HIV

SELF-TESTING IN GHANA

An Implementation Guide

MINISTRY OF HEALTH

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NACP

NATIONAL AIDS CONTROL PROGRAMME

HIV SELF-TESTING IN GHANA

An Implementation Guide

CONTENT

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Foreword

Ghana has made significant progress in the fight against HIV and AIDS. In 2019, the national adult prevalence was estimated at 1.7% with an estimated 342,307 people were living with HIV. In 2019, a total of 153,901 PLHIV received antiretroviral drugs. The National AIDS/STI Control Programme adopted the new World Health Organization recommendations to treat all people living with HIV with ART, regardless of immune status or clinical stage in 2016. The adoption of this recommendation sits alongside the ambitious 95-95-95 targets to ensure that 95% of people living with HIV know their status, 95% of people who know their status are on ART, and 95% of those on treatment are virologically suppressed by 2025.

To achieve these targets requires innovative approaches to identifying people living with HIV and linking them to care. Introducing HIV self-testing will augment testing efforts across the country. HIV self-testing will complement standard testing services, expanding access to individuals who will otherwise not patronize these services. HIV self-testing has proven to be acceptable, convenient, and regarded as more confidential than standard testing services. It has been proven effective in reaching hard-to-reach and high risk populations thereby improving testing yield.

As Ghana rolls out HIV self-testing, this guide will serve as the blueprint for step-wise phasing of the different structures to ensure efficiency, effectiveness and maximum impact. This document defines the populations to be targeted and outlines the principles that will guide the implementation of HIV self-testing in Ghana. It also describes methods to be adopted to deliver test kits to the priority populations with a focus on linking reactive results to confirmatory tests, care and treatment. This document also outlines monitoring and evaluation considerations and those of supply chain management.

Synergies are drawn from both the private and public sector. It is therefore hoped that all stakeholders will put shoulders to the wheel to ensure a successful and effective implementation of HIV self-testing in Ghana.

It is hoped that together, implementing partners, donors, civil society organisations, private sector players, regulators and all stakeholders through the use of this implementation guide will be able to develop robust structures to support implementation.

Dr. Patrick Kuma-Aboagye
Director General, Ghana Health Services

Executive Summary

The National AIDS/STI control Programme's (NACP) aim to increase testing coverage among high risk and vulnerable populations has resulted in differentiated testing such as Orphanage testing, Ante-Natal Care (ANC) testing and Family-Based Index testing strategies. Taking this further to augment the yield, HIV self-testing (HIVST) will be introduced and implemented across the country.

The objectives of implementing HIVST will be to provide quality and affordable HIVST services, ensure access, promote uptake and strengthen linkage to testing and treatment services. Priority populations to be targeted include: high risk men, key populations (KP) and their sexual partners and partners of persons living with HIV (PLHIV), Adolescent Girls and Young Women (AGYW), Adolescent Boys and Young Men (ABYM) and people with Ssexually Ttransmitted Iinfections (STI's), HIV negative partners of HIV discordant couples, and HIV negative partners of STI and Tuberculosis (TB) clients.

Delivery models include a facility-based approach where kits will be distributed to individuals via secondary distribution to partners of clients who visit facilities. A community-based model will include utilizing existing community engagement and outreach programmes, faith-based and workplace programmes for free or at discounted cost as part of programmatic activities implemented in conjunction with key implementing partners. The private sector will also be engaged, distributing kits through pharmacies, licensed chemical sellers and private health facilities at a cost.

Trainings and certification for both private and public actors will be conducted under the auspices of the NACP. Demand generation activities such as peer outreach education, social and mass media campaigns, HIVST Champions, Interactive Voice Response (IVR) and Text platforms, Helpline and Public-Private Partnerships will be employed to promote HIVST.

Support tools to back linkage to testing and treatment services will be through the use of technology such as a Helpline, IVR and Text platforms, websites and social media platforms such as WhatsApp, Facebook and Instagram. A bespoke HIVST Application will also be developed to track HIVST distribution and follow-up, and will be linked to the national supply chain and monitoring and evaluation structures. Linkage to testing and treatment services will be the key to deriving maximum impact of HIVST.

The cadre of community-based, healthcare workers, volunteers and peer-led network of mobilizers will be utilized to follow-up on clients. A referral coupon system will also be established, utilized by both the private and public sector together with support tools to track clients who access HIVST and link them to further testing and treatment services.

Existing monitoring and evaluation tools will be modified to accommodate HIVST, ultimately integrating HIVST indicators in the national reporting system. Modifications will also be made to existing supply chain structures to reflect HIVST, from quantification to distribution and inventory management.

List of Acronyms

ABYM	- Adolescent Boys and Young Men
ACSM	- The Advocacy, Communication and Social Mobilisation
AGYW	- Adolescent Girls and Young Women
ANC	- Ante-Natal Care
CATS	- Community Adolescent Treatment Supporters
CHN	- Community Health Nurse
CHO	- Community Health Officer
CHW	- Community Health Worker
CITC	- Client Initiated Testing and Counselling
CSO	- Civil Society Organisations
DHS	- Demographic and Health Survey
FBIT	- Family-Based Index Testing
FP	- Family Planning
FSW	- Female sex workers
GAC	- Ghana AIDS Commission
GHS	- Ghana Health Service
GHILMIS	- Ghana Integrated Logistics Management Information System
GKPUIS	- Ghana Key Populations Unique Identification System
HIV	- Human Immunodeficiency Virus
HIVST	- HIV Self-Testing
HTC	- HIV Testing and Counseling
HTS	- HIV Testing and Counseling Services
IBBS	- Integrated Bio-Behavioural Surveillance
ICHPP	- Integrated Community Health Promotion Programmes
IEC	- Information Education and Communication
ILO	- International Labour Organization
IVD	- In Vitro Diagnostics
IVR	- Interactive Voice Response
JSI	- John Snow Inc.
KP	- Key Populations
MSM	- Men who have sex with men
NACP	- The National AIDS/STI Control Programme
PITC	- Provider Initiated Testing and Counselling

PLHIV	- People living with HIV
PPP	- Public-Private Partnerships
PrEP	- Pre-Exposure Prophylaxis
PWID	- People who inject drugs
TB	- Tuberculosis
TWG	- Technical Working Group
UNAIDS	- The Joint United Nations Programme on HIV/AIDS
VCT@Work	- Voluntary Counselling and Testing at Work
VMMC	- Voluntary Male Medical Circumcision
WHO	- World Health Organization

Chapter 1

1. Introduction

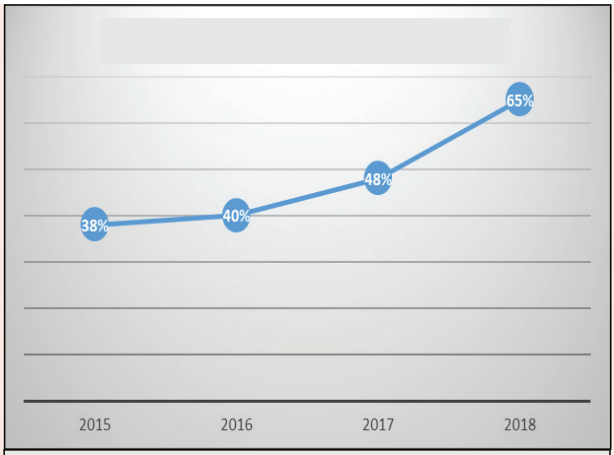
1.1 HIV Testing Services (HTS): Ghana's epidemiology and testing gap

The World Health Organization (WHO) estimates that 8.1 million people remain unaware of their HIV status representing 21% of all people living with HIV1. The Joint United Nations Programme on HIV/AIDS (UNAIDS) also estimates in its 2020 Global Report that globally, the gap to reaching the first 90 stands at 3.3 million people. Ghana has made progressive efforts towards achieving its 90-90-90 goals. In 2019, 58% of PLHIV knew their status, 77% of the PLHIV who knew their status were placed on ART and 68% achieved viral suppression2. For the first 90, the country achieved 52% in 2017 of people living with HIV who knew their status, increasing progressively to 55% in 2018 and 58% in 20193. The Ghana AIDS Commission estimated that in 2019, 342,307 persons were living with HIV in Ghana4.

The NACP has implemented various testing strategies aimed at increasing the testing coverage among high risk and vulnerable populations. These have included Orphanage testing, ANC testing and Family-Based Index testing strategies. In 2019, 4,668 facilities in Ghana were offering HIV Testing and Counselling Services (HTS) to clients. This represents a significant increase from 2018 (3,775 facilities). Majority of HIV testing occurs at the facility level, implying room for other innovative approaches to testing which captures populations that would otherwise not test at facilities.

In 2019, Ghana achieved its testing target of conducting 1,222,449 tests. This set target was a downward revision from an initial target based on the premise of mass testing. The achievement for 2019 was based on the premise of employing tailored approaches to testing instead of conducting mass testing. In years prior to changing the approach to testing, incremental achievements were obtained; from 38% target achievement in 2015 to 65% in 2018 (Figure 1)[5]. In 2018, a total of 1,702,543 persons were tested and in 2017 the number was 1,271,347.

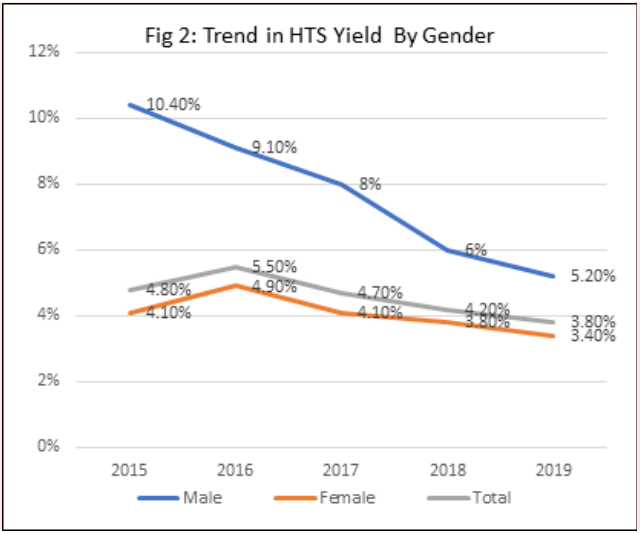
Fig 1: Coverage of annual HIV Testing Target



Source: NACP Annual Reports 2019

HTS yield has seen a steady decline since 2016 from 5.5% to 3.8% in 2019 although number of tests conducted has increased steadily over the years except for 2019 when targets were revised (Figure 2).

