# Guidance for HIV Self-Testing Program Implementation and Data Reporting

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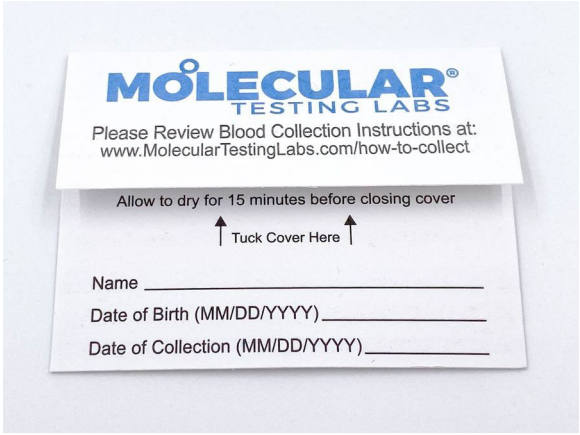
## DEFINITIONS

**Rapid HIV self-test (HIVST)** - Rapid HIV self-testing refers to HIV tests where the client collects the sample, performs the rapid test, and interprets the test result in their own home or other private location. The only FDA-approved rapid self-administered over the counter (OTC) HIV self-test is the OraQuick® In-Home HIV Test. It is an oral swab test. The test kit consists of a test stick (oral swab device) to collect the specimen, a test tube (vial) to insert the test stick (device) and complete the test, testing directions, two information booklets ("HIV, Testing and Me" and "What your results mean to you"), a disposal bag, and phone numbers for consumer support. HIV self-tests can be ordered by physicians, are available at most pharmacies and may be covered by insurance.




**HIV/STI self-collection (HIV/STI SC)** - HIV/STI self-collection refers to HIV/STI testing using a mail-in self-collection kit. With this method, the client receives a specimen collection kit(s), collects the needed specimen(s) (e.g., dried blood spot, urine sample, swab, etc.), and sends it to a laboratory for processing.

HIV/STI self-collection kits can be used to test for HIV and sexually transmitted infections (STI). Self-collection kits can only be ordered by entities with medical oversight and active contracts with an approved processing laboratory. Specimen kits are mailed to a preferred address and contain supplies to collect blood from a fingerstick or other appropriate methods (e.g. self-collected swabs and urine). The kit is then mailed back to the lab with test results returned to the clinician who acts on results accordingly. This laboratory-conducted test is sensitive enough to detect recent HIV transmission. If you would like to inquire more about HIV/STI self-collection kits, please contact MDHHS through SHOARS (STI/HIV Operations and Resource System) with questions.

**Throughout this document only the OraQuick Rapid HIV Self-test will be referenced.**

# 1 OVERVIEW

## PURPOSE

This document provides guidance on the creation of policies and procedures for program implementation and data entry for the HIV rapid self-administered over-the-counter (OTC) test (HIVST or rapid HIV self-test). This guidance is intended for use by programs funded or otherwise supported by the Michigan Department of Health and Human Services (MDHHS).

## BACKGROUND

People may be reluctant to visit a health care provider or other agency to be tested for HIV due to barriers such as unreliable transportation, time restraints, stigma, or other social and economic challenges. Based on the 2020 HIV Care Continuum Report from the Michigan Department of Health and Human Services (MDHHS), there are an estimated 19,230 persons living with HIV (PLWH) in Michigan, with an estimated 13% who have not received an HIV diagnosis and are living without the life-extending benefits of treatment.

Through the dissemination of this guidance, MDHHS aims to expand and ensure access to HIV testing and support linkage to medical care and/or other prevention services. The COVID-19 pandemic has made it more difficult to access services through traditional testing locations, such as clinic-based testing sites, community-based organizations (CBOs), and healthcare settings. The Centers for Disease Control and Prevention (CDC) and MDHHS encourages people who have an increased likelihood of acquiring HIV to have increased availability and options to access testing services, including rapid HIV self-testing (HIVST).

HIVST refers to a process in which a person collects their own specimen and then performs an HIV test and interprets the result, often in a private setting, either alone or with someone they trust. As with all approaches to HIV testing, HIVST must be voluntary and not coercive. **It is important to note that HIVST does not provide a definitive HIV diagnosis**. This is because, as with all HIV testing, a single rapid diagnostic test is not sufficient to make an HIV diagnosis. Thus, HIVST is considered to be a preliminary screening test which requires persons with a reactive test result (i.e. preliminary positive) to receive further testing from a trained tester using a validated national testing strategy.

