positive result with this test?</p>	<p>An incorrect or 'false' positive result can occur for any of the following reasons:</p> <ul style="list-style-type: none"> ■ Incorrectly reading test results as positive ■ Not following the instructions for use carefully ■ Not waiting 15 minutes after eating, drinking, or 30 minutes after using oral care products before taking the test ■ Having received an HIV vaccine ■ Swiping each gum several times during oral collection 	<p>An incorrect or 'false' positive result can occur for any of the following reasons:</p> <ul style="list-style-type: none"> ■ Incorrectly reading test results as positive ■ Not following the instructions for use carefully ■ Having received an HIV vaccine

Where can I get additional help or care for HIV? You can get additional help through a local clinic, doctor, or health-care professional.

Can I use this test if I am taking medicine to prevent HIV (oral PrEP)? If you are taking oral PrEP for HIV, you may get a false result.

How can I tell if my test is working correctly? If your test is working correctly, you will see a line next to the “C” on your test device. If there is no line next to the “C” your test did not work.

Can I use this test if I am pregnant? Yes, you can use the test at any time, even during pregnancy.

8. Annex

Annex 1: Global List of In-vitro diagnostic tests kits pre-qualified by WHO and their performance as per manufacturers that are currently available.

Year prequalified by WHO	Kit name	Manufacturer	The type of sample used	Sensitivity*	Specificity*
2017	OraQuick HIV Self-Test ^a	OraSure Technologies, Inc.	Oral fluid	99.4%	99.0 %
2018	INSTI HIV Self-Test	BioLytical Laboratories Inc.	Capillary blood	99.5%	100%
2019	Mylan HIV Self-Test	Atomo Diagnostics Pvt. Ltd	Capillary blood	99.6%	95.2%
2019	SURE CHECK HIV Self-Test	Chembio Diagnostic Systems, Inc.	Capillary blood	97.0%	100%
2022	Wondfo HIV Self-Test	Guangzhou Wondfo Biotech Co., Ltd	Capillary blood	95.8%	99.6%
2022	CheckNOW HIV SELF TEST ^b	Abbott Rapid Diagnostics Jena GmbH	Capillary blood	100%	99.9%

*As per the manufacturers kit insert

Source: Pre-qualified in vitro diagnostics [Internet].WHO-Prequalification of Medical Products (IVDs, Medicines, Vaccines and Immunization Devices, Vector Control). 2020 [cited 2022 Nov 29]. Available from: <https://extranet.who.int/pqweb/key-resources/documents/list-prequalified-vitro-diagnostic-products-excel-version>

a Available in Nepal (being implemented through the EpiC Nepal project since 2018)

b Available in Nepal (currently in the introductory phase)

Annex 2: HIVST register

Demographic Information											
क्र. सं.	मिति	नाम	थर	सेवा दर्ता नं	उमेर र लिंग			जिल्ला	गा.पा.नं नगरपालिका	हटस्पट नाम	सेवाग्राहीको दर्ता कोड नं.
					म	पु	यो.अ				
१	२	३	४	५	६	७	८	९	१०	११	१२

Demographic Information										Supervised					
वैवाहिक अवस्था	शैक्षिक अवस्था	शैक्षिक योग्यता	औसत मासिक आमदानी	मोबाइल नं	सेवाग्राहीको किसिम १ नयां / २ पुरानो	पहिला एचआइभी जाँच गरेको (छ/छैन)	सौचिक सहमति (छ/छैन)	स्व परेक्षणको किसिम १ सुपरिवेक्षित २ असुपरिवेक्षित	एचआइभी स्व-परिक्षणको नतिजा	एचआइभी परामर्श (१:दियो/२:दिएन)	यदि नतिजा रि एचआइभी परामर्श (१:दियो/२:दिएन)				
															रियाक्टिभ (R)/नन रियाक्टिभ (NR)
१३	१४	१५	१६	१७	१८	१९	२०	२१	२२	२३	२४	२५	२६	२७	२८