Fig 2: Trend in HTS Yield By Gender



Profiling persons who are being tested reveals mostly pregnant women (48% in 2019 of all persons tested and 51% in 2018). Men remain largely untested recording only 19% of total people tested in 2019 and 20% in 2018.

Key Populations have been a focus for HIV interventions in Ghana. Programmatic data from WAPCAS, key implementers of KP HIV interventions, reports a steady increase in number of men who have sex with men (MSM) tested from approximately 8,000 in 2017 to 9,556 in 2019. Positivity rate has increased correspondingly from 5% to 10% within that same period. Testing among female sex workers (FSW) has also seen a steady increase from about 14,000 in 2017 to close to 26,000 in 2019. The positivity rate has however remained the same for 2018 and 2019 (6%) from an initial 3% in 2017. Outreach or mobile testing accounted for 53% of the tests conducted between 2017 and 2019 compared to 47% using the fixed approach. The 2014 Modes of Transmission (MoT) study revealed the rate

of new infection from sex work had declined from 27% in 2009 to 18.4% in 2014. In total, 27.5% of new infections occurred in KP (People Who Inject Drugs-PWID, MSM and FSW) and their regular partners. Therefore, tailored approaches to reaching KP with HTS services will be essential in reducing the rate of new infections and HIV prevalence among this population.

Bridging the testing gap to reach men, KP and other vulnerable populations will place the country on track to attaining country-specific and global goals for HIV. This will also provide ample opportunity to extend innovative testing services to under-served populations. Ultimately, new and innovative testing approaches aimed at populations who would otherwise not be captured under facility-based or other traditional testing services is needed to push the needle on HTS services towards achieving the national HIV goals. A focus of these innovative approaches on the combined populations of under-served groups for HTS and populations that drive the epidemic in Ghana: high risk men, FSW, MSM and their sexual partners would heighten the impact.

A robust HTS strategy serves as the entry point to HIV care and treatment, setting the tone for the achievement of all other goals in the testing, care and treatment cascade. In Ghana, it is anticipated that by 2023 a total of 332,853 persons living with HIV would be tested and know their results to be on track to attaining the first of the 95-95-95 goals by 20256. Some of the key strategies identified by the NACP to help achieve this include providing quality HTS and promoting HIVST as a complementary service to traditional testing services.

To bend the trajectory towards achieving fast-tracked goals for HIV requires more than a business as usual approach. Combining innovative and targeted approaches to HTS will contribute to these efforts. Offering HIVST to targeted populations has been identified as an HTS approach which when implemented in conjunction with other targeted approaches will augment the HIV positivity rate.

1.2 HIVST background: Global perspective's and Ghana's journey and policy environment

In 2015, WHO released consolidated guidelines for HTS which included the potential of HIVST to augment HTS efforts in reaching particularly men, KP and young people. As recognition and interest from member states grew, more comprehensive guidelines specifically tailored for HIVST was developed. The first HIVST global guidelines were published in 2016 and updated guidelines published in 2019. WHO has so far recorded 77 countries including Ghana, who have adopted HIVST policies with others in various stages of development[7].

Ghana's recent efforts in implementing and scaling-up HIVST has been in the form of feasibility studies and consultative meetings. In 2018, The USAID Strengthening the Care Continuum Project (the Care Continuum), implemented by John Snow Inc. (JSI) in partnership with the Population Council, conducted a study in Accra in the Greater Accra region and Sunyani in the Brong-Ahafo region to:

1. Document FSWs' and MSMs' abilities to correctly use the oral HIVST kit (OraQuick™ Rapid HIV 1/2 Antibody Test),
2. Describe perceptions and attitudes regarding oral HIVST among FSW, MSM, service providers, and policymakers
3. Describe potential strategies for distributing HIVST for FSW and MSM.

Forty participants (20 MSM and 20 FSWs) were purposively recruited by outreach workers. Eligibility criteria included being 17–59 years of age and self-reporting having an unknown or negative HIV status three months ago or more. Participants were provided pre-test information and post-test counseling; however, they were not given any specific instructions on the use of the HIVST kit. A research assistant observed the participant's usage through a video camera and used a checklist to indicate correct or incorrect usage. Participants responded to a few open-ended questions about the usage after performing the test.

The findings from this study indicated that close to 90% of MSM and FSW completed the test correctly and read their results correctly. Study participants liked the pictorial instructions and the test was highly acceptable among both MSM and FSW. Participants liked the oral HIVST for its confidentiality, privacy and convenience. They were also keen on its potential to reduce the stigma they face at health facilities and the painless,

quick and easy manner the test can be administered. Concerns expressed was centered on the lack of counseling, the need for further confirmatory testing and the potentially poor linkage to care. Another concern raised was about obtaining the HIVST kits in ways that do not compromise privacy and anonymity. MSM and FSW were inclined to receiving kits from KP-friendly organizations and peer educators.

A laboratory evaluation exercise and field usability assessment was conducted on four HIVST products. Results from these studies will feed into implementation and procurement of test kits. Consultative meetings were also conducted with accredited retail and community Pharmacy Practitioners. The outcomes of these meetings included:

1. Identifying the role of retail pharmacies in HIVST implementation,
2. Accessing the capacity needs of pharmacy staff of retail and community pharmacies,
3. Determining the cost implication to retail and community pharmacies in the implementation of HIVST,
4. Linkage modalities for HIVST implementation.

Other consultative meetings were conducted with key stakeholders including Civil Society Organisations (CSO), KP-led organizations and KP community representatives as well as implementing partners. Outcome of these meetings included identifying ways of engaging respective communities with HIVST and the most effective modes of linkage to care.

Policy Environment: The policy environment for HIVST is largely dictated by policies that govern overall HTS. Policies outlined in the 2017 Ghana Health Service (GHS) Differentiated Service Delivery Manual therefore serve as the policy framework within which HIVST operates . The document stipulates that HIVST will be initially introduced to support index client and KP HIV testing services. The age of consent for HIV testing is 16 years. It however, also outlines special considerations for "matured minors", defined as persons between the ages of 14-16 years who are sexually active, married, pregnant, or a parent. Such persons are able to give full informed consent for HIV testing.

An HIVST and Pre-Exposure Prophylaxis (PrEP) Technical Working Group (TWG) has been established at the national level to steer the initial stages of implementation of both HIVST and PrEP before full scale-up is achieved. The TWG comprises key actors from the Ministry of Health and key stakeholders drawn from implementing partners and civil society. The

mandate of this group is to:

1. Provide overall recommendations on and supervision to the planning, implementation, and monitoring of the PrEP and HIVST activities to inform future national scale-up.
2. Act as key resource persons for in-depth interviews and other consultations to provide insight, opinions, references, and recommendations on how to better plan, implement and monitor the PrEP and HIVST strategies.
3. Support and reinforce the capacity of key stakeholders to provide quality, on-demand technical assistance on PrEP and HIVST initiatives.

Impact of COVID -19: The emergence of the COVID-19 pandemic has revealed both weaknesses and opportunities in our public health response globally. A 2020 UNAIDS report describes how HIV lessons learned and existing HIV structures are being used by countries to drive the response to the pandemic8. The pandemic has also forced to the forefront, ways of working differently to maintain the momentum and safeguard gains made by global public health responses. HIVST offers a unique opportunity during the COVID-19 pandemic, to ensure reaching people with HTS services whiles at the same time freeing up infrastructure and human resources to tackle the pandemic.

1.3 HIVST products

HIVST kits on the global market are either blood-based or oral fluid-based rapid tests. Several are quality-assured by globally-acclaimed quality assurance entities. They have either been pre-qualified by WHO, passed the requirements of the Global Fund Quality Assurance Policy or one of the founding members of the Global Harmonization Task Force on Medical Devices. WHO pre-qualified HIVST kits as of the year 2020 available on the global market are: OraQuick manufactured by Orasure Technologies Inc.; Sure Check manufactured by Chembio Diagnostic Systems Inc., Mylan manufactured by Atomo Diagnostics Pty Ltd and; INSTI manufactured by bioLytical Laboratories Inc.

Four test kits have undergone evaluation studies in Ghana namely: First Response self-test kit, Oraquick, Mylan and Biosure. The Oraquick self-test kit has been registered and approved by the Ghana Food and Drugs Authority (FDA) for use in Ghana. Periodically, the government of Ghana

will review and subsequently update the list of approved self-test kits for use in the country. As HIVST is scaled-up, it is anticipated that other blood-based products will become licensed for use. By law, only Ghana FDA registered and approved HIVST kits can be used in the country.

HIVST kits will be available at minimal cost in public sector facilities. They will also be available for purchase at private health facilities, pharmacies, licensed chemical shops or vending machines placed at strategic KP hotspot areas. The kits will also be distributed for free as part of pilot projects and other programme activities implemented by implementing partners across the country.

1.4 Objectives of HIVST Implementation in Ghana

The rationale for implementing HIVST in Ghana is to introduce an HTS approach that will boost HTS coverage by improving case findings and reaching under-served populations who may otherwise not be reached by traditional approaches to HTS. The objectives of HIVST implementation in Ghana are to:

- Provide quality and affordable HIVST services across the country.
- Promote uptake of HIVST services.
- Increase access to HIV testing services to those at high risk or those not seeking standard services.
- Strengthen linkage to testing and treatment services for persons with reactive results.

This implementation guide outlines parameters for implementation of HIVST in both the private and the public sectors in Ghana. These parameters include:

- Defining the priority population and geographic focus of HIVST services.
- Outlining the guiding principles for HIVST.
- Describing service delivery models to be adopted for HIVST implementation.
- Describing linkage to testing and treatment services and monitoring and evaluation considerations.
- Outlining supply chain considerations.