Effective HIVST approaches are based on three main components:

## CORE HIVST PROGRAM COMPONENTS

- *Mobilization and Social Marketing:*
  - Programs should advertise and encourage utilization of services via a comprehensive, user-centered communications and marketing strategy. These should increase awareness and demand among priority populations and engage with key stakeholders. Messaging should be disseminated through community appropriate platforms and venues. Messages about eligibility and request processes should also be included.
- *Testing Process:*
  - Distribution strategies can be either direct (offered to the client who will use it) or indirect (offered to an intermediary). Testing can be unassisted or assisted, and preformed on site or in a private setting as determined by the user. Pre- and Post-test counseling messages must be included.
- *Linkage:*
  - Programs must establish processes for follow up and linkage to care/support services regardless of the reporting of results. Testers must have tools available that support linkage to counseling, treatment, and/or prevention after a self-test. These tools should allow a tester to opt-in, use the level of technology most appropriate to the communities of focus (e.g., phone, Internet, smartphone), offer the option of speaking to a human and direct community follow-up, and protect the privacy and confidentiality of the self-testing experience.

Tools should not pressure self-testing clients to disclose their test results nor compromise the privacy of the testing experience. People who use a self-test at a facility or community event should be offered confirmatory testing and linkage services on site. Linking self-testers who test off site is more challenging, requiring innovative follow-up approaches, such as calls, SMS, doxy.me, Google phone numbers, online scheduling platforms, or community outreach etc. Depending on your

community and/or location, certain methods may work better than others. Please note that follow-up is difficult with HIVST and is a known challenge so when your program begins, please don't be deterred by the initial lack in reporting response from your HIVST clients. Please see the resources.

**KEY POINTS OF A SELF-TESTING PROGRAM:**

**Mobilization/Social Marketing:**

- **Appropriate, validated, clear and concise instructions for the use of self-testing kits are critical to minimize errors** and maximize the performance of HIVST used for self-testing. Printed instructions – written and/or pictorial – are essential to support correct use and interpretation. In-person demonstrations of how to use an HIV self-test, along with additional population-specific information, can be very useful.
- **Educating the community** – including networks of people with HIV, such as key and affected populations, trained testers and health workers – about HIVST is critical in order to increase the uptake of self-testing and minimize the chance of misuse. Information tools such as brochures, job aids and standard operating procedures can also be useful in **increasing understanding and raising awareness, especially when combined with training and information sessions.**
- Other support tools, such as **telephone-based or Internet-based messaging services**, which provide information on HIVST and answer questions about how to perform a self-test and interpret a self-test result, may also be appropriate and potentially improve performance for some populations.
- **Integrating HIVST into comprehensive sexual health service** programs is critical to program success and to maximize effectiveness of the HIVST. Although HIVST is an innovate way of encouraging greater uptake of HIV testing among clients who might otherwise not know their HIV status, enabling people to test without having to attend a sexual health clinic can mean some users may access other health services, such as STI testing, less frequently.

**Testing Process:**

- **Pre-test information and post-test counselling messages should be readily accessible and available** – for instance, through package inserts or brochures, hotlines, text message services, in-person demonstrations, counselling delivered by trained providers, volunteers or peers, Internet- or computer-based programs, or videos posted on the Internet.
- **HIVST is not recommended for people with a known HIV status who are taking ARV drugs for treatment or prevention**, as this may lead to an incorrect self-test result (false non-reactive), particularly when using oral fluid-based rapid HIV testing devices.
- **A reactive (preliminary positive) self-test result always requires further testing.** Clear messages are essential to ensure users understand that HIVST does not provide a definitive HIV-positive diagnosis, and they are aware of what to do after a reactive self-test result.
- **A non-reactive self-test result does not usually require further HIV testing**. However, clear messages are needed to ensure that users understand that a non-reactive test result does not always indicate an HIV-negative status.

