

HIV SELF TESTING

Standard Operating Procedures
For the Delivery of HIV Self-testing
Services in Georgia

GEORGIA DEPARTMENT OF PUBLIC HEALTH
Office of HIV/AIDS

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ACRONYMS

ARV - Antiretroviral therapy
CBA - Capacity Building Assistance
CBO - Community Based Organization
CDC - Center for Disease Control and Prevention
DPH - Georgia Department of Public Health
F/U - Follow Up
FQHC - Federally Qualified Health Center
GPACC - Georgia HIV Prevention and Care Council
HIV - Human Immunodeficiency Virus
HIV ST - HIV Self-Testing
HCW - Health Care Workers
M&E - Monitoring and Evaluation
MSM - Men who have Sex with Men
MTCT - Mother to Child Transmission
nPEP - non-Occupational Post Exposure Prophylaxis
OHA - Office of HIV/AIDS
PEP - Post Exposure Prophylaxis
PHIP – Public Health Information Portal
PMI - Personal Medical Information
PrEP - Pre-Exposure Prophylaxis
PP - Priority Population
QA - Quality Assurance
RPC - Regional Prevention Coordinator
SOP – Standard Operating Procedures
SENDSS - State Electronic Notifiable Disease Surveillance System
TasP - Treatment as Prevention
USPS - United States Postal Service
WHO - World Health Organization

DEFINITION OF TERMS

HIV Self-Testing (HIV ST): this is a process whereby an individual collects their own specimen, performs an HIV test and interprets the results, often in a private setting either alone or with someone they trust. HIV ST can either be assisted or unassisted.

Assisted HIV Self-Testing: Refers to when an individual who is performing a self-test for HIV receives an in-person demonstration from a trained provider or peer before and/or during HIV ST. This assistance is provided in addition to the manufacturer supplied instructions for use and other materials found inside HIV ST kits.

Unassisted HIV Self-Testing: Refers to an individual obtaining a kit for HIV ST and performing the HIV test following the instructions on the insert on their own without assistance.

Reactive results: This means that the test indicates that HIV antibodies are present in the specimen. Anyone whose result is reactive to a self-test must be followed by additional HIV testing services by a trained provider following the DPH HIV testing algorithm.

Non-reactive results: This means that the test indicates that HIV antibodies were not found in the specimen. Anyone whose result is nonreactive to a self-test does not need further testing but should be supported to re-test if they have had a recent potential HIV exposure or are at on-going HIV risk.

Service provider: In the context of HIV ST is an organization or trained health care worker that offers HIV ST services.

HIV Testing Services: Indicates the full range of services that a client is offered together with HIV testing. This includes counseling (pre-and post- test); linkage to appropriate HIV prevention, care and treatment services and other clinical support services. Coordination with additional services to support quality assurance and delivery of a confirmed results is mandatory.

EXECUTIVE SUMMARY

HIV Self-Testing (HIV ST) has the potential of being a high impact, low cost intervention to target hard-to-reach populations, and to increase the number of people living with HIV in Georgia who are identified and linked to care. HIV ST also provides an opportunity to provide linkages to HIV prevention services for those who test negative. This approach will apply to the implementation of HIV ST activities implemented through public health clinics, Community Based Organizations (CBO), pharmacies, non-traditional agencies and locations funded or supported by the Georgia DPH, Office of HIV/AIDS. This testing model may either be directly supervised by a DPH-trained Counseling and Testing staff member or unsupervised. The HIV ST strategy is guided by the principles of the Georgia DPH Counseling and Testing Protocols Manual as outlined on pages 13, 14 and 24. It has similar requirements with current HIV testing and counseling approaches including linkage to care and prevention services, data collection and quality assurance.

The coordination of HIV ST services will be a multi-faceted and multi-level activity that spans the state, district and county level structures and needs to be implemented in accordance with currently held best practices and minimum quality standards relative to the authority held by each entity.