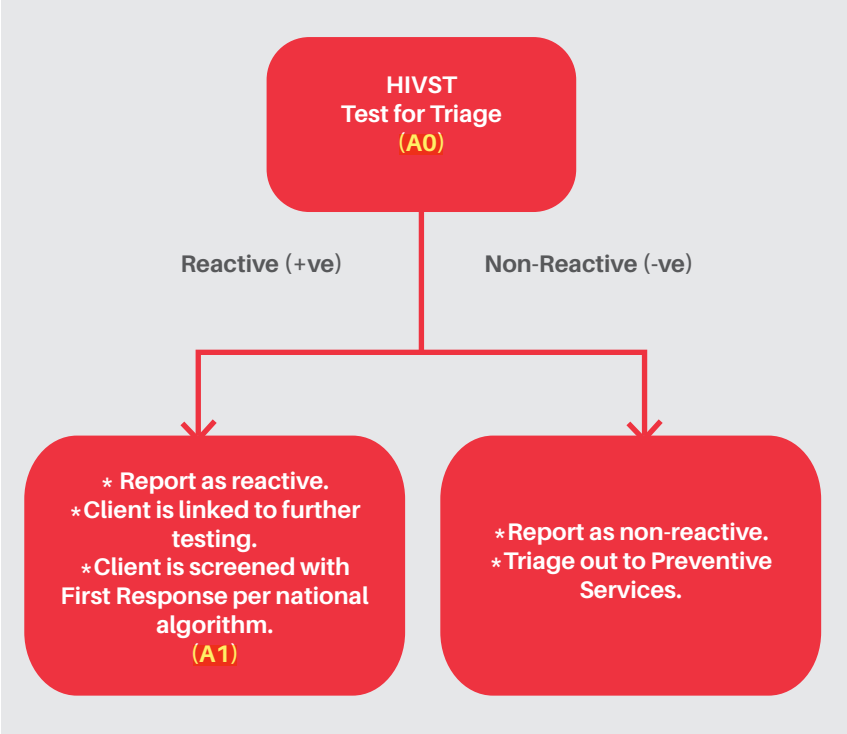
HIVST implementation and scale-up in Ghana will be in a phased approach. An HIVST Implementation Plan with timelines is included in this document, outlining steps and phases for rolling out the various aspects of HIVST (See Appendix 3). The NACP together with its partners, donors and key stakeholders will embark on a committed journey towards HIVST implementation, attaining the endpoint of scaled-up HIVST across the country. This implementation guide will serve as the roadmap to achieving that goal and should be utilized by implementing partners, donors, regulators and private sector actors seeking to engage in HIVST.

Chapter 2

2. Approaches to HIVST

HIVST is a process in which a person collects their own specimen, either oral fluid or blood, using a simple rapid HIV test and then performs the test and interprets their results, when and where they want.[9] This approach to HIV testing is versatile and convenient and removes some of the confidentiality barriers which plague traditional testing. HIVST is a test for triage. It therefore provides the advantage of reducing the number of tests in the national algorithm to be conducted prior to confirmatory tests. A reactive HIVST result is not indicative of an HIV positive diagnosis. Further tests as per the national algorithm will have to be conducted before a positive diagnosis is pronounced (see Appendix 1). A non-reactive HIVST result requires no additional testing except in the event that pre-exposure prophylaxis (PrEP) is to be initiated.

Fig 3: HIVST as test for triage



2.1 Guiding Principles for HIVST Implementation

HIVST will operate within the parameters of the national HTS framework as it is a complimentary approach to existing testing services. Guiding principles outlined for HTS and differentiated service delivery approaches will therefore apply for HIVST. The tenets of context and specific populations as stipulated for differentiated service delivery will apply. The building blocks of When, Where, Who and What will also be applied[10]. The context for HIVST speaks to the geographic focus and the different service delivery models of HIVST services. HIVST in its initial stages will be actively promoted to specific, defined populations evolving to a maturation phase where the entire population will have full access to HIVST services. HIVST will become freely available and accessible to the general population across the country.

2.1.1 Geographic focus and targeted populations

In Ghana, HIV prevalence is high in urban settings compared to rural settings although the gap is reducing. In 2019, the prevalence was 1.9% in urban areas compared to 1.7% in rural settings[11]. HIVST services will therefore be initially focused in urban and peri-urban settings, expanding to rural settings as its structures expand and scale-up is achieved. Additionally, based on sub-national data trends, geographic focus will be shifted to those districts that have high HIV prevalence. This will be contingent on continually reviewing data to prioritize areas where disease burden is highest. Ultimately, geographic focus will become irrelevant as implementation saturates the entire country.
Based on current testing trends and gaps, priority populations to be initially targeted with HIVST services will include the following:

- Partners of PLHIV
- High Risk Men
- MSM and their sexual partners
- FSW and their sexual partners
- PWID and their sexual partners
- AGYW
- ABYM
- STI clients
- HIV negative partners of HIV discordant couples
- HIV negative partners of STI and TB clients

For these populations, HIVST services will be actively promoted to enhance uptake. The long term focus will be eventually making HIVST available and accessible to general populations.

2.1.2 HIVST counselling and ethical considerations

The ultimate reason for testing is for the benefit of the individual being tested and improvement of the entire population's health outcomes. WHO's 5-C tenets which govern all forms of HTS will be applied to HIVST.

Consent: Like HTS, individuals receiving HIVST must give their informed consent to be tested and counselled. Verbal consent would be sufficient and they should be informed that it is voluntary thus they have the right to

decline. Individuals who self-test should be adequately informed that it is not mandatory, neither should they be coerced. Additionally, individuals who test positive should be informed that assisted partner notification is voluntary, and partners of HIV-positive clients should also be made aware that HIV testing is voluntary, not mandatory. The age of consent for HIV self-testing will be 16 years. Matured minors, defined as persons between the ages of 14-16 years who are sexually active, married, pregnant, or a parent, will be able to give full informed consent for HIV self-testing. HIV self-testing will not be offered to persons who fall below the age limit.

Confidentiality: HIVST would be confidential. Discussions held between the HIVST service provider and the client should not be disclosed to a third party without the express consent of the person being tested. Counsellors should always ask clients, among other things, who they wish to inform and how they would like this to be done.

Counselling: Pre-test information and post-test counselling will be provided using the directly assisted approach or the unassisted approach (described in later sections of this guide), as well as other support tools, such as brochures, links to Internet- or computer-based programmes or videos, telephone helplines, mobile phone applications or text or voice message services.

Correct test results: A single reactive self-test result does not provide an HIV-positive diagnosis. In the event of a reactive result, the individual should be entered into the national HIV testing algorithm. A confirmatory test is required to verify their diagnosis before initiation of ART. A non-reactive HIVST result does not require further confirmatory tests except for when PrEP is to be initiated.

Connection: HIVST structures will make provision for linkage to additional HIV testing within the national algorithm. This will be in either community- or facility-based testing sites where trained providers will perform additional tests to confirm a diagnosis of HIV positive. Strong linkage and follow-up structures will be established for each service delivery model to derive the maximum benefits from HIVST.

2.2 Mode of Testing and Distribution Approaches of HIVST Kits

Directly Assisted HIVST: This refers to when individuals who are self-testing for HIV receive 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 HIVST kits[12].

Unassisted HIVST: This refers to when individuals who are self-testing for HIV do not receive any in-person demonstrations from a trained provider or peer before or during HIVST, opting to either use the manufacturer-supplied instructions for use and/or other instruction materials (for example YouTube videos, instruction brochures or recorded voice prompts).

Direct Distribution: This approach refers to providing HIVST kits directly to a primary beneficiary. The HIVST kit distribution is made to the individual seeking to self-test.

Indirect (Secondary) Distribution: This refers to providing HIVST kits to individuals with the intent to deliver to a secondary beneficiary. This approach will be employed for distribution to client's sexual partners, peers and some individuals identified as part of the index testing approach.

2.3 Demand Generation

Awareness creation, sensitization and demand generation will be a key component to delivering HIVST services. Existing demand generation activities will be exploited to include HIVST as well as new channels created to maximize impact. Community engagement and advocacy efforts for HIVST will be sustained to generate demand. The Advocacy, Communication and Social Mobilisation (ACSM) plan of the NACP will serve as a backdrop for majority of the demand generation activities outlined for HIVST. The ACSM plan seeks among others to increase by 50%, safer sexual behaviour and demand for HIV prevention, care and treatment services through engagement of key stakeholders including Civil Society Organisations, the Ministry of Education/Ghana Education Service, faith-based organizations and traditional leaders[13].

Existing prevention programmes targeted at FSW, MSM and PWID include peer outreach education and the use of social media to reach hard-to-reach KP. Information Education and Communication (IEC) materials used for these outreach programmes will include HIVST to promote the service among KPs. They will be translated in local languages and tailored to the different target populations. Existing platforms, for example, Integrated Community Health Promotion Programmes (ICHPP) and condom distribution. PrEP will also be utilized to promote HIVST by using PrEP clients as referrals for secondary distribution to their networks.

In addition to printed materials, electronic media will be employed in its various forms to promote HIVST. Social media, website, radio and television advertisements will be launched to increase the reach of awareness. These media campaigns will be largely tailored towards high risk men and KPs. Local celebrities, opinion leaders, politicians and other prominent members of the general public will be engaged as champions for HIVST, promoting the service and engaging in media campaigns. Private sector companies who procure and distribute HIVST kits will have the option to partner with the NACP for advertisement. Should they opt to advertise independently, their advertisements should be in conformity with the messaging on HIVST by the NACP. The NACP will liaise with the FDA to ensure that approved and vetted advertisement on HIVST carry the same messaging and that no conflicting messaging is emanating from private procurers. An Interactive Voice Response (IVR) and text message platform will be established to promote HIVST whereby persons can dial a number and receive information on HIVST interactively in English or their local language. A helpline for HIVST will also be established to support the IVR and text platform, whereby individuals can interact directly with trained staff to receive information on HIVST.