Unsupervised															
आफ्नो एचआइभी स्व-जाँचको लागि लगेको जम्मा किट	साथीको एचआइभी स्व-जाँचको लागि लगेको जम्मा किट	अन्यको लागि एचआइभी स्व-जाँचको लागि लगेको जम्मा किट	सात दिनभित्र फर्लाउप गरेको	एचआइभी स्व-जाँचको लागि लगेको जम्मा किटको नतिजा		रिजल्ट प्राप्त मिति (DD/MM/YY)	एचआइभी स्व-जाँचको नतिजा प्राप्त गरेको का स्व-जाँचको जम्मा किट	एचआइभी स्व-जाँच पछिको परामर्श	यदि नतिजा रि एचआइभी परामर्शको संस्थाको नाम र ठेगाना	यदि नतिजा रि एचआइभी परामर्शको संस्थाको नाम र ठेगाना	यदि नतिजा रि एचआइभी परामर्शको संस्थाको नाम र ठेगाना				
				रि एचआइभी (R)	नन रि एचआइभी (NR)							Invalid नतिजा			
२९	३०	३१	३२	३३	३४	३५	३६	३७	३८	३९	४०	४१	४२	४३	४४

Annex 3: HIVST result recording form

१. मिति:..... २. सामुदायिक कार्यकर्ताको नाम:.....
३. लक्षित समुदायको नाम: ४. दर्ता कोड (UIC): लक्षित समुहको प्रकार (KP Type).....
५. ONHIS दर्ता कोड :
६. हटस्पट एरियाको नाम: जिल्ला: गा.पा./नगरपालिका:..... वडा नं.
७. पहिले एचआईभीको जाँच गरेको? छ छैन
८. एचआईभीको स्व-परीक्षण जाँच बारे मौखिक स्विकृती दियो/ दिएन?
९. एचआईभीको स्व-परीक्षण गरेको माध्यम? सुपरिवेक्षित सुपरिवेक्षण नगरेको
१०. एचआईभीको स्व-परीक्षण सुपरिवेक्षित भएमा:
- क) परीक्षणको नतिजा Reactive Non-reactive Invalid
- ख) परीक्षण पश्चात शिक्षा दिएको छ छैन
- ग) Reactive नतिजा आएको क्लाइन्टलाई एचआईभी परीक्षणका लागि नजिकको एचआईभी जाँच केन्द्रमा रेफर गरिएको छ छैन
- घ) ननुरियाक्टिभ आएमा PrEP सेवाको लागि प्रेषण गरेको : छ छैन
- ङ) ननुरियाक्टिभ सेवाग्राहीलाई प्रेप सेवाको स्क्रिन गरिएको: छ छैन
११. एच आईभीको स्व-परीक्षण असुपरिवेक्षित भएमा:
- क) स्व-परीक्षण किट दिएको जम्मा संख्या:
- आफ्नै लागी: यौन साथीको लागी:..... अरुको लागी:.....
- ख) स्व-परीक्षण किट दिएकोलाई सात दिन भित्र फलोअप गरिएको छ छैन
- ग) स्व-परीक्षणको Reactive नतिजा संख्या :
- घ) स्व-परीक्षणको Non-Reactive नतिजा संख्या :
- ङ) स्व-परीक्षणको Invalid नतिजा संख्या :
- च) स्व-परीक्षणको नतिजा प्राप्त भएको मिति:
- छ) नतिजा आए पश्चात शिक्षा दिएको छ छैन
- ज) प्रयोग गरिएको स्व-परीक्षण किट फिर्ता गरिएको संख्या :
- झ) Reactive नतिजा आएको क्लाइन्टलाई एचआईभी परीक्षणका लागि नजिकको एचआईभी जाँच केन्द्रमा रेफर गरिएको छ छैन
- ञ) ननुरियाक्टिभ आएमा PrEP सेवाको लागि प्रेषण गरेको : छ छैन
- ट) ननुरियाक्टिभ सेवाग्राहीलाई प्रेप सेवाको स्क्रिन गरिएको : छ छैन
१२. स्व परिक्षण गर्नको लागि रेफर गरिएको व्यक्तिहरूको संख्या :
- क) इपिओए बाट
- ख) मेरो साथी बाट
- ग) अनलाइन आउटरिच बाट
- घ) इन्हेक्स क्लाइन्टको पार्टनर बाट
- ङ) आउटरिच शिक्षा बाट

Annex 4: HIVST take-away register

Name of IP:				
Week/ Month/ Year				
	Number of HIVST kits taken	Number of clients seeking assistance for testing (HIVST_ supervised)	In case the distributed kit is returned, result of test	
			Reactive	Non-Reactive
Day 1				
Day 2				
Day 3				
Day 4				
Day 5				
Day 6				
Day 7				
Total				



Government of Nepal
Ministry of Health and Population
National Center for AIDS and STD Control
Teku, Kathmandu