These standard operating procedures outline the programmatic approaches to HIV ST, describe the package of supporting materials required for distribution with each test, describe requirements for ordering and storing test device and controls, and outline data collection, reporting, and follow-up requirements. They also outline quality assurance strategies, and monitoring and evaluation for HIV ST.

CHAPTER 1: INTRODUCTION

HIV ST has the potential of being a high impact, low cost intervention to reach high-risk individuals that are not seeking testing through OHA's traditional delivery systems, and to increase the number of people with undiagnosed HIV infection who are identified and linked to care services. HIV ST also presents an opportunity to provide linkages to HIV prevention services for those who test negative, including PrEP.

This Standard Operating Procedure (SOP) defines the delivery of HIV Self-Testing services in Georgia for agencies and locations that are funded or supported by DPH.

1.1 Overview of HIV Self-Testing

HIV ST is a process whereby an individual collects their own specimen, performs an HIV rapid diagnostic test and interprets the result, often in a private setting, either alone or with someone they trust and/or a healthcare provider. HIV ST is a *screening* test and is not sufficient to make an HIV-positive diagnosis. A reactive self-test result must **always** be confirmed using the DPH approved testing algorithm with appropriate health department follow-up to ensure timely entry into care and provision of partner service (PS) and prevention education. A non-reactive self-test result does not need to be confirmed. A person will be advised to re-test as per DPH HIV Counseling and Testing Training Manual, Page 35, Non-reactive results.

1.2 Potential benefits of HIV ST

HIV ST has several benefits, including:

- Expanding access to HIV testing services
- Increasing client's autonomy
- Assuring confidentiality
- Empowering individuals
- Convenience

HIV ST is intended as a HIV screening tool that has the potential to better meet the needs of individuals at risk for contracting HIV and address challenges in individuals knowing their HIV status. It is a complementary strategy to increasing knowledge of HIV status and uptake of prevention, care and treatment services. HIV ST has been shown to be acceptable to

many diverse population groups in a variety of settings¹. It is generally accurate when performed with regulated and quality rapid diagnostic tests². When provided in conjunction with adequate instructions for use and post-test support information, self-testing is also an effective and efficient strategy requiring fewer human resources than other approaches. HIV ST can also be convenient and empowering for individuals who do not utilize traditional healthcare facilities offering HIV testing services.

Evidence from various research and pilot projects has shown high acceptability and feasibility for HIV Self-Testing as well as high consumer-demand. Although evidence shows that these tests have high sensitivity and specificity it is important to note that HIV ST does not provide a confirmed HIV positive result³. **All reactive self-test results must be confirmed using the recommended Georgia DPH HIV testing algorithms.** Studies have shown evidence that those who self-test typically do access additional testing for confirming the HIV positive results and post-test counseling⁴.

HIV ST has been reported to be less costly than provider-based screening in resource limited settings⁵. It is likely that HIV ST will enhance HIV testing services efficiency by focusing resources on individuals with a reactive self-test result who need further testing, support, referrals and linkage. In addition, by reducing the number of clinic visits for frequent non-reactive testers and eliminating the need for individuals to travel distances or navigate clinic testing schedules to access HIV testing, HIV ST may increase convenience for both consumers and providers.

¹ WHO recommends HIV self-testing Policy brief. Available: <http://www9.who.int/hiv/pub/vct/who-recommends-hiv-self-testing/en/>

² UNITAID, WHO and PSI. Market and technology landscape. HIV rapid diagnostic test for self-testing, 4th edition, 2018. Available: https://unitaid.org/assets/HIV-Rapid-Diagnostic-Tests-for-Self-Testing_Landscape-Report_4th-edition_July-2018.pdf

³ Choko AT, Desmond N, Web EL, Chavula K, Naierala-Mavedzenge S, Gaydos CA, Makombe SD, Chunda T, Squire SB, French N, Mwapasa V, Corbett EL. The Uptake and Accuracy of Oral Kits for HIV Self-Testing in High HIV Prevalence Setting: A Cross-Sectional Feasibility Study in Blantyre, Malawi. 2011. Available: <https://doi.org/10.1371/journal.pmed.1001102>