Public-Private Partnerships (PPP) with corporate Ghanaian entities will be pursued to promote HIVST. Telecommunication, Oil and Gas companies and other industrial entities will be approached with a two-part partnership. The first will be to act as voices and champions for HIVST and the second will be to directly promote HIVST among their employees. Corporate entities will be encouraged through the PPP to provide subsidized or free HIVST kits to employees (particularly male employees) as part of a Voluntary Counselling and Testing at Work (VCT@Work) programme. The robust global VCT@Work programme established by the International Labour Organization (ILO) will be modelled for this purpose.

Clients who present to a pharmacy or licensed chemical shop to enquire or purchase condoms and family planning products will be presented with HIVST services. HIVST will also be promoted to clients who present with symptoms of STIs and HIV. At health facilities, it will be promoted to clients as a means of reaching their sexual partners via secondary distribution. HIVST will be actively promoted to priority populations who present to STI and Family Planning (FP) clinics.

Demand Generation Approaches

- Peer outreach education
- Social media campaigns
- Mass media campaigns
- HIVST Champions
- Interactive Voice Response and Text Platform
- Helpline
- Public Private Partnerships
- Promotion at pharmacy, licensed chemical shop or facility

Secondary distribution will be promoted whereby clients are offered the option of taking HIVST kits to sexual partners or members of their families. HIVST kits, through secondary distribution, will be offered to sexual partners of the following: pregnant women, PLHIV, MSM, FSW and PWID. The reach of secondary distribution will also include sexual partners of AGYW and ABYM, HIV negative partners of HIV discordant couples, and HIV negative partners of STI and TB clients. HIVST will also be integrated with the Family-Based Index Testing (FBIT) Approach, targeting through secondary distribution, family members within the age of consent who cannot be easily reached for testing. Provider Initiated Testing and Counselling (PITC) and Client Initiated Testing and Counselling (CITC) approaches will be adopted.

2.4 Technical Considerations

- HIVST does not replace initial testing for people beginning PrEP. Facility-based testing should be conducted to affirm HIV negative status before PrEP initiation. Neither does it replace scheduled facility-based visits for people already on PrEP. Clients already on PrEP should not self-test with oral-fluid based test kits as this will produce false test results.

- People living with HIV on ART should not self-test. This is because false negative test results can be generated among this population. Communication messaging should clearly include information to this group not to self-test.

- Using oral fluid-based tests might give a false impression that the virus is present in the saliva being swabbed. It is important to craft communication which explains the fact that it is HIV antibodies in oral fluids that the test detects and not the actual virus.

- Self-testing is an individual activity. Parents and caregivers should not administer self-test kits to their children or wards. In addition, self-test kits are known to not provide accurate results in children less than 18 months because they may still have their mother's antibodies.

- In Ghana, HIVST should not be promoted to pregnant women who present to ANC clinics. They should be promoted as secondary distribution to sexual partners of these pregnant women. Pregnant women should be encouraged to make their scheduled visits to the clinics. Promoting self-testing to pregnant women may inadvertently promote the notion of not requiring attendance to clinics and should be avoided.

Chapter 3

3. Service Delivery Models

Both the private and public sector will be engaged in HIVST distribution. An enabling environment will be created for private sector actors to engage in providing HIVST services. Different delivery models will be adopted for each sector while maintaining the overall goal for HIVST. A facility-based delivery model will be utilized to deliver HIVST services to clients who present to both public and private health facilities for distribution to their sexual partners at risk. On-site HIVST will not be conducted at health facilities that offer standard HIV testing.

A community-based delivery model tailored to different target populations will be adopted to promote HIVST within communities. This will be through existing community outreach programmes, faith-based outreach and workplace programmes. Workplace testing programs will serve as a key platform to reaching individuals with HIVST, particularly men. ILO's VCT@Work programs which capture both formal and informal organized labour forces will be utilized to distribute HIVST kits. KP Drop-In Centers will also serve as HIVST kits distribution points to reach key populations and their sexual partners. Outreach and other peer-led programs within the community and those conducted in faith-based settings will be utilized for HIVST kit distribution to reach high risk men, young adults and partners of PLHIV. Existing platforms such as condom distribution and PrEP programs will be utilized to distribute kits within the community.

Pharmacies and Licensed Chemical Shops will be the main channels of distribution of HIVST kits in the private sector at the initial stages. Public and Private health facilities trained under the NACP umbrella to provide HIV services will also distribute HIVST kits under the facility-based delivery model. Based on feasibility results from future pilots, the NACP and implementing partners will make provision for vending machines, if applicable, as part of on-going community outreach programmes targeting KPs and their clients in hotspots. As robust support structures become

established and mature, HIVST kits will ultimately become available to the general population via regular vending outlets such as online market places, malls and shops. See Table 1 below for a full list of initial service delivery models and target populations.

3.1 HIVST Test Kit Procurement

All HIVST kits used in Ghana must be approved and registered with the FDA. No HIVST kit will be sold on the market or distributed for free that has not been registered by the FDA. Kits pre-qualified by WHO will also be encouraged for license for use in the country. Kits should:

- Have passed the requisite quality assurance tests.
- Contain clear and appropriate instructions for use and disposal.
- Instructions for use and disposal should be in English.
- Have referral coupons that can be filled in by service providers to link self-testers to testing and treatment services.
- Have information on how to connect to a helpdesk which provides additional support to users.

3.2 Trainings and certifications

To ensure uniformity in the quality of service provided by all HIVST service providers, training and certification will be provided across both public and private sectors. Training modules, course materials and job aids will be developed by the NACP in conjunction with other training partners like the Pharmacy Council and HIVST experts.

Initial and periodic trainings on HIVST will be provided to all superintending Pharmacists. It will then be expanded in subsequent phases to Licensed Chemical Sellers. This will be incorporated into Continuous Professional Development training courses after which the requisite certificates will be provided by the appropriate professional body.

Trainings for staff of private and public health practitioners will be in a phased approach. The NACP in the first phase of training, will pull qualified staff from health facilities that have the highest volume of clients accessing the various channels of distribution outlined for HIVST. Staff trained to offer HTS services per the Ghana Health Service Task Sharing Policy will be trained to offer HIVST services alongside the traditional testing services

at the facilities. These will include nurses, midwives, Community Health Officers (CHO's), Community Health Nurses (CHN's), enrolled nurses, technical officers and lay counsellors (volunteers). At completion of all training phases, HIVST services training would have been conducted for qualified staff in all facilities.

Staff identified to deliver HTS services in the community include CHO's, CHN, enrolled nurses and lay counsellors (volunteers). These will be trained to deliver HIVST services in the community. Again, this will be in a phased approach, prioritizing personnel who provide services to KPs and other populations targeted for HIVST in targeted geographic areas in the initial phases and expanding with other phases. Training will also be provided to personnel who offer HIVST support services using support tools like helplines and online service platforms and also personnel who conduct community mobilization and sensitization activities.

Refresher trainings on HIVST services will be provided periodically to trained staff. This will take the form of in-person trainings and online courses that generate certificates and/or professional development points once the course has been successfully completed.

Table 1: HIVST as test for triage

Service Delivery Model	Where	Who	When	Linkage to other programs
*Facility-Based	Health facility settings (both public and private facilities)	• KP and sexual partners: FSW, MSM, PWID. • High risk individuals accessing FP and STI services. • Partners of PLHIV including partners of positive ANC clients. • HIV negative partners of HIV discordant couples. • HIV negative partners of STI and TB clients. • Young people (AGYW and ABYM within age of consent and their sexual partners).	• KP-friendly services • PITC • CITC • Partner referrals • STI services • Family Planning services • ANC services	• Syphilis testing • PrEP • PEP

Service Delivery Model	Where	Who	When	Linkage to other programs
Community-Based	Community Outreach settings	• KP and sexual partners: FSW, MSM, PWID. • High Risk Men. • Young people (AGYW and ABYM within age of consent and their sexual partners). • Partners of PLHIV.	• KP outreach • KP Drop-In Centers • AGYW and ABYM outreach • Peer-led programs • Male hotspot areas (e.g. trotro and taxi stations, bars)	• AGYW /ABYM package of interventions. • KP package of interventions.
	Workplace settings	• High Risk Men. • Employees and members of organized labour organizations (focus on males and spouses of female employees through secondary distribution). • Young adults	• VCT@Work programs	
	Faith-based settings	• High Risk Men • Young people (AGYW and ABYM within age of consent and their sexual partners).	• Church and Mosque Outreach programs	

