UNASSISTED HIV SELF TEST (HIVST) IMPLEMENTATION MANUAL FOR DELIVERY OF HIV SELF TESTING SERVICE IN ETHIOPIA

FEDERAL MINISTRY OF HEALTH

Ethiopia

May 2020

Forward

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

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

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

I strongly encourage to expand and advocate the utilization of the HIVST in the country but within the framework of relevant national policies and operational manual. The development of the unassisted HIV self-testing (HIVST) implementation manual is a result of the efforts by the National HTS technical working group, drawn from different organizations and coordinated by National HIV Case team. I thank the National HIV case team for spearheading this process and working tirelessly with the other organizations to develop this manual. Special and sincere appreciation also goes to our partners, individuals and all members who participated in many meetings and workshops to share useful ideas towards the development of this document.

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1. Background

Learning one's HIV status through HIV testing is the gateway to prevention and treatment services, which are highly effective in reducing HIV-associated morbidity and mortality and can prevent onward transmission of HIV. HIV testing services are also key to achieving the United Nations 95-95-95 targets by 2030, which start with diagnosing 90% of people living with HIV.

Inadequate uptake of testing for HIV remains a primary bottleneck toward universal access to treatment and care as well as an obstacle to realizing the potential of new interventions for preventing HIV infection, including treatment for prevention and pre-exposure prophylaxis (PrEP). HIV self-testing (HIVST) is an empowering and innovative way to help achieve the first of the United Nations 95-95-95 treatment targets (1) for 95 % of all people with HIV to know their status by 2030. HIVST is a process whereby an individual conduct his or her own HIV test using a simple oral test. It is an emerging approach that provides an opportunity for people to test themselves discreetly and conveniently, thereby empowering those who may not otherwise test, particularly among high-risk populations to know their HIV status. Considerable efforts have been made in Ethiopia to respond to the HIV testing gap of the first 90. However, there still remains a testing gap for the country and new approaches must be considered.

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

This implementation manual defines the unassisted approaches delivery of HIV Self-Testing services phase-based implementation at selected KP friendly public health facility and Drop-in center (DICs) in Ethiopia.

2. Rationale

This manual serves as additional guidance for the National HIV self-Testing services with specific focus on Unassisted HIVST.

There is a global initiative to accelerate universal access to HIV prevention, treatment and care. HIV testing remains the key point of entry in the continuum of care for any individual living with HIV. The HIV testing gap remains significant and new modalities such as HIVST have been recommended as alternative approaches to conventional HIV-testing services (HTS) to reach key and under-tested populations.

Closing the HIV testing gap and diagnosing 90% of all people with HIV by 2020 is critical to the success of the global HIV response to reach the triple 90% target. In December 2016, the WHO released the *Guidelines on HIV Self-Testing and Partner Notification*: *A Supplement to the Consolidated Guidelines on HIV Testing Services*.[1]. These globally recognized guidelines have paved the way for in-country implementation manual development on HIVST that aims to support countries to provide two additional HTS approaches (Self-testing and partner notification and testing). These approaches can be utilized to reach people, particularly those at high HIV risk who may not otherwise test, However, today, only 54% globally and 79% (in Ethiopia) of people living with HIV know their status meaning that significant number of PLHIVs still don't know their HIV status. Hence increasing uptake of HIV testing is crucial to reaching the 95-95-95 goals. By addressing key barriers to uptake of HIV testing service, self-testing could play an important role in increasing the uptake and frequency of testing, while still ensuring linkage into care. Expanded use of HIV Self-Testing (HIVST) can contribute to these global targets by reaching first-time testers, people with undiagnosed HIV or those at ongoing risk who need frequent retesting.

HIVST has been shown to be an empowering, discreet and highly acceptable option for many users, including key populations, health workers, and highly mobile workers, partners of PLHIVs, pregnant women and their male partners and couples. Providing the HIVST through both assisted and unassisted approach represents another forward step to HTS in line with efforts to increase patient autonomy, decentralization of services and create demand for HIV testing among those unreached by existing services.

HIVST may enhance health system efficiency by focusing health services and resources on people with a reactive self-test result who need further testing, support and referral, thereby directing services more appropriately. It also helps to reduce the number of facility visits for frequent testers and eliminate the need for individuals to travel distances or wait in long lines to access HIV testing by making HIVST more convenient for users. The 2016 WHO guideline on self-testing also recommended that HIV self-testing should be offered as an additional approach to HIV testing services.