⁴ Pant Pai N, Sharma J, Shivkumar S, Pillay S, Vadnais C, Joseph L, et al. (2013) Supervised and Unsupervised Self-Testing for HIV in High- and Low-Risk Populations: A Systematic Review. PLoS Med 10(4): e1001414. Available: <https://doi.org/10.1371/journal.pmed.1001414>

⁵ Potential Impact and Cost-effectiveness of Self-Testing for HIV in Low-Income Countries, Benjamin P. Linas, The Journal of Infectious Diseases, Volume 212, Issue 4, 15 August 2015, Pages 513–515. Available: <https://doi.org/10.1093/infdis/jiv041>

1.3 Potential for harm

Although available evidence suggests that there is no significant harm associated with HIV ST, programs should be sensitive to risks associated with disclosure and coercion to forceful testing.

As with all HIV testing services supported by the Office of HIV/AIDS, providers need to consider context-specific approaches to implementing HIV ST in ways that are ethical, safe, and acceptable. In addition, risk mitigation in relation to social harm and the establishment of active monitoring and reporting systems are important. An HIV ST information line is in place for testing support and referral to additional support systems (Georgia HIV and STD InfoLine 800-551-2728).

1.4 SOP objectives and target audience

The HIV ST SOP provides the framework within which HIV ST can be implemented safely, effectively, and accurately.

The specific objectives of this SOP are to:

- Outline programmatic approaches to HIV self-testing
- Describe the package of supporting materials and services required for implementation of HIV ST
- Describe materials ordering and storage requirements for HIV ST
- Outline the coordination mechanisms for HIV ST
- Outline quality assurance strategies for HIV ST
- Describe the monitoring and evaluation strategy for HIV ST

The target audience for this guideline includes:

- Program managers and staff responsible for HIV testing
- All service providers and program staff involved in HIV prevention services

CHAPTER 2: HIV ST DELIVERY MODEL

HIV ST can be delivered through two distinct approaches to reach different target populations. The approaches vary in terms of the level and type of support provided

2.1 HIV ST Delivery Options

HIV ST is characterized by an individual's use of a HIV ST kit without the help of a trained HIV counseling and testing provider. HIV ST may be distributed through *direct* client pick-up (local health department or non-traditional location) or via *second* party delivery service e.g. United States Postal Service (USPS) or Federal Express. Secondary distribution may also include clients who receive HIV ST kits through a partner that was tested for HIV in a health department or partnering organization.

HIV ST providers may utilize additional tools such as flyers and online material, telephone helplines, mobile phone text messages, videos, social media and internet based applications to provide technical support, counseling and referrals for further HIV testing, prevention, care treatment and support services as approved by local Public Information Officer (PIO) and leadership.

Table 1: HIV ST Distribution Methods

DIRECT HIV ST DISTRIBUTION TO CLIENT
<ul style="list-style-type: none"> ■ Client is given information on HIV ST as an option for HIV testing ■ Provide pre-test information on HIV transmission, risk-assessment, partner services, prevention and treatment ■ Provide links to instructional video through secured communications platform e.g. WhatsApp ■ Client encouraged to use the Georgia HIV/STD InfoLine 800-551-2728 for questions and resources ■ Provider will emphasize confirmation of HIV positive result within no less than 1 week and provide written and electronic instructions for follow-up
SECONDARY HIV ST DISTRIBUTION TO CLIENT
<ul style="list-style-type: none"> ■ For any client undergoing HIV testing, up to one (1) additional HIV ST kit can be provided to be distributed to their partner. Priority groups to receive secondary distributed HIV ST kits include: <ul style="list-style-type: none"> ● Partner(s) of pregnant and lactating women ● Partner(s) of previously tested HIV positive clients ● Partner(s) with unknown HIV status ■ Additional HIV ST kit(s) should be offered to client to take to the partner(s) identified in PS interview ■ Instructional video should be shared with client ■ Client gives partner information on HIV ST and shares the video with partner ■ Client gives partner(s) kit to perform the HIV test ■ If partner is negative, they are encouraged to retest as per ongoing risk ■ If the partner is reactive, partner is encouraged to go to any preferred facility for confirmation test within 1 week