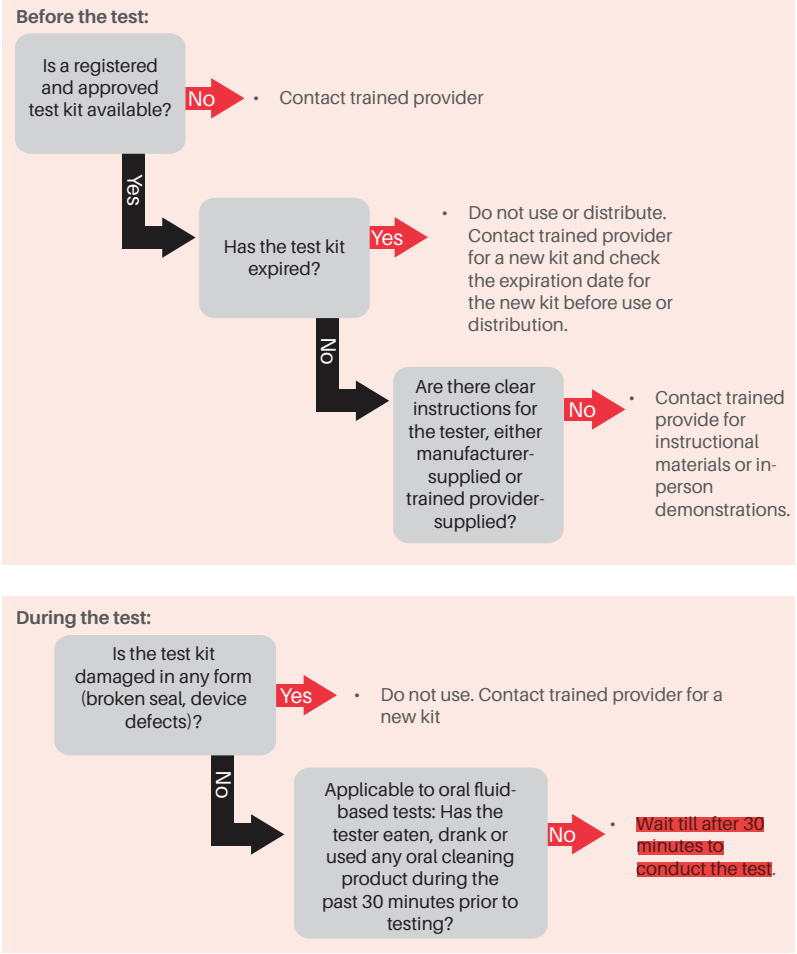
Service Delivery Model	Where	Who	When	Linkage to other programs
Community-Based	Pharmacies, Licensed Chemical Shops, Vending Machines	• High Risk Men • KP and sexual partners: FSW, MSM, PWID. • Individuals accessing HIV prevention services (e.g. purchasing a condom), FP, STI services. • Individuals presenting with symptoms of HIV or STI's. • Young people (AGYW and ABYM within age of consent and their sexual partners).	• Over the Counter services	• HIV Prevention Package

⁎ *On-site HIVST will not be conducted at health facilities that offer standard HIV testing.*

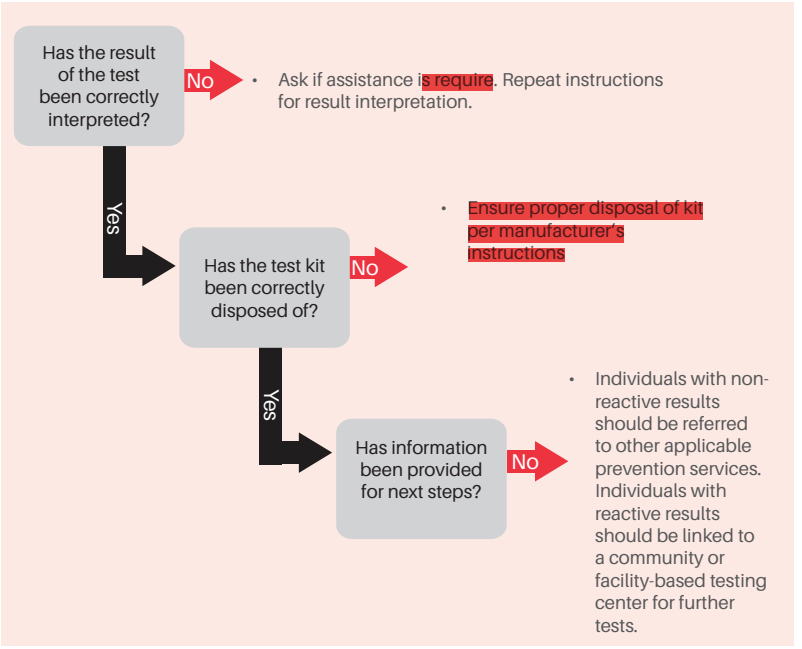
3.3 HIV Self-Testing Checklist

Whether the test is performed in the comfort of an individual's private space or at a designated place in the community, ensuring the instructions are clear and processes are followed, are key to a successful self-testing. A simple checklist to follow before, during and after the test has been performed, should be available for both the individual and trained staff.

Fig 3: HIVST as test for triage



After the test:



3.4 Considerations for on-site self-testing services

Private sector providers may offer on-site self-testing services. Beyond the distribution of an HIVST kit, this will involve the provision of a secure, private space for individuals to safely conduct their self-test on the shop or pharmacy premises. This could be a private cubicle, room, enclosed tent or space with optimum ventilation, lighting and adequate work surface to place the self-test kit and its accessories. There should be provision to safely and securely dispose of the self-test kit after it has been used. Health facilities can also provide on-site self-testing services to primary recipients of HIVST kits. This will however be in the absence of standard HIV testing services. Health facilities that provide standard HIV testing services should not offer on-site HIVST.

Once verbal consent has been granted by a client for HIVST, a trained staff should explain the instructions for administering the test and interpreting the results through an in-person demonstration or through a demonstration video. HIVST demonstrations should not be conducted by untrained personnel. Trained staff should be present to answer clients' questions after an in-person or video demonstration. The checklist for test administration as earlier described should be followed. The pre-test information should be provided in a private and confidential setting. Service providers with a designated self-testing space as described above, can offer on-site self-testing. Service providers without such designation should not provide on-site testing at the medicine counter or any open, unsecured space on their premises. Those clients should be encouraged to take the tests in the comfort of their own secured space.

After the test has been successfully conducted, results should be read and interpreted correctly. The test kit should then be safely and securely disposed of per the manufacturer's instructions.

What to do when the results are positive (reactive): trained staff should explain to client that a reactive result does is not equal to a positive diagnosis for HIV. Client should be informed clearly of the need to conduct further tests including a confirmatory test as per the national testing algorithm. Client should be referred to community- or facility-based testing centers where further tests can be conducted. Client should be counselled on the importance of HIV preventive measures.

What to do when the results are negative (non-reactive): trained staff should counsel client on the importance of HIV preventive measures (e.g. condom use, STI treatment, PrEP) and good health seeking behavior. High risk clients should be encouraged to re-test at a frequency as per the national guidelines. Clients can also be referred to HIV preventive services within the community or facility.

What to do when the results read an error: trained staff should explain to client that another test should be conducted with a different self-test kit, following the checklist and instructions as provided.

Fig 4: Actions to take after test results are disclosed

- Refer to community- or facility-based testing centers for further testing.

- Link to HIV Prevention Services (e.g. condom use, STI treatment, PrEP).
- Re-test per the national guidelines.

- Conduct HIVST with a different self-test kit, following the checklist and instructions as demonstrated

3.5 Support Tools

HIVST support tools will be developed to support pre-test information sessions, follow-up and linkage to testing and treatment services. Tools to support pre-test sessions will include printed job aids to guide trained staff when conducting in-person demonstrations to an HIV self-tester. Also, demonstration videos in different local languages describing instructions for administering the self-test will be developed. This will be in the appropriate format for viewing on a smart phone or tablet and playback on a television screen.

Technology such as Helplines, Social Media and Interactive Voice Response (IVR) and Messaging platforms will be used to follow-up on self-testers and link them to confirmatory testing, care and treatment. Existing helpline platforms will be expanded to include trained caller staff to respond to queries on HIVST and also link clients to facility-based testing centers for further tests. An Opt-In Follow-Up platforms will be established for both facility- and community-based models. These platforms will be either WhatsApp or traditional call and text platforms that trained staff will use to follow-up on self-testers when they opt to provide their telephone numbers at the time of kit distribution. For secondary referrals, primary contacts will be used to initially reach secondary recipients followed up from that point. The IVR and Messaging platform established for demand generation will

also serve as a support tool for linkage to care and treatment. By dialing a number or texting a short code, a self-tester will be introduced to a series of voice prompts and pre-recorded voice messages in their preferred local language which will provide an array of information including pre-test instructions, information on facility-based testing sites and available community support systems like peer networks. These information will also be packaged as text to cater for non-smart phone consumption.

Social Media and websites have been known to be good channels for reaching men and young adults. Social Media presence on Facebook, Instagram, Twitter, TikTok, etc. established for demand generation will provide information on pre-test, testing and post-test processes as well as links for connecting to care and treatment. Content for these platforms will be carefully crafted to suit the different target populations.

In the final phases of scaling-up HIVST, a bespoke HIVST Application will be developed which will host trackers to monitor HIVST distribution, follow-up and linkage to care and treatment. It will be linked to the HIV supply chain system as well as the monitoring and evaluation structures. This App will be deployed nationwide and will provide near real-time information on HIVST at community, district, regional and national levels.

3.6 Linkage to testing and treatment services

To derive the maximum benefits from HIVST, a robust follow-up with confirmatory test and linkage to care and treatment strategy should be in place. Different pathways of linkage will be adopted for different service delivery models. Different support tools as described above will be employed to link clients to further tests, care and treatment.

Linkage for facility-based testing: Individuals who receive HIVST services at health facilities where standard HIV testing is not available will be followed up via existing channels of following up persons in the community as well as exploring new and innovative means. The same will apply to clients who receive the test kits through secondary distribution to clients who visit health facilities. This will include Opt-In Follow-Up calls, whereby a self-tester who voluntarily provides their telephone number will be called by community health workers and linked to confirmatory test, care and treatment or other preventive services. At the point of distribution, trained staff will encourage self-testers to disclose their results to their healthcare workers, explaining follow-on actions after the test is completed. Case

managers, peer educators, Mentor Mothers, Models of Hope, Community Adolescent Treatment Supporters (CATS) and other peer-led network mobilizers assigned to KP and other vulnerable groups at the facility will make in-person follow-ups and escorted referrals where applicable to link self-testers to confirmatory testing, care and treatment. Support tools as described above (e.g. helpline, WhatsApp, Text platforms) will also be employed to assist with linkage.