3. Objectives

General Objective

- To provide framework within which unassisted HIVST can be implemented safely, effectively and accurately.

Specific objectives

- Outline implemnation approaches to unassisted HIV self-testing
- Describe the package of support services required to undertake unassisted HIVST
- Describe commodity management systems required for HIVST
- Outline quality assurance strategies in HIVST
- Describe the monitoring and evaluation strategy for HIVST

4. HIVST Strategy and Linkage to Conventional HTS

HIVST Strategy

As per the WHO HIV-ST guideline, there are many possible public and private sector HIVST approaches. HIVST can be delivered through community-based (door to door or outreach), facility-based (pick-up or self-test onsite) and partner delivered (like PLHIV, pregnant women and FSW) approach. Programs should evaluate their existing HIV testing approaches and determine where and how to implement HIVST so that it is complementary and addresses gaps in current HIV testing coverage.

A reactive (positive) self-test result always requires further testing and confirmation from a trained tester starting from the beginning of a validated national testing algorithm. Clear messages are essential to ensure users understand that HIVST does not provide a definitive HIV-positive diagnosis, and they are aware of what to do after a reactive self-test result.

All self-testers with a non-reactive test result should retest if they might have been exposed to HIV in the preceding **six weeks** or are at high ongoing HIV risk.

HIVST is not recommended for people taking anti-retroviral drugs, as this may cause a false non-reactive (NEGATIVE) result.

Any person who is uncertain about how to correctly perform the self-test, or interpret the self-test result, should be encouraged to access facility or community-based conventional HTS.

5. Target population groups

- FSWs & their sexual partners
- partners of ANC
- partners of PLHIV

- Sexual partners of ICT
- Priority Populations (Prisoners, Long distance truck drivers, widows, divorced and separated. Mobile workers in hot spot areas)

6. Implemnetation Approches

As the HIV self- test is a new approach that expands the HTS to the population groups and individuals who are not reached through the conventional institution-based HIV testing service, it will be implemented in three phases. Both at facility (ART/PMTCT, KP friendly clinics/public health facilities) and community based (DICs, PLHIV association, IDIR office and confidential clinics)

Phase 1: Scale up of the approved directly assisted HIVST

Phase 2: Unassisted HIVST implementation in semi- restricted approach, and

Phase 3: Scale up of unassisted HIVST implementation in open access through social marketing approach.

To maximize the utilization by eligible groups and minimize the utilization by unintended population groups, and to create awareness for cost-effective outcome, implementation of HIV self-test will be in phases. The **first phase** is the implementation of the directly assisted HIVST implementation which is already piloted and implementation manual prepared for.

The **second phase** will be implementation of the unassisted HIVST in semi-restricted approach. At this stage, the access to the service will remain restricted under the implementing delivery outlets wavering the engagement of assistance. Even though the distribution points are limited, eligible clients can access the kits and perform the tests wherever they feel comfortable. In the meantime, implementing partners will work on disseminating the information on the HIV self-testing and promoting the service among eligible population groups like FSWs. The supply of test kits will also be covered by the implementing partners.

The demand creation, promotion among the targeted groups and the process of creating access to the test kits will be established by implementing partners and FMoH in collaboration. The strict directly assisted HIVST is implemented by partners whose working projects are in direct relation with the key and priority population groups at health facilities and community level.

As ICAP has a technical support for health facilities providing HIV prevention, care and treatment and it will plan, implement and monitor the health facility level unassisted HIV self-test implementation that includes the logistic supply of self-test kits, promotion and awareness creating among the target groups with the existing structure.

At community level implementing partners will work on both demand creation and making the HIVST kit available among target groups. Together with implementing partners, the necessary promotional

materials will be developed and distributed to target groups. Development of hot line and electronic information will be considered at this phase.

The **third phase** is the last phase when HIVST will be available at different outlets to open access through social market approach. At this stage, clients who consider themselves as having the risk and who determine for HIVST can access the HIVST kit and information from specific outlets for minimum fee that include standalone pharmacies. At this phase, it is expected that the general population and clients with the risk of HIV in particular have information about HIVST and what the results mean with the importance of confirmation using conventional tests and linkage to treatment and care for reactive results. There will be information centers and hotlines established that support clients on HIVST and where they get additional service.