2.2 Access to HIV ST Rapid Test Kits

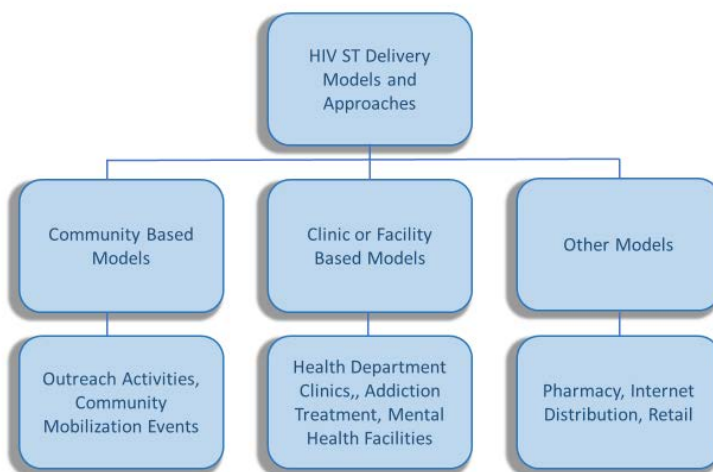
Only self-test kits supplied or authorized by DPH may be utilized. HIV ST kits will be availed through public health programs and non-traditional locations as well as for public consumption through manufacturer. For programmatic utilization, HIV ST will be distributed through funded or supported partners. DPH strongly encourages sites to increase access to HIV ST kits through other service delivery channels such as pharmacies

and non-health related or traditional locations.

2.3 HIV ST Service Delivery models

The selection of HIV ST 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 traditional client initiated HIV testing and provider outreach HIV testing services and should seek to address gaps in testing coverage rather than to compete or replace existing testing services. The channels can be clinic based, community based or through other conduits, e.g. pharmacies, bars, beauty salons/barber shops, addiction treatment centers, mental health services and other non-traditional locations.

Figure 1: Georgia HIV ST delivery models



Community based models: HIV ST can be offered to community members and targeted populations through existing partnerships such as CBO drop-in centers and faith-based organizations and innovative community-based venues that provide services to priority populations, particularly those that are underserved or may not access more traditional channels for HIV testing. HIV observance day events and community mobilization activities also present opportunities for

reaching individuals that may not voluntarily access traditional HIV counseling and testing services.

Healthcare Facility based models: HIV ST can be integrated into both public and private health care facilities. All clients seeking health services can be offered an opportunity to self-test for HIV while waiting for other services or be provided with a self-test kit to take home for use on themselves or distribute to a sexual or needle sharing partner. Self- testing is considered complementary to the existing approaches for HIV testing in Georgia.

Other channels: Alternative HIV ST service delivery channels may include provision of HIV ST services through public-private organizations or distribution at key points as per table 2.

Table 2: Alternative HIV ST Service Delivery Channels

Public-Private sector channels (Health Department Clinics, Pharmacies, Internet, Voucher Programs	Distribution at key points (Colleges and Universities, Youth centers, Community based organizations, Faith- based organizations)
<ul style="list-style-type: none"> ▪ Clients access kits at partnering Health Departments, Clinics, Pharmacies, Internet and Voucher Programs free of charge ▪ Clients pick up kits and take them home to self-test in their own environment ▪ Clients will perform unassisted HIV ST (see table 1). 	<ul style="list-style-type: none"> ▪ Kits can be placed at strategic key points where anyone can access them. ▪ Clients pick up kits and take them home to self-test in their own environment ▪ Clients will perform unassisted HIV ST (see table 1).