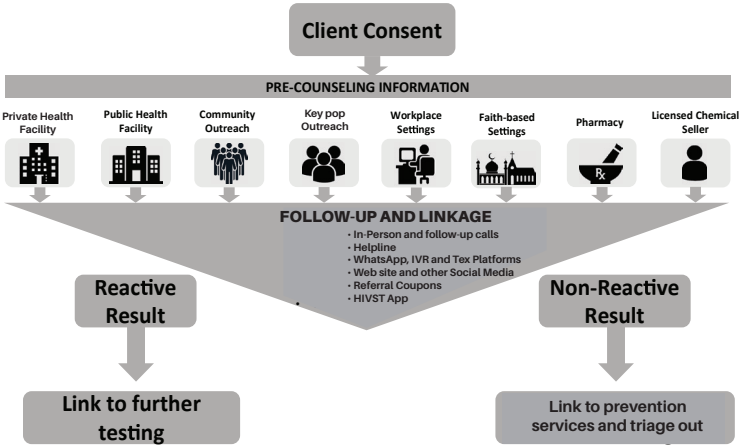
Linkage in the community: Peer-led referrals and a referral coupon system will be employed to link individuals whose results are reactive with a self-test to testing sites for further testing. The cadre of community health outreach personnel including lay volunteers and peer-led network mobilizers will provide Opt-In Follow-Up services to clients. In addition, they will provide referral coupons to clients who receive self-test kits. These coupons will contain information on testing centers in the catchment area and contact information for further assistance. Clients will be encouraged to present these referral coupons at testing facilities to access further testing or prevention services.

Linkage at Pharmacies and Licensed Chemical Shops: A referral coupon system will be adopted for all pharmacies and Licensed Chemical Shops. Similar to that for community linkage, a trained service provider will provide a client with a referral coupon together with the self-test kit. Information on the referral coupon will include the name of the shop or Licensed Chemical Seller, information on the nearest testing facilities within the catchment area of the shop and contacts for community-based testing support if applicable.

Pharmacies and licensed chemical shops will be required to have on hand a list of all HIV testing centers within their catchment area and be knowledgeable on community testing support programmes operating in that area. This information will be accessible to them via a website and other Social Media platforms which will be facilitated by the NACP and its affiliates. Connecting community outreach testing programmes with Pharmacies and Licensed Chemical Shops, will provide the self-tester options to either go directly to a facility to access follow-on testing services or be connected to a peer educator, navigator or Community Health Worker (CHW) to support them to go through that process at the facility.

Linkage at workplaces: trained staff will be designated to each workplace program acting as a focal point person and assisting clients to navigate pre- and post-test processes. For example, a trained CHW will be assigned to a "trotro" station as part of a testing outreach programme targeting commercial vehicle drivers at that station. The CHW becomes the focal point person utilizing Opt-In Follow-Up or other support tools at their disposal (e.g. helpline or IVR) to link 'trotro' drivers (Commercial minibus drivers) to care and treatment at testing facilities within that catchment area.

Fig 5: Actions to take after test results are disclosed



3.7 Considerations for Key Populations

One of the main target groups for HIVST are KPs, hence a tailored approach will be adopted to reach them with HIVST services to ensure maximum impact. Community engagement for KPs will be conducted through community mobilizers and peer educators. Drop-In-Centers, community gatekeepers, one-on-one interactions and social events will be utilized to promote HIVST. In addition, social media platforms like Grindr, Facebook and Hornet will be engaged to reach MSM.

Trained Staff: Peer educators and case managers proven to be effective in their outreach will be trained as lay counsellors to provide HIVST services in the communities they serve. This will be essential in providing a cadre of trusted and familiar trained staff to cater for KPs within their communities.

Distribution Options: The primary distribution channel will be through trained peer educators who can offer directly assisted HIVST at KPs preferred location and time. KPs will also have the option within their communities to discretely pick-up self-test kits at approved vantage pick-up points or have the kits delivered to them where applicable. Eligibility for pick-up will be determined via a short questionnaire administered at the point of promotion of HIVST service (e.g. online, physically or helpline). This will provide a tailored approach to target hard to reach KPs who are averse to traditional approaches. KPs who are already comfortable accessing standard HIV prevention services at Drop-In Centers, social events and health facilities need not be targeted with this approach. In addition, HIVST kits vending machines will be placed at key hotspot areas to dispense self-test kits. These options for distribution will be made available together with other service delivery options described in this document. FSW and MSM networks will be actively employed to promote secondary distribution to high risk men.

Linkage for Key Populations: Privacy and confidentiality are key to successfully reaching KP with interventions. The privacy and confidentiality provided with HIVST services will be maintained when linking KP to testing and treatment services. KP will be encouraged to disclose their test results to case managers and peer educators to be linked to care. Importantly, they will also be provided the option to link directly with KP-friendly health workers within facilities should they not wish to disclose their results to their peers. A directory of KP-friendly health workers and facilities, M-Friend nurses and Community Champions will be provided to trained staff and community mobilizers to notify clients of contacts they can connect with post-test. This information will also be available through the support tools (e.g. online, texting a short code or via the helpline).

Effective HIVST among KP

- Adopt a Unique Identifier Code system to track clients who access HIVST services whiles maintaining their anonymity.
- Collect data and ensure follow-up and linkage on clients reached via secondary distribution.

Data Reporting: tracking and monitoring HIVST implementation among KP will require collecting accurate data whiles protecting the identity of KP. In ensuring anonymity, the Ghana Key Populations Unique Identification System (GKPUIS) will be used to generate unique identifier codes to track KP clients who access HIVST services. Existing electronic and paper-based tools used for other HIV KP interventions will be modified to include HIVST where applicable to reduce data-entry burden on staff. Refer to Chapter 4 for data elements to be monitored.

3.8 Quality Assurance: Post-Market Surveillance, Pharmacovigilance, Accreditations

Continuous monitoring of HIVST kits will be conducted to ensure that their quality after they come on the market is maintained. Post market surveillance of HIVST kits will be conducted in both a reactive and proactive manner. With the reactive approach, Ghana's Pharmacovigilance systems coordinated by the FDA, will be employed to investigate complaints. Additionally, WHO's system for complaint reporting of In Vitro Diagnostics (IVD) will be utilized. Field safety corrective actions will then be made after conclusion of investigations and a field safety notice issued. WHO's field safety notices will also be checked regularly for updates.

The proactive approach will involve Lot Verification testing. As part of their mandate, the FDA will conduct Lot Verification testing on HIVST kits imported into the country to ensure they meet approved standards. This will be in two parts; first at the importation stage and also during post market surveillance.

Ensuring the quality of HIVST services provided across the country is as important as ensuring the quality of the test kits being distributed. Supervision, monitoring and mentorship will be conducted in both the private and public sector to ensure standards of services are maintained. Existing platforms for supervision and mentorship will be employed to check quality of HIVST service in the public sector. Periodic surveys will be conducted using Social Media platforms to ascertain whether quality of services in the private sector is sustained. This will be in the form of short user satisfaction surveys posted on various social media platforms utilized for HIVST demand generation and support services.

Accreditation governing HIVST services will be in the form of certificates issues during training and refresher training sessions discussed under Trainings and Certifications.

3.9 Social Harm

Social harm associated with HIVST is largely infrequent[14]. Large-scale trials and actual HIVST implementation have so far not reported any suicide or self-inflicted damage following HIVST[15]. It is prudent however, to establish a system to be able to report any social harm. Support tools described for strengthening linkage to care will be used to report social harm. Self-testers will be encouraged to report any social harm to CHWs or support tool channels through phone, text, the helpline or the social media platforms. Any social harm reported will be thoroughly investigated, documented and any necessary follow-on measures effected.

Chapter 4

4. Monitoring and Evaluation

It is important to track and measure HIVST activities to determine its contribution and impact towards HTS and national HIV goals. Information on HIVST will be used for course correction of implementation, for decision making at all levels of implementation and for accountability to stakeholders and donors. To streamline monitoring and evaluation of HIVST will require integration into existing tools and reporting systems. Key aspects to be monitored will include uptake of HIVST, reported test results and linkage to care and treatment. In addition to this, questions on HIVST will be included in future national surveys such as the Demographic and Health Survey (DHS) and Integrated Bio-Behavioural Surveillance (IBBS) to estimate achievements at the outcome level.

4.1 Integration of HIVST data elements into national reporting systems

To sustain continuous analysis and interpretation of HIVST data requires integration into national reporting systems. Disaggregated data reported through tools described below will be fed into DHIMS2 and reported and analyzed along with other HIV data on a regular basis. At the national level, the number of self-test kits distributed will be reported using supplier distribution data from the private sector and programme data. Additional indicators as outlined in the table below will be reported using programmatic data and operational research to inform implementation decision-making and course correction.

Indicator	Disaggregation	Data Source	Frequency of Reporting
Number of self-test kits distributed.	Target population, Distribution Channel, Age, Sex	HTC and Community registries	Monthly
Number of reactive test results returned.	Target population, Age, Sex	HTC and Community registries	Monthly
Number of confirmatory test results per the National algorithm.	Target population, Age, Sex	HTC Monthly Summary Sheet	Monthly
Number of tests distributed through secondary distribution.	Target population, Age	HTC and Community registries	Monthly
Percentage of new ART initiations among people diagnosed with HIV who report self-testing in the past 12 months.	Target population, Distribution Channel, Age, Sex	At point of ART registry	As part of operational research and can be conducted once every 2 years.
Number of social harm cases (adverse events) recorded.	Target population, Age, Sex	Social harm reporting form	Quarterly

Other programmatic indicators that can be monitored include:

- Number of sites distributing HIVST kits.
- Percentage of PrEP initiations among people who report prior self-testing in the past 12 months.

4.2 HIVST tools

As a rule of thumb, one should only collect data one will use. Data painstakingly collected, should be continuously analyzed into useful information that will inform HIVST implementation and decision-making. Tools for capturing programmatic data will be harmonized across all implementing partners to facilitate reporting and aggregation. The following tools will be used to capture data on HIVST:

- **Community HIVST registry:** this will capture the following minimum information: CHW name or id, details of client who received the HIVST kit (if a primary recipient) and characteristics of secondary recipients including phone numbers if they opt to. It will also capture reported results after follow-up and subsequent actions taken. This tool will be utilized by implementers of HIVST within the community, including health facilities where standard HIV testing is not offered.
- **Facility HIVST registry:** this will not be a new tool to be created. The existing HIV Testing and Counselling (HTC) registry will be modified with an additional column after "type of client" to capture information on clients who present for further testing after the initial self-testing. This column will be titled "Self-Testing (Reactive/Non-Reactive)". By integrating this single column in the existing registry, all relevant information on self-testing will be captured alongside the standard testing information. See Appendix 2 for HTC registry.
- **HTC Monthly Summary Sheet:** An additional summary table will be added to this existing form. This will be a Self-Testing table with elements summarized from the HTC registry. Summary will include test results (whether reactive or non-reactive) parsed by: age groups, population type (e.g. MSM, FSW, or AGYW) and linkage to care and treatment. See Appendix 2 for HTC Monthly Summary Sheet.
- **Referral Coupons:** The referral coupon will capture at a minimum, the name of the pharmacy or licensed chemical shop making the referral and the date the test kit was distributed. For community

referrals, it will contain the name of the referring community health worker and will be used in conjunction with the Community HIVST registry. Clients will be encouraged to present this to testing sites they visit for further testing.