**Linkage:**

- **Users who receive a reactive result must be immediately referred and linked to confirmatory testing**. If the follow-up testing confirms the HIV-positive status, appropriate counseling and treatment options should be provided including ART and other care options. As with all HIV testing, users who receive a non-reactive result should be encouraged to retest at least every year dependent on their individual likelihood of exposure.
- Even if clients with higher chance of HIV have **a non-reactive HIV self-test result, they should be provided with information on further HIV testing, PrEP and treatment**, as well as information on other STIs and viral hepatitis, and be encouraged to access comprehensive sexual health services.
- Reactive results must be reported per MDHHS disease and program reporting requirements.
- Device issues or failures, as well as instances of social harm, should be documented and reported to appropriate entities.

## 1.1 HOW TO USE THIS GUIDE

This guide is to be utilized to help develop agency specific protocols and procedures for HIV self-testing. All components (messaging, testing, and linkage) must be addressed.

**NOTE:** The content in this guide is a culmination of information from the WHO, PEPFAR, Greater than AIDS, MDHHS agencies, and CDC. Therefore, some information may not be relevant to your agency.

## HIV SELF-TESTING COMPONENTS

- Resources and Requirements
  - Adherence to federal, state, local regulations, and statutes
  - Medical oversight and authorizing agency
  - Confidentiality and privacy
  - Cultural humility
  - Laboratory, universal standards, and related procedures (CLIA)
  - Quality assurance
  - Supplies and resources
  - Agency capacity
- Agency Readiness Assessment
- Mobilization and Social Marketing
  - Test request
    - Eligibility/priority criteria
  - Advertising
  - Data collections
  - HIPAA compliance
- Testing
  - Distribution approach
    - Primary
    - Secondary
- Linkage
  - Follow up
  - Linkage
- Reporting
  - Disease reporting
  - Data requirements reporting
  - Monitoring and quality improvement

# 2 Guidelines for the Development of Agency Specific Policies

Programs funded by MDHHS may order HIVST kits through MDHHS, who will have HIVST kits delivered to the requesting agency who will then send them to eligible persons based on their assessment forms and established policies and procedures. Programs implementing this activity must develop and maintain a MDHHS-approved policy. Please communicate with MDHHS regarding your plans to implement self-testing and note that MDHHS is available to assist with the planning process.

## 2.1 Resources and Requirements

Agencies must ensure programs comply with the following rules and regulations. Laws, policies, and regulations that address misuse and abuse (such as coercive testing, violence, discrimination, and prosecution) may need to be developed or adapted to protect people who self-test. It may be important, also, to develop channels through which misuse or abuse can be reported, monitored, and addressed.

### ADHERENCE TO FEDERAL, STATE, LOCAL REGULATIONS AND STATUTES

Providers of HIV prevention services must adhere to federal, state, and local regulations and statutes. Michigan regulations and statutes are summarized in the document entitled Michigan HIV Laws: How They Affect Physicians and Other Health Care Providers and Michigan HIV/STI Law Updates.

Disease reporting, program and data collection protocols must be followed as described in MDHHS HIV/STI program policies and procedures QA/Test procedures. Please reach out to Prevention staff via SHOARS for these documents.

### MEDICAL OVERSITE AND AUTHORIZING AGENCY

Medical authority by a licensed physician is necessary to collect specimens and order HIV antibody/antigen, HIV genotype, HIV incidence, syphilis, gonorrhea, chlamydia, and hepatitis C testing. According to Part 15 of the Public Health Code MCL 333.17001(j), 'practice of medicine' is defined as

> *"The diagnosis, treatment, prevention, cure, or relieving of a human disease, ailment, defect, complaint, or other physical or mental condition, by attendance, advice, device, diagnostic test, or other means, or offering, undertaking, attempting to do, or holding oneself out as able to do, any of these acts."*

Agencies must also be an existing CTR HIV rapid testing site and all staff involved with testing programs must be certified test counselors verified by an active counselor ID. Upon implementation of HIVST programs, agencies must update their 211 profiles to reflect HIVST.

### CONFIDENTIALITY AND PRIVACY

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) addresses the protection and privacy of personal health information. Testing sites are required to establish policies and procedures to protect the confidentiality of health and personal information about their program participants, including client identification, test results, and all records of testing. All personnel should receive training on maintaining the confidentiality of participant information. Several states have medical privacy laws that apply to testing sites. Personal identifying information about a client, including information about HIV status, is not to be divulged to others in ways which are inconsistent with a client's written consent. Outreach and internet-based prevention efforts may require additional considerations to ensure a client's privacy and confidentiality are assured. Refer to the following link for more information on HIPAA – HHS.gov/ocr/privacy.