CHAPTER 3: HIV SELF-TESTING PACKAGE

This section covers the components of the HIV ST service package. The section provides guidance on:

- HIV self-testing promotion and communication
- The guiding principles of HIV ST
- The standards and procedures for HIV ST
- HIV ST information package
- Linkage and referral
- Partner services

3.1 HIV Self-Testing Promotion and Communication

Healthcare workers

- Introduction of counseling and testing staff to HIV ST as an additional strategy for increasing access to HIV testing services. This can be done through HIV ST SOP dissemination and review of relevant sections of the Certified HIV Counseling and Testing District Trainers, review of relevant sections of the HIV counseling and testing training manual and establishing Health District mentors for ongoing support and guidance.
- Integration of HIV ST into existing programs e.g. PrEP, PEP, community mobilization, outreach programs, HIV care and treatment and other routine health services.
- Encouraging HIV Prevention Coordinators and other HIV prevention staff to promote use of HIV ST as a convenient and accessible HIV testing strategy among target populations, particularly in rural areas and among other populations that may not readily access traditional testing services.

General population

- Raise awareness in the general population of HIV ST as an option for knowing one's HIV status. This can be done through organization websites, campaigns, brochures and flyers, billboards, digital platforms such as the internet, social media platforms, e.g. WhatsApp, Facebook, Twitter etc.
- Use of self-testing champions like peer educators, community

- advisory board members to promote the use of HIV ST
- Leverage existing social structures such as student wellness programs to promote HIV ST. This could be useful in reaching those who are hesitant to access existing HIV testing services in the due to stigma and discrimination as well as reaching men who have sex with men and other key populations.
 - Identifying opinion leaders, gatekeepers and advocacy groups to engage their networks, creating demand and offering HIV ST support and encourage linkage.

3.2 Guiding Principles of HIV ST

The HIV ST strategy is guided by the principles of HIV testing services as is outlined in Georgia HIV Counseling and Testing Training Manual.

Consent

Clients must provide consent prior to distribution of the HIV ST package. Providers may utilize the same consent documents and processes that are used for traditional opt-out or targeted HIV testing. Record of consent does not need to be submitted to the Office of HIV/AIDS but should be maintained as a part of client file according to local retention schedule for private medical information (PMI).

Confidentiality

HIV ST enables people to screen themselves for HIV in the privacy of their preferred space; there is minimal opportunity for breach of confidentiality.

Counseling

Opportunities for HIV counseling may be reduced because of the self-implementation aspect of HIV ST. However, risk assessment and development of safer behavior goals should be provided when requested and as opportunities arise. Providers should utilize the standard HIV counseling principles and procedures outlined in the Georgia HIV Counseling and Testing Training Manual.

Accurate results

Each test kit includes manufacturer instructions which provides clear, concise directions with graphic illustrations on how to conduct self-

testing and helps to ensure all clients obtains accurate results. Clients should be directed to follow manufacturer instructions included in the test kits. Specific quality assurance measures should be in place to ensure correct test result. Whenever possible, Providers must clearly communicate the window period for HIV infection and the potential need for re-testing to ensure accurate results. (See page 17 of Rapid HIV Testing Protocols and Quality Control Training Manual).

Linkage to Care and Prevention Services

All clients seeking HIV ST should receive up-to-date information on linkage and referral to HIV post-test services and other needs, based on outcome of the test. Clients with a negative result but with recent exposure or with an on-going risk should seek guidance from a trained HIV counseling and testing provider, this includes PrEP education and other STI testing. It is recommended that clients whose self-test results are reactive seek HIV testing services from a qualified service provider for additional testing using the standard DPH HIV testing algorithm. If at any time the provider becomes aware of a reactive HIV ST result, contact with a local DPH linkage coordinator must be facilitated within 7 days. All printed and electronic informational materials should clearly display information on this requirement.