- **Social Harm reporting form:** this will capture at a minimum, details of the reporting client, where and when HIVST kit was received, nature of social harm and remedial actions taken.

4.3 Reporting and feedback loop mechanisms

Reporting and feedback for HIVST at all levels will be patterned on existing structures for HTS. The current reporting mechanisms are from the facility level to the sub-district level, going up to the district, region and national level. The feedback loop is the same but cascading in the opposite direction. Facility level reporting will be on a monthly basis alongside other forms of reporting to ensure seamless integration of HIVST data with other data generated from the facility.

Technical considerations:

- **Test de-duplication:** reactive self-test results require further testing hence it is important in estimating number of tests that these are de-duplicated when calculating total number of people tested and diagnosed with HIV.
- **Late reads:** Readings recorded after the manufacturer read window has lapsed will not be used to estimate HIV positivity. Evidence suggests this may overestimate HIV positivity[16].
- **Data Quality:** data quality audits will be conducted regularly to check completeness and consistency. Included in the HIVST training will be sessions on data quality.

Chapter 5

5. Sustainable Supply Chain

The supply chain for HIVST commodities in the private sector will be handled solely by private actors with the NACP and FDA providing oversight for compliance and quality assurance purposes. Procurement, distribution and management for the public sector will be handled through existing supply chain management processes for other HIV commodities.

5.1 Integration of HIVST kits in supply chain management

Quantification: Forecasting and supply planning for HIVST kits will be conducted through the national quantification process currently used for other HIV commodities including test kits and scaling down to the regional level in the future as appropriate. Quantification will take into consideration consumption data from the private sector as described below in section 5.2.

Commodity Storage: HIVST kits procured will be received and stored at a central level pharmagrade warehouse. Regional Medical Stores will store kits distributed to the regions for onward distribution to facilities. Private sector procurers will be required to store HIVST kits in warehouses of their choice but which meet FDA standards.

Distribution and Inventory Management: In the public sector, HIVST kits will be distributed as per existing Standard operating procedures. The maximum and minimum inventory levels for the supply chain (Central, Regional and facility levels) will be adapted for the HIVST kits. Distribution from the central to the regional level will be as per the national distribution

schedule. Distribution from the regional to the facility level will be as per Last Mile Distribution schedules in each region. Private sector procurers will adopt distribution and inventory management measures that are suited to the sector but which do not violate FDA standards.

Product Quality Assurance: The FDA will exercise authority over ensuring product quality is maintained. They will sample HIVST kits from both public and private sector and conduct quality control monitoring procedures to ensure quality assurance. FDA will also conduct checks on storage conditions at all distribution levels in both public and private sectors to ensure compliance to standards.

Data Reporting: A manual system is currently in use for reporting stock availability and commodity usage from the service delivery point. This system will be adopted for HIVST kits. The Ghana Integrated Logistics Management Information System (GhiLMIS) is currently being rolled out and will be the source for all logistics data reporting including HIVST kits. Data reporting will be transitioned to the GhiLMIS on an incremental basis until full operating capability is reached. Migration to an electronic platform will allow for integration with other electronic systems to be developed for HIVST as described in section 3.5.

Planning Ahead for Supply Chain Management

- Modification of existing tools to reflect HIVST kits.
- Training of supply chain staff at all levels.
- Continuous supportive supervision to maintain and improve quality performance.
- Future considerations for quantification to district levels.

5.2 Data Triangulation

The referral coupons distributed by pharmacies and licensed chemical shops will be essential in tracking distribution information in the private sector. When a client arrives at a testing facility, data captured on the referral coupons will be collated for each catchment area and aggregated up to the national level. This will provide some proxy information on estimated number of test kits distributed and returned through private sector channels. Triangulating this data with supplier distribution data will provide visibility on trends in the private sector.

Chapter 6

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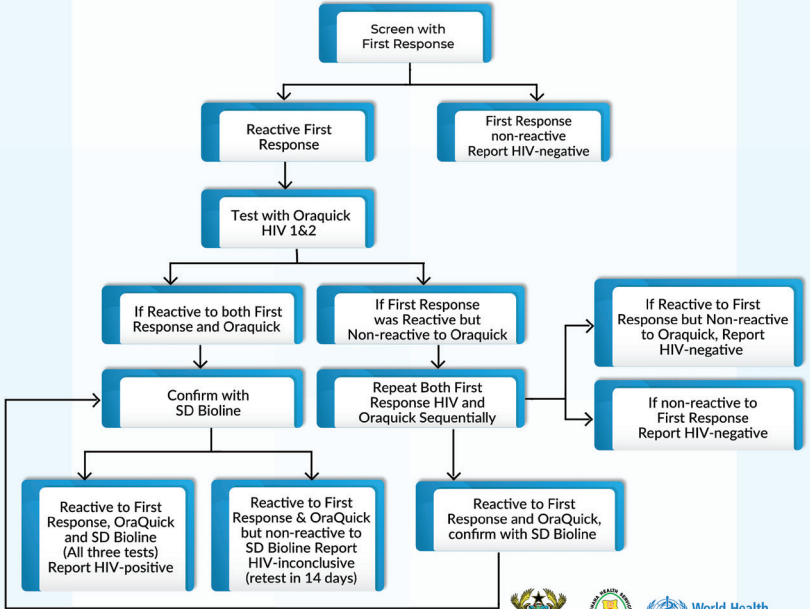
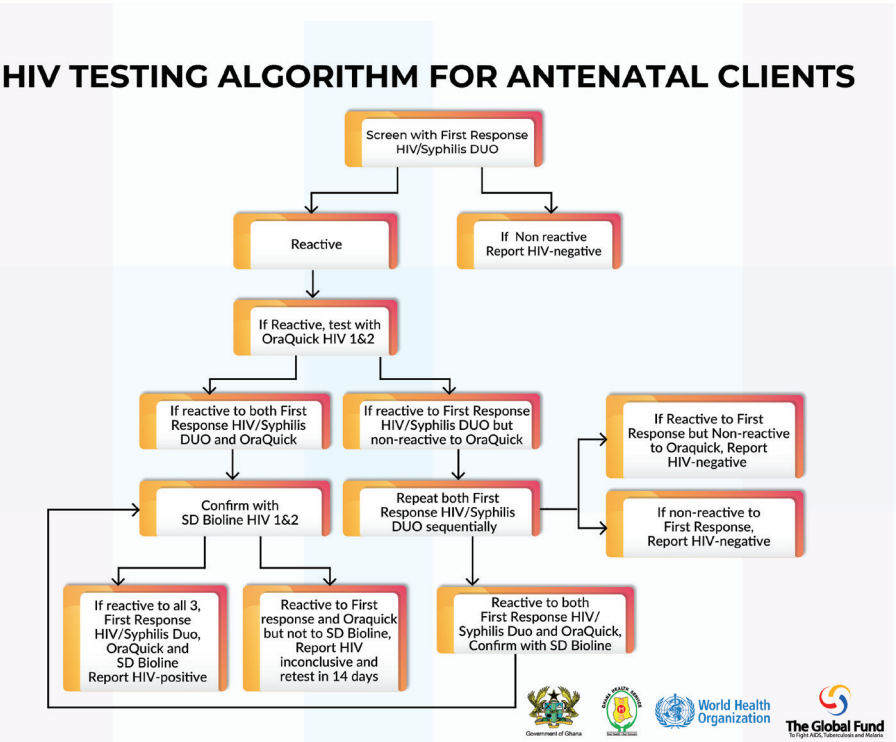
HIV TESTING ALGORITHM FOR NON-PREGNANT WOMEN AND GENERAL POPULATION




HIV TESTING ALGORITHM FOR ANTENATAL CLIENTS
Screen with First Response HIV/Syphilis DUO
Reactive
If Non reactive Report HIV-negative
If Reactive, test with OraQuick HIV 1&2
If reactive to both First Response HIV/Syphilis DUO and OraQuick
If reactive to First Response HIV/Syphilis DUO but non-reactive to OraQuick
If Reactive to First Response but Non-reactive to Oraquick, Report HIV-negative
Confirm with SD Bioline HIV 1&2
Repeat both First Response HIV/Syphilis DUO sequentially
If non-reactive to First Response, Report HIV-negative
If reactive to all 3, First Response HIV/Syphilis Duo, OraQuick and SD Bioline Report HIV-positive
Reactive to First response and Oraquick but not to SD Bioline, Report HIV inconclusive and retest in 14 days
Reactive to both First Response HIV/ Syphilis Duo and OraQuick, Confirm with SD Bioline
Government of Ghana
World Health Organization
The Global Fund
To Fight AIDS, Tuberculosis and Malaria