7. Demand creation Mechnism to the target population

- Through person to person (health extension proffessionals,peer educators, Health workers,youth voulenteers, PLHIV voulunteers).
- Through print media (banners, poster, fliers)
- Audio visual

8. HIVST Service Delivery models

The selection of HIVST service delivery channels should be dependent on the context, setting and target population. The channels used should complement other existing HIV testing models such as Provider Initiated HIV Testing Services (PIHTS), Voluntary HIV Counseling and Testing (VCT) and address any gaps in HTS coverage.

8.1. Facility based models

HIVST can be integrated at both public and private health facilities. Clients seeking health services can be offered an opportunity to self-test by providing with a self-test kit to take home for use on themselves or distribution to a sexual partner. Self testing is complementary to the existing approaches for HIV testing.

Through the facility based model HIVST kits can be distributed by community care/support provider at a health facility.

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

- Partners of ANC and PLHIV
- Sexual partners of index cases

Instructional video shared with clients that supports the use and interpritation of the results:

The index client gives partner information on HIVST and shares the video with partner:

- ✓ If partner is negative, they are encouraged to retest as per ongoing risk.
- ✓ If the partner screens positive, partner should go to any nearby preferred facility for confirmation of the test result within one week.

8.2. Community based models

HIVST can be offered to community members and target populations through different mechanisms including; sexual partners of PLHIV(index), partners of ANC client,through existing community based structures such as drop in Centres, Ider bet, PLHIV associations,confidential clinics,andworkplace settings.HIVST kits can be distributed by trained lay providers, peer educators or community workers. Depending on the context, HIVST kits can be distributed to individuals at home (in high HIV prevalence settings), at community venues or through mobile outreach services (key populations and hotspots in high or low HIV prevalence settings).

8.3. Other channels (open source distribution) will be practical at the third phase

Alternative HIVST service delivery channels include provision of HIVST services through open source distribution points including pharamacies through social marketing or commercial market settings public-private channels or distribution at key points.

HIVST kits can be offered in the workplace or at institutions as part of health and wellness initiatives (in high HIV prevalence settings). A health worker or trained community/peer provider can promote HIVST alongside many other health services including HIV prevention, treatment and care. In workplaces without wellness program, HIVST may be appealing to employers and employees as it can save time by providing a quick way to test on-site or in private at home.

9. Linkage to further HTS and HIV prevention, treatment and care

In addition to identifying the best approach for delivering HIVST, program need to consider how to facilitate linkage to prevention, treatment and care following HIVST. Further research, monitoring and evaluation of strategies that facilitate linkage to care following HIVST are needed.

Possible ways to increase linkage following self-testing include:

- Referral/appointment cards: distributing referral/ appointment cards together with HIVST kits – with information and contact details on where to access further HIV testing, prevention and treatment can help facilitate linkages. Depending on the setting, these cards can either be included

by manufacturers inside the HIVST kits or provided as supplementary materials by implementing partners.

- Community outreach and follow-up: follow-up by trained peers or community workers can be a useful strategy for facilitating linkage to further testing, prevention and treatment. This can include offering community-based confirmatory testing, prevention and treatment while HIVST kits are distributed or on an ad hoc basis. Community workers and peer navigators may also accompany those with a reactive self-test result to receive further testing and care in a facility

- Telephone calls, text messages or social media counselling messages and reminders: follow-up counselling, messages and reminders can be used to encourage self-testers to link to further testing, prevention and treatment. These follow-up messages can be integrated in a variety of HIVST approaches as well as within existing HIV testing services.

10. Monitoring and Evaluation

HIVST provides some unique challenges in terms of M&E, and globally, there are not many systems outside of research-controlled environments that can effectively provide this. The mere notion of a self-test shifts the focus away from a healthcare facility to an individual. Measurement of uptake cannot be inseparably linked to usage, as individuals who receive a test may not necessarily use it. The following have been proposed as minimum M&E during the initial rollout of HIVST:

- Periodical assessment of the hotline for HIVST related calls requesting information, assistance, counselling and support
- Site-level and facility-level logbooks/testing registers can be modified to include HIVST, for example by noting if clients have self-tested before attending an HIV testing service facility and recording the reported self-test result. These registers can also be used to monitor linkage to prevention, treatment and care.
- Community-based surveillance systems and household/population-based surveys, health impact assessments and behavioral surveys can be modified to include HIVST by collecting data not only on the uptake of HIV testing but also on the mode of testing in order to be able to assess what proportion of all diagnoses are identified through HIVST and record instances of social harm and adverse events.