### CULTURAL HUMILITY

A client's culture, language, gender, sexual orientation, age, socioeconomic status and/or developmental level influence how a client seeks, accepts, and accesses HIV services. Providers should address these factors in program development and implementation.

## LABORATORY, UNIVERSAL STANDARDS, AND RELATED PROCEDURES

All clinical and non-clinical HIV testing sites using waived rapid HIV tests must either obtain their own certificate of waiver under CLIA or establish an agreement to work under the CLIA certificate of an existing laboratory.

> **NOTE:** Laboratory procedures associated with rapid HIV testing are described in the following documents: Procedure Manual for HIV-1 Rapid Testing by Alere Determine HIV-1/2 Ag/Ab Combo, Specimen Collection: Blood Collection by Finger Puncture and Heel Stick, RQA.08.04 Generic Quality Assurance Manual, Procedure manual for the Chembio Sure Check, and the Procedure manual for the OraQuick®. Please reach out to Prevention staff via SHOARS for these documents.

## QUALITY ASSURANCE

Quality Assurance is a series of planned, step-by-step activities that ensure testing is being carried out correctly, results are accurate, and mistakes are found and corrected in a timely fashion to avoid adverse outcomes. These activities must be followed during the entire testing process, from the time a person agrees to be tested until after the test results are reported. Quality assurance systems may need to be reinterpreted and adapted to include HIVST. In addition, community-based monitoring systems and other tools can be used to document, monitor, and address potential social harm. To ensure the reliability of the program and test device, Quality Assurance activities that must be conducted include:

- Inventory and Environmental Monitoring
    - Lot numbers, dates used and received, expiration dates of reagents, kits and material, daily temperature checks, test system or equipment function checks and maintenance.
- Social Harm Concerns
    - As with any HIV testing, there is a need for information and tailored messaging on disclosure to mitigate the chance of social harm and help the person, their partners, and friends/family to cope with a reactive self-test result or mixed self-test results. Persons or couples who report intimate partner violence (IPV) in their current relationship should be counselled to disclose or undergo couples testing only if the safety of both partners can be assured. Linkages to further testing, prevention, treatment, and care, as well as services for domestic abuse and gender-based violence, should be offered as part of HIVST services, either during the counselling session in directly assisted approaches or in the package inserts/instructions in unassisted approaches.
- Reporting of Device Errors/Failures
    - Test system failures, troubleshooting, and corrective action taken when problems have been identified, test or product recall notices.
- Data Quality
    - Data should be regularly checked and monitored to ensure quality and accurate data reporting and collection. Self-testing programs require the tests to be entered into the appropriate data management system once distributed and edited once results are reported. Please refer to section 6 for further details on data and reporting.

## SUPPLIES AND RESOURCES

All agencies must utilize approved MDHHS testing devices and procedures. This includes:

- MDHHS CTR Labels/Sticky Numbers:
    - 10-digit sticky numbers starting with 26xxxxxxxxx
- Rapid HIV Self-Testing:
    - The OraQuick® In-Home HIV Test is an in-vitro diagnostic home-use test for HIV (HIV-1 and HIV-2) in oral fluid. This test works by looking for your body's response (antibodies) to fighting the HIV virus. A positive result is preliminary, and follow-up confirmatory testing is needed.

AGENCY CAPACITY

STAFFING AND TRAINING

Regardless of the size of the program, any staff directly interacting with clients as part of a self-testing program must complete the MDHHS CTR trainings and have a current counselor ID number. Staff also must complete any additional MDHHS requirements as outlined in contractual agreements and/or policies and procedures.

Staff must:

- Successfully complete all training, certifications, and updates relevant and/or required to perform roles and responsibilities associated with their position.
- Be provided with copies of relevant programmatic guidelines and standards, including a professional boundary policy.
- Be provided with and oriented to program plans, including objectives, work plans, and timelines. Opportunities to periodically review and discuss progress toward meeting objectives should be provided.
- Staff must be provided with and oriented to all forms (e.g., consent forms), data collection tools, agency-specific procedural documents (e.g., record keeping, referral protocol), and data management systems (e.g., Aphirm) and trained regarding their use.
- Be knowledgeable about confidentiality laws and agency-specific confidentiality policies and procedures.

**NOTE**: If HIVST is to be implemented by staff working in remote locations, include information about how staff will ensure confidentiality is maintained while working from home. Be sure to address confidentiality of data (both physical and electronic) of the person being tested when staff engage with them from their homes, including how information will be protected from members of the staff's household.