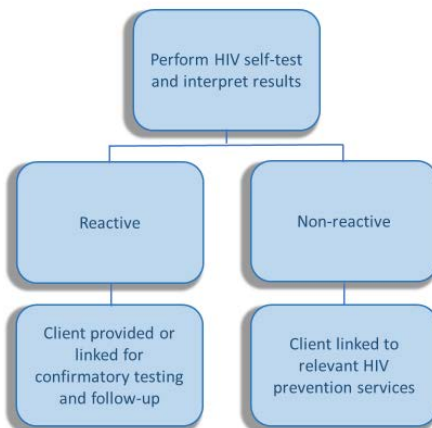
3.3 Standards and procedure for HIV self-testing

HIV ST must be conducted using the OHA approved HIV rapid self-test devices. The manufactured kit will include instructions in English and Spanish as well as pictorial diagrams to aid ease of use and accurate interpretation of results. It is mandatory that all HIV ST kits distributed also be accompanied with the DPH-provided insert that includes guidance on resources and linkage to PrEP and/or HIV treatment. Providers may also distribute HIV/STI-related materials that support client education.

Clients with non-reactive self-test results should be advised to re-test based on their risk for HIV infection as outlined in the Rapid HIV Testing Protocols and Quality Control Training Manual (page 32). If the HIV ST test result is reactive, the client should be advised to seek further testing from a DPH trained counseling and testing provider within 7 days. When

client presents at the provider facility for confirmatory or follow-up testing, the standard HIV counseling, testing and linkage protocols should be adhered to, and data collection and submission procedures using the standard HIV Test Template (bubble sheet) must be followed.

Figure 2: HIV ST Flow Chart



A reactive HIV self-test result always requires additional HIV testing per the Georgia DPH HIV testing algorithm.

3.4 HIV ST information package

Providers and users should be made aware that HIV ST is **NOT** recommended for people who are already taking ARV drugs, because rapid HIV tests (including HIV ST) may give false negative results as antibody levels may be low when people with HIV are on ART.

3.5 Referral and Linkage

In addition to delivery of effective HIV ST services in Georgia, utilize programmatic strategies in place to facilitate linkage to HIV prevention, care, treatment and support following HIV ST. These strategies should be integrated into the provider's current HIV Counseling and Testing Program. Clients whose self-test results are reactive must seek confirmatory testing within 7 days. The Counseling and Testing provider should provide

appropriate referral and linkage in alignment with OHA processes and procedures for linkage to care and prevention services. Information on referral to additional support and ancillary services can be made available through active referral processes, online resources, and through the Georgia HIV/STD InfoLine (800-551-2728).

Adequate support for clients utilizing HIV ST is highly recommended as part of HIV ST service delivery model. Such support may include a demonstration on how to use the test kit, interpretation of results, post- test information and referrals to additional services. Resources should be provided as part of the support.

Linkage approaches for HIV ST

- Community based organizations utilize internal staff (e.g. health care workers, peer educators/navigators, outreach workers) to contact clients through telephone or encrypted texts messaging services to ensure confirmatory testing occurs within 7 days. All reactive results should be reported to the county health department or their designee for appropriate linkages and follow-up.
- Incentives (e.g. vouchers, coupons, gift cards) for encouraging prompt confirmatory testing and entry into treatment or prevention services are allowable at the discretion of the Provider.
- Telephone or internet counseling services and step-by-step instructions on what to do following a reactive self-test may be provided. HIPAA regulations should be observed for all digital, electronic, computer-based programs and applications (such as Facebook, WhatsApp, Twitter etc.).
- The Georgia HIV/STD InfoLine may also be utilized as a resource for pre-test and post-test counseling, technical support with the testing device, and linkage/referral to additional supportive services.

3.6 Partner Notification and Disclosure

Clients should be informed about the potential health benefits of disclosing their HIV status to sexual and needle sharing partners prior to receiving their self-testing kits. This information can be included in the HIV/STI-

related materials offered by the Provider. Clients with reactive HIV ST results should be encouraged to visit a HIV testing clinic with their partners for further testing as per the Georgia DPH HIV testing algorithm and receive supported PS and disclosure assistance. Clients whose test result is non-reactive should also be encouraged to disclose their status to their sexual partners and encourage their partners to know their HIV status through use of HIV ST kits or a visit to a local Health Department of HIV testing clinic.