Indicators for HIVST

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

The following indicators will be reported to the national level:

1. Total number of test kits issued/sold (Supply chain report)
2. Number of HIVST kits distributed: HIVST distribution register
3. Total number of persons reporting having done self-testing source: (HIVST distribution register)

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

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

Reporting tools and systems need to develop HIVST tools to capture and report on data at service delivery points.

These tools should include:

- The HTS register with HIVST incorporated or HIVST register
- Commodity tools (IFRR)
- Linkage register
- To incorporate HIVST in the DHIS reporting tools

Additional HIVST-specific monitoring and reporting tools will sometimes be needed. Tablet or paper-based tools can be used, particularly for collecting data on people receiving HIVST kits across various service delivery points. For instance, when distributing self-test kits, a client data card or HIVST register can be used to determine who is accessing HIVST. When collecting information on HIVST indicators it is important to consider the quality of the data. It is recommended that routine quarterly reviews be conducted to ensure the accuracy of any data collected and to further optimize implementation. The following considerations should be kept in mind when monitoring HIVST implementation:

- Collecting data on HIVST kit distribution, including the persons who receive the kits, will provide essential information on the target populations reached
- Retesting is an issue with all routine HIV testing data. Since all reactive self-test results should be followed by further testing, it is important to ensure estimated numbers of tests are duplicated when calculating the total number of people tested and diagnosed with HIV
- Some testers may have been previously diagnosed with HIV and some may already be on ART. Therefore, it is important to utilize existing monitoring systems to measure testing and self-testing

among these individuals, including when assessing any data on linkage to care as some testers may already be on treatment.

HIVST client data card for HIV self-testing

Thank you for taking this bold step to perform your own HIV testing. This information will remain anonymous and will assist in improving Self-testing services. Please do not include your name or your phone number • Age (years): [_____] • sex: Female [__] Male [__] • Have you ever tested for HIV before? Yes [__] No [__] • How long ago did you have the HIV test • Never [__] Last three months [__] Last one year [__] Longer than one year [__] • What Type of HIV self-test kit have you purchased today: Oral [_] Blood [_]	What is the main reason for testing? (select one only): • To understand illness/ symptoms that I have/had • Advice from the pharmacist/ my doctor • I recently had a possible exposure to HIV • To plan the future/ take charge of my own health/ getting married • Encouraged by sex partner • It has been longer than 1 year since I last tested • Other reason (please indicate): _____

HIVST client data register

Name of Service Delivery Point					**Type of service delivery point: Public [ ] , Private[ ],Hospital[ ],Clinic[ ],Pharmacy[ ],HTS site[ ],DIC[ ],others**						
S.N	Date	Client Name	Age	Marital Status	Phone no.	Kit Information			Referred	Received HTS	Remark
						Name	Batch No	Exp. Date			
						Test Result N/P/I					

11. Supply chain for HIVST

The pharmaceutical supply management system of the country ensures the adequate and continuous availability of safe, effective, quality assured HIV self-test kit(s) at service delivery sites in the right quantity and timely manner at the lowest cost. Principally, the supply chain for HIVST kit will be managed by implementing partners at initial two phases and on third phase of the implementation, it will be maintained in the commercial market and through social marketing and the clients using HIVST should be encouraged to return for subsequent prevention, care and treatment services; the partners and other stakeholders should try their best to observe/track the added value/effect of HIVST distribution.. The government of Ethiopia will be responsible for ensuring quality, WHO approved test kits are available in the country. EPSA will facilitate the procurement using revolving fund so that WHO approves quality HIVST kits will be commercially available in the market. Hence, HIVST kits will be available with certain cost at pharmacies and selected service outlets through social market approach.

Inventory Management /Tracking System

Supply chain: This represents the set of practices that must be coordinated to ensure that appropriate, high quality supplies are available whenever and wherever they are needed. It requires proper coordination and management of commodities in order to ensure availability and utilization of the kits. The kits must be WHO pre-qualified and in-country validations must be conducted. Proper quantification of the kits must be done either through forecasting or on consumption base after collecting the necessary data and information by involving all the relevant stakeholders. After kits are procured, a proper distribution plan

must be done at all level. This will make the monitoring of test kits easier. Parallel to this, service delivery outlets must have reports on the amount of kits distributed to beneficiaries.

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

It is important to routinely monitor HIVST implementation in order that programmatic approaches can be further optimized to achieve impact and reach national testing targets.

Linkage to confirmatory testing and treatment following self-testing may be facilitated where HIVST kits are distributed and/or where HIVST is performed. HIVST also has the potential to link users to prevention services, for example linking key populations and other populations at high ongoing risk to PrEP.