## 2.2 READINESS

To ensure program success, agencies should complete a readiness assessment in order to identify gaps and program needs and inform protocols and procedures. "Readiness for Home HIV Self-Testing Table" (see Appendix A) should be used to address the following required items:

- Staffing
- Eligibility/Recruitment
- Marketing and Contact
- Data Collection and Analysis
- Follow up Linkage to care and treatment
- Privacy and Security
- Quality Assurance and Evaluation

## 2.3 PROGRAM DEVELOPMENT

When developing the procedure it is important to consider agency capacity (staffing, resources), HIPAA compliance, and the specific populations or individuals who will engage in the program.

| QUESTIONS TO CONSIDER WHEN DEVELOPING PLAN: | |
|---|---|
| **Agency Capacity** | • Who on your team will manage the program? Is any additional training required?<br>• Where will you store the tests and track inventory?<br>• Do you need to make any adjustments to your system for recording and reporting test results?<br>• Do you have a procedure to detect test result errors, so that you promptly notify the responsible clinical personnel or reference laboratory and issue a corrected report? |

| | |
|---|---|
| | • Do you keep records of testing, including equipment logs, maintenance records, QC documents, and test results? |
| **Request** | • What will be your eligibility criteria for who gets the tests?<br>• How will you collect that information?<br>• Ordering/requesting/providing results approach must be conducted in a way that is HIPAA compliant and adheres to those standards. If utilizing an online system make sure it adheres to this standard. |
| **Distribution** | • How will you distribute your tests?<br>  ○ by mail<br>  ○ pick-up<br>  ○ drop-off<br>  ○ pop-up location<br>  ○ partner or network distribution<br>• If mailing, do you have shipping materials and postage on hand? Be sure to check mailing costs.<br>• Do you have information printed about your organization and follow-up services to provide with the tests? Other items? |
| **Client Support** | • Supporting your clients before/during/after the test.<br>• Come up with a plan for engagement with your clients throughout the process, including before, during and after the test.<br>• Some communication tools to consider (please ensure the tool you use is HIPAA compliant):<br>  ○ Telehealth platform<br>  ○ Zoom, etc.<br>  ○ By phone<br>  ○ Via text<br>• Consider opportunities to engage the client in care whether that is prevention strategies like PrEP or to connect with HIV treatment.<br>• How will you address social harm, IPV, and quality assurance concerns about the testing device? |
| **Follow up** | • What will be your process for receiving and following up on test results from the client?<br>• How will you handle follow up and referrals (for PrEP or HIV treatment and care)? |
| **QA and Evaluation** | • How will you monitor your inventory and track distributed tests?<br>• How will you evaluate your process?<br>• Consider client surveys.<br>• How will you measure success? |

### Procurement

The process for ordering HIV Self-Test kits will follow the same procedure as ordering other Rapid HIV tests from BHSP. Agencies will submit their requests for testing devices through SHOARS. Once tests are requested via SHOARS, agencies will have their test kits mailed directly from OraSure, based on the number of tests requested and confirmed by BHSP staff via SHOARS. Please note that HIVST kits are delivered from OraSure in cases consisting of six HIVST kits, please place orders based on factors of six.

Additionally, to place orders for Rapid HIVST kits via BHSP, please note that agencies should have the following elements in place:

- HIVST Policy and Procedure reviewed and approved by BHSP

- Contract in place with MDHHS for HIV/STI services (e.g., HIV Prevention, Ending the HIV Epidemic, Ryan White B, etc.).

For more details on the ordering process via SHOARS, please refer to the following link – SHOARS Resources.

# 3 REQUEST AND DISTRIBUTION APPROACH

**WHEN TALKING ABOUT TEST REQUESTS, MDHHS IS REFERENCING HOW CLIENTS WILL REQUEST TESTS FROM AGENCIES AS OPPOSED TO HOW THE AGENCIES WILL REQUEST AND RECEIVE TESTS FROM MDHHS.**

## 3.1 TEST REQUEST

The process for requesting tests can vary depending on the agency's community and distribution strategy, however It is important that, regardless of the approach, HIPAA compliance, and MDHHS QA and contractual agreements must be followed. The key components that must be included in a request include:

- **Consent**
- **Eligibility Criteria and Assessment**