HIV TESTING AND COUNSELLING (HTC)										HIV TES
NO.	DATE	NAME	TRACEABLE ADDRESS AND TELEPONE NUMBERS	AGE	SEX (M/F)	PRE-TEST INFOR. YES/NO	TESTING POINT OPD / IPD/ CWC/ FP/ OTHERS	TYPE OF CLIENT PIC, CIC, STI, HR, MSM, FSW, Prisoners, PWID, TB, DT, Others (check	FIRST RESPONSE RI, RII, RI & II, Non reactive	ORAQUICK Reactive / Non reactive
		TYPE OF CLIENT								
		1. PARTNER OF AN INDEX CLIENT (PIC)	INDEX TESTING							
		2. CHILD OF AN INDEX CLIENT (CIC)								
		3. STI CLIENT (STI)								
		4. HIGH RISK (HR)	Men in Uniform, Long Distance drivers							
		5. MSM	KP							
		6. FSW								
		7. Prisoners								
		8. PWID								
		9. TB PATIENTS (TB)								
		10. DIAGNOSTIC TESTING (DT)								
		11. OTHER POPULATION (OTHERS)								

STING							
SD BIOLINE	FINAL TEST RESULT	POST TEST C.	PREVIOUSLY TESTED POSITIVE	LINKED TO HIV CARE		COMMENTS	SERVICE PROVIDER
HIV I, HIV II, HIV I&II, Non Reactive	(Positive/Negative)	(Yes/No)	(Yes/No)	(Yes/No)	If Yes, Folder Number	Further Actions/ Clarification	Full Name

NATIONAL AIDS / STI CONTROL PROGRAMME HIV TESTING AND COUNSELLING (HTC) MONTHLY RETURNS FORM

Facility	Subdistrict			District			Region		Region			Year	
							AGE GROUP						
		0-4	5-9	10-14	15-19	20-24	25-29	30-34	35-39	40-44	45-49	50+	Total
# Tested for HIV	Male												
	Female												
# Tested HIV Positive	Male												
	Female												
# Previously tested positive	Male												
	Female												
# Newly Tested Positive	Male												
	Female												
# Linked into HIV Care	Male												
	Female												

Indicators		POPULATIONS											
		INDEX TESTING		STI	High Risk	KP				TB	Diag-nostic Testing	Other Pop	Total
		Partner of Index Clients	Children of Index Clients			MSM	FSW	Prison-ers	PWD				
# Tested for HIV	Male												
	Female												
# Tested HIV Positive	Male												
	Female												
# Previously tested positive	Male												
	Female												
# Newly Tested Positive	Male												
	Female												
# Linked into HIV Care	Male												
	Female												

Indicators		ENTRY POINTS					
		OPD	IPD	CWC	FP	Others	Total
# Tested for HIV	Male						
	Female						
# Tested HIV Positive	Male						
	Female						
# Previously tested positive	Male						
	Female						
# Newly Tested Positive	Male						
	Female						
# Linked into HIV Care	Male						
	Female						

Form Completed by .....

Name:..... Designation: .....

Signature: ..... Phone number: .....

Appendix 3: HIVST Implementation Plan

No	Activity	Yr 1-1st Half	Yr 1-2nd Half	Year 2	Year 3	Year 4	Year 5	Be-yond Year 5
1. Development of HIVST strategies and SOPs								
1.1	Develop a budget based on implementation plan							
1.2	Develop a Public-Private Partnership Strategy Document							
1.3	Develop an advocacy strategy and associated materials to engage faith-based organizations							
1.4	Develop Standard Operating Procedures for HIVST models of implementation							
2. HIVST M&E								
2.1	Identify HIVST data elements to be included in national reporting through stakeholder engagement							
2.2	Integrate HIVST data elements into national reporting systems							
2.3	Develop HIVST tools for tracking and monitoring (both print and electronic)							
2.4	Conduct trainings, orientation and capacity building for usage of data elements and tools							
3. Demand Generation and Communication								
3.1	Develop a Communication Strategy for HIVST including HIVST Champions							
3.2	Develop communication materials (print and electronic) in local language: brochures, short videos, text messages, radio and tv advertisements							
3.3	Conduct Advertisement on different media platforms							
3.4	Conduct orientation and training of cadre of community workers for community-led demand generation							
3.5	Community-led demand generation activities, monitoring and supportive supervision							
4. Kit Distribution								
4.1	Develop instructions and instructional guides for HIVST administration and proper disposal (print and electronic)							
4.2	Develop training curricula							
4.3	Conduct orientation and training on HIVST implementation in phased approach to all relevant cadre of workers in both public and private sector							
4.4	Design and deploy support tool platforms: WhatsApp, SMS messages, IVR, Helpline, HIVST Mobile Phone App							
4.5	Develop 2 directories: testing facilities and KP-friendly health workers							

4.6	Monitor implementation of the different models of HIVST implementation							
4.7	Conduct evaluations and operational research on the different HIVST distribution models and test new models							
5.	**Supply Chain Management**							
5.1	Revise and conduct quantification exercises to include HIVST commodities							
5.2	Revise SOPs to include management of HIVST commodities in supply chain							
5.3	Revise supply management forms to include HIVST commodities							
5.4	Conduct orientation and training to relevant staff on HIVST supply chain							
5.5	Integrate HIVST kits in GILMIS							

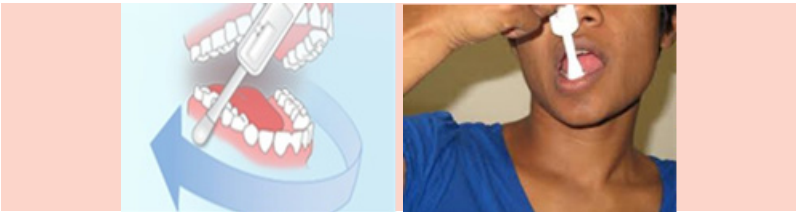
Appendix 4: Information on use of OraQuick

The best conditions for the administration of an HIV self-test are:

- It can be done at any time of the day
- In order to facilitate its reading and performance, appropriate light is recommended
- The HIV self-test is a screening test, and the manufacturer's instructions most be followed
- The HIV self-test must be conducted voluntarily and autono mously with no coercion
- It is important to remember that no one should be forced to per form an HIV self-test. Any medical test requires the voluntary and informed consent of the individual to be tested
- Before performing an HIV self-test, it is important to think about what to do once the result is available; whether reactive or non-reactive
- Carrying out an HIV self-test is indeed different from a consultation with a health care professional who can advise on the test, provide professional psychological support and facilitate access to other biological tests for diagnostic confirmation
- The user can ask for advice

HIVST procedures with ORAQUICK® HIV

- The supervisor must ensure before the test that the subject hasn't taken anything (food, drinks, etc.) during the previous 15 minutes.
- Ask the subject to wait 30 minutes before the test if he/she has used oral hygiene products such as a toothbrush/toothpaste
- Remove the Oraquick HIV-1/2 test from the sachet
- Don't touch the spatula or the flat pad
- Pass once on the lower and upper gums to collect the oral fluid
- Don't pass over the palate, cheeks or tongue



Antibodies to HIV from the oral fluid are collected through the swab
Once the device is inserted into the test tube, the oral liquid mixes with the liquid and goes through the test stick
If the line C becomes dark, it confirms that the test is correctly operating
If no C line has appeared, the test is not operating
The results must be read after twenty minutes and before forty minutes (e.g. between 20-40 minutes)
If only line C appears, the test is non-reactive
If a line appears on T, the test is reactive

How can we be sure that the test performance is correct and that the result is accurate?

It is important that the kit is stored (temperature between 2 and

27 degrees Celsius) and conducted based on the manufacturer's instructions.

During the administration of the test, a colored "control" band (or dot) should appear. If not, it means that the test was incorrectly performed or that it was not operational. It is therefore uninterpretable or invalid. If a kit is invalid, another HIV self-test or another HIV screening test should be performed with a new kit.

→ If only line C appears, the test is non-reactive.

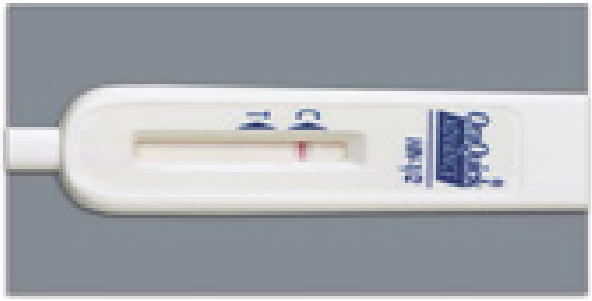
→ If a line appears on T, the test is reactive.

The results should be read after twenty minutes and before forty minutes. The result is unreliable if read outside of the reading window (20-40 minutes).

Reading and interpretation of the results
Reactive Result:
A line appears next to the triangle labeled "C" and another appears next to the triangle labeled "T". The intensity of the lines may vary. Note that the test is reactive if a line appears next to the triangle "T" and next to the triangle "C", even if this line is of weak intensity.

A reactive self-test result means that anti-HIV-1 and / or HIV-2 antibodies were detected in the sample. The test result is interpreted as REACTIVE for HIV-1 and / or HIV-2 Antibodies and should be confirmed by blood tests.

Non-reactive result:
A line appears next to the triangle labeled "C" and any line appears next to the triangle labeled "T".



A non-reactive self-test result means that anti-HIV-1 and anti-HIV-2 antibodies were not detected in the sample.

The screening test result is interpreted as UNREACTIVE for anti-HIV-1 and HIV-2 antibodies. The beneficiary should redo the test in one month if there has been a recent behavioral risk.

Minimum information package on HIVST
Counselors or agents providing HIVST kits should be able to provide all the necessary information on the use of the kits.

The information on HIVST to provide to clients will cover:

- General instructions for using the test kit
- How to handle and store test kits before starting the test
- How to interpret the test results
- What to do after reading the results, including information about available post-test services, such as counseling, additional tests, available counseling/emotional/social support, care and treatment, and PrEP if unreactive
- How to safely dispose of used test kits
- Ethical and legal obligations, such that no one should test a third party without his/her consent.

Providers and users should be informed that HIVST is not recommended for people who are already HIV positive and/or taking ARV drugs as part of HIV treatment or as part of PrEP because quick HIV tests (including HIVST) may give false negative results.

Peer assisted support is highly recommended for HIVST. This support may include a demonstration on how to use the test kit, pre-test counseling, administration of the test, interpretation of the results, post-test information, and referrals/accompaniment to additional services. Tools should be provided as part of this support

Notes

Notes

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