Through unassisted HIVST distribution models, clients are encouraged to return used kits after testing. These used kits will be dropped into a collection box placed in the nearby community settings including health facility (public/private), Kebele administration offices, schools, kiosks etc. The collection of the kits will mainly facilitate proper disposal and uses as a proxy indicator for number of actual tests. Generally, the positivity rate through HIVST is measured by a change in trend in ART uptake within the catchment population.

12. Quality assurance

An effective Quality Assurance (QA) program is one that is integrated into routine practices in the country. This section aims to provide guidance on how to ensure the quality of HIV self-testing test kits and testing processes.

Human Resource

Having qualified, trained staff that perform and monitor the quality of HIVST and the various activities in the QA program is one of the most important factors for ensuring accurate and reliable results. All HIVST service providers should be trained per the HIVST training package. This includes capacity building and knowledge on how to conduct the tests and how to test and/or where to refer clients for additional testing and further support. Mentoring and supportive supervision need to be conducted at periodic interval to ensure the quality of HIVST. The mentor and site supervisors should document HIVST counselors' competency in performing all tasks for which an individual is responsible, including both the overall HIVST process and demonstration skills.

Provider and Clients Support Tools

HIVST provider support tools including how to conduct a HIV self-test and results interpretation should be readily available to all clients. Adequate and locally translated clear instructions with pictorial

illustrations on how to conduct self-testing should be provided with the test kits to ensure a person obtains the correct results. Clients should follow manufactures instructions in the test kits insert. User instruction should be available in each test. All clients must also be aware of correct practices to minimize biosafety risks the need to confirm any reactive test results as per the national HIV testing algorithm.

HIVST kits

For the national procurement, HIVST kits must fulfill HIV self-test WHO pre-qualification. Test kits must undergo in-country laboratory validation to ensure that they meet the minimum inclusion criteria.

Lot to lot validation

The safety, quality and performance of HIVST should be further verified upon delivery and before distribution to the target groups. The procurement agency must ensure that any new shipments and lots of HIVST test kits coming into the country are evaluated to ensure that products delivered meet criteria for quality and performance. A "lot" consists of multiple tests kits that were manufactured together, and which will all bear the same lot number on the outside of the test kit package. A "shipment" is the quantity of test kits that arrive in a single delivery. External control testing will verify that the lot/shipment is functioning properly after the shipping process. If a shipment contains units from a single lot, one set of controls on that shipment will verify the functionality of both the lot and the shipment. If the shipment contains units from more than one lot (i.e. contains more than one lot number), external controls must be run on each lot.

If the test kit storage area in either at any location is suspected to have fallen outside the acceptable temperature range as specified in the manufacturer's package insert, external controls must be run to verify that the test kits are still functioning properly prior to resuming use of the kits to test client specimens. Only lots with satisfactory results should be distributed to service delivery health facilities.

13. Quality Control

Each rapid SELF-testing device is equipped with an "internal" control device that consists of a line that appears next to the "C" in the device window when a valid result is obtained. This control verifies that enough sample was applied, and that the sample and reagent migrated through the device properly. Adequate orientation and demonstration should be given to the clients to verify the presence of control line irrespective the result. In addition to this internal control, the test manufacturer also makes available external controls, which must be run periodically to verify that the device is accurately detecting HIV antibodies and to check if the person conducting the test performs it correctly.

Specification for HIVST kits in Ethiopia

Criteria	Requirement
Sensitivity	≥99%
Specificity	≥98%
Specimen type	Oral fluid
Easy of use	• Not require additional equipment to perform the test and interpretation of results • No require technical training to perform the test
Reading time	• ≤ 30 minutes • Relatively maximum end point stability
Packaging	• Complete set within single packaging
Storage temperature	• Not require refrigerator/ freezer • Can be stored in ambient temperature (2-30^{o}C)

Inventory Control

It is also important to control inventory by using secure storage areas and sufficiently stringent monitoring procedures. Inventory log sheets should account for each test, and indicate whether it was used to test a client sample, to run external controls, for training/practice purposes, or was not used for some reason, such as past expiration date, faulty packaging, storage temperature non-compliance, etc.

Temperature Monitoring

A log documenting storage temperature for test kits should be used to document storage temperatures in primary storage sites and temporary storage sites, such as a KP clinics. Temperature should be recorded periodically daily when the facility or the distribution point is open, but more frequently for less temperature-stable settings such as mobile units.

Post-market surveillance

The purpose of post-market surveillance is to protect individual health and public health through continued surveillance of in-vitro diagnostics once they are placed on the market by reducing any risks. Such activities should ensure the manufacturer's obligations are fulfilled through ensuring they are aware of event which enables them to undertake and assessment of any risks, and as appropriate any suggested steps to risk mitigation**.** Post-market surveillance will be conducted periodically by an authorized government agency to assess the quality and performance of the test kits in use, in compliance with the set standards.

14. Roles and Responsibilities

MOH

- Responsible for the development and dissemination of HIVST implementation manual and support tools
- Coordinates the implementing partners who provide HIVST services
- Facilitate the HIVST kit distribution in collaboration with partners
- Regularly monitor, review and support the overall implementation of the program

RHBs

- Coordinate and support the implementation of unassisted HIVST at regional level
- Regularly monitor the consumption of the HIVST kits and manage the supply
- Monitor and support the recording and reporting activities
- Lead and support the monitoring of the implementation through joint supportive supervision and performance review at regional level
- Regularly monitor, review and support the overall implementation of the program
- Encouraging healthcare providers to advocate for use of HIVST to increase testing among partner of PLHIV and targeted key populations.

EPSA

- Lead and support the quantification, clearance, storage and distribution of HIVST kits
- Coordinate the distribution of the HIVST kit as per the agreed upon distribution plan

HAPCO

- Demand creation/ promote utilization of HIVST services among the intended target groups
- Mobilize resource for sustainable availability and procurement of HIV self-test kit

Partners

- Collaborate with the MoH, agencies and regional health bureaus in the planning, coordination, implementation and programmatic management of HIV self-test (assisted and unassisted)
- Provide the necessary technical and financial support for the development and duplication of materials
- Support the monitoring of HIVST implementation along with the national and regional offices

- Collect and analyze data as per the monitoring tools and submit/present for national team quarterly
- Follow the implementation of the overall HIVST implementation program
- Sensitization of healthcare providers on HIVST as an additional strategy for increasing access for HTS
- Provide financial and technical support for the procurement and supply of HIVST kit
- Provision of patient education information tools

EPHI

- Overall quality assurance in HIVST services
- Test Kit validation and new lot verification
- Conduct post market surveillance HIVST test kit

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Annexes:

Definition of terms

HIV Testing Service: is the whole service package that enable provision of pre and post-test information/ counseling, rapid HIV testing with determination of final status to clients. It includes different modalities- provider-initiated, self-initiated, integrated/ targeted.

HIV self-Testing (HIVST): this is a process of HIV testing in which an individual collects his or her specimen (Oral fluid or blood) and then performs an HIV test and interprets the result, often in a private setting either alone or with someone he or she trusts.

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

Unassisted HIVST: refers to when individuals self-test for HIV and only use an HIVST kit with manufacturer-provided instructions for use.

HIV status: is the final report that is given to the patient; it is the final interpretation of the patient disease state and is based on a collection of testing results generated from one or more assays. HIV status may be reported as HIV-positive, HIV-negative or HIV-inconclusive.

HIV test result: is the immediate result from a single test on a given assay. It is not possible to tell ones HIV infection using one HIV test result.

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

Reactive results: It means that the test indicates that HIV antibodies are present in the blood or oral fluid sample. Anyone whose result is reactive to a rapid HIV test (including a self-test) must be followed by additional HIV testing services by a trained provider following the national HIV testing algorithm. Furthermore, self-testing users may be provided with links or contact details to access additional support, such as telephone hotlines or instructional videos. This is confidently performed when there is adequate awareness and knowledge about HIV testing among the beneficiary community.

Window period: is the period between HIV infection and the early detection of HIV1/2 antibodies using serology assays, which marks the end of the diagnostic window period and the end of seroconversion. It

is the early time of HIV infection when existing HIV testing kits cannot detect or show infection. It is the first 6-12 weeks of HIV infection.

Community care/support provider: is a person who is responsible for the HIV self-testing demand creation, kit distribution, counseling and assisting the client before, during and after self-testing, recording and referral/linkage of a tester. This can be trained community health care providers, health extension professionals, peer educator, peer navigator, peer supervisor, community resource person or community mobilizer.

Partner and family-based Index testing: often referred to as index case, index patient or index partner HIV testing. This is a focused HTS approach in which the household, family members (including children under 15 years) and partners of people diagnosed with HIV are offered HIV Testing Service (including self-testing). **However, children are not eligible for HIVST.**