- Providers should assess for possible social harm and/or domestic violence and provide guidance and referral as appropriate.

CHAPTER 4: TEST KIT PURCHASES AND INVENTORY MANAGEMENT

This section covers the management and coordination of HIV ST supplies and quality control products to ensure the correct OHA approved materials and quantities are procured, that appropriate conditions of delivery and storage are maintained, and that the best value can be negotiated for the state.

4.1 Kit Selection

Only self-test kits supplied or approved by DPH may be utilized. The selection of the kits will be guided by DPH OHA in collaboration with the state purchasing and procurement staff.

4.2 Inventory Management

The management of the test kits and quality control materials will be aligned to the existing inventory management system. This will include receipt of kits, storage per 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 (i.e. HIV ST Distribution Logs, inventory logs, and temperature logs) and reporting systems.

CHAPTER 5: COORDINATION

This section outlines the various roles and responsibilities in the coordination of HIV ST.

5.1 Roles and Responsibilities

Table 3: Roles and Responsibilities

Organization/Agency	Roles and Responsibility
Office of HIV/AIDS	<ul style="list-style-type: none">▪ Development and dissemination of HIV ST policy, guidelines and implementation support tools▪ Provision of technical assistance and capacity building assistance for contracted and supported Providers▪ Coordination of HIV ST Providers to ensure a uniform and strategic state-wide initiative▪ Development of HIV ST monitoring and evaluation (M&E) tools, indicators and quality assurance (QA) processes.

<p>Health Districts and other Providers</p>	<ul style="list-style-type: none">▪ Provide pre-test information on HIV▪ Distributes HIV ST kits▪ Ensures kits are stored and maintained at recommended temperatures▪ Explains the HIV ST process to communities and individual clients▪ Responds to questions and concerns of clients engaging in self-testing services▪ Ensures clients have access to linkage information, direction to care and treatment facilities, and the assistance of a local Linkage Coordinator▪ Collects tracking log data for reporting requirements▪ Ensures follow up for clients consenting to follow up
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CHAPTER 6: QUALITY ASSURANCE

This section aims to provide guidance on:

- Ensuring the quality of HIV ST test kits
- Ensuring quality of the HIV ST process

6.1 Benefits of Quality Assurance in HIV ST

Quality Assurance provides a systematic planned approach to monitor, assess and improve quality of services on a continuous basis. Quality assurance is an integral part of all HIV Counseling and Testing services and should be implemented through simple and practical approaches at all levels.

6.2 Components of quality assurance for HIV ST

Quality assurance for HIV self-testing can be considered in terms of:

- QA of the test device
- QA of the HIV self-testing process

6.2.1 Quality assurance of HIV ST kits

All test kits must be FDA approved to ensure that they meet the minimum inclusion criteria.

Table 4: Specification of OraQuick HIV ST in Georgia

Criteria	Desired Characteristics
Sensitivity	Above 99%
Specificity	Above 99%
Ease of Use	<ul style="list-style-type: none"> ▪ Should not require additional equipment to perform ▪ Should not require technical training to perform the test ▪ Stable end-reading points
Results	<ul style="list-style-type: none"> ▪ Results should not need interpretation with additional equipment
Rapidity of Test (Time of result)	Results available within 20 minutes of specimen collection
Storage Condition	35-86 degrees Fahrenheit
Shelf-Life	Above 6 months
Packaging	Single packing of complete set

6.2.2. Quality assurance of the HIV ST procedure

Capacity building and technical assistance for HIV ST

All HIV ST service providers should be trained per the online Office of HIV/AIDS HIV ST training course. This includes capacity building and knowledge on how to conduct the tests, how to ensure confirmatory tests are conducted for all reactive self-test results, how to facilitate quick and convenient linkage for HIV care and treatment, prevention services, and PS.

Assurance of abilities necessary for clients to test themselves and for providers to operate a viable HIV ST program

Information on HIV ST including but not limited to how to conduct the HIV self-test and interpret the results should be readily available to all clients. Clients must also be made aware of the need to confirm any reactive test results as per the Georgia DPH HIV testing algorithm.

Infection prevention and control

While the risk of HIV transmission through HIV self-tests has been demonstrated to be minimal, clients should be made aware of correct practices to minimize biohazard risks.

Referral and linkages

Information on referral and linkage to appropriate services should be made available to all clients. In the event of a reactive HIV self-test result, clients must be made aware of where additional testing can be conducted. A referral directory should be available for additional HIV testing and other services. If at any time the provider becomes aware of a reactive HIV ST result, contact with a local DPH linkage coordinator must be facilitated.

CHAPTER 7: MONITORING AND EVALUATION

This section outlines the monitoring and evaluation (M&E) requirements for operation of a HIV self-testing program.

7.1 Indicators for M&E in HIV ST

Pilot sites will be required to complete HIV ST Distribution Logs each month and all Logs will be submitted securely at the end of the 3-month pilot to the assigned Regional Coordinator. These logs allow for an accurate account of self-test kits being distributed to clients. Every Health District or CBO participating in the pilot must identify a contact person to be responsible for completing the distribution logs on behalf of the Health District or CBO. This person will also maintain the responsibility of coordinating the distribution and reporting of partnering agencies (i.e. non-traditional sites/locations within their District) and submission at the end of the pilot. Non-Pilot sites are not required to complete monthly HIV ST Distribution Logs.

Logs will be submitted by Pilot Sites using the Public Health Information Portal (PHIP). This is a Georgia Department of Public Health, Office of Information Technology supported system allowing for secure transfer of confidentially protected information. Once the contact person has their account created from the Office of HIV/AIDS, this person will receive an email notification from PHIP on how to access a secure folder and an email from the State Office with your password. At that time, they will also receive a one-page user's guide on how to complete the file transfer.

Pilot Sites and Non-Pilot Sites must complete the HIV Self-Testing section within the Electronic Monthly Report, documenting monthly activities focused on ST. The following information will be collected within the electronic monthly report:

- Number of HIV Self-Test Kits received this month? (These responses should only include kits received through the PS18-1802 Grant)
 - Of the total kits received this month, how many were

Delivery of HIV Self-Testing Services in Georgia and pertains specifically to the Monitoring and Evaluation requirements for pilot participants between October 1 – December 31, 2020.

Monitoring and Linkage Activities

1. During the roll-out period of this pilot project, participating pilot Health Districts and CBOs will be required to participate in a monthly “check in” call to discuss findings, best practices and needs. The one-hour call will be facilitated by Office of HIV/AIDS staff.
2. Pilot participants are expected to oversee and support the direct distribution of test kits by partner agencies and nontraditional sites.
3. The pilot sites must serve as the primary point of contact for follow-up including linkage to HIV care, PrEP, partner services or additional STI testing.
4. As the pilot advances, participating sites will have the ability to monitor self-reported test result via SENDSS. Pilot participants should conduct weekly monitoring of post-test survey data to assess the need for follow-up on self-reported reactive test results.
5. Pilot participants should consistently monitor the uptake and distribution of HIV ST kits to ensure accessibility in all partnering community delivery sites. Pilot participants should monitor HIV ST supply inventory and shift supplies as necessary to ensure availability in areas of highest demand.
6. Participating Health Districts and CBOs are required to submit the HIV Testing Distribution Log at the close of the 3-month pilot through PHIP. Narrative reporting of HIV ST activities (successes, challenges and best practices) is due in the Electronic Monthly Report on the 15th of every month.

Lot Number: Series of numbers printed on the manufactured test self-kit.

Expiration Date: Date printed on the manufactured self-test kit.

Initials: Respective initial of staff member confirming/documenting client's information and distributing self-test.

Notes: Section to capture any relevant information pertaining to client or self-test provided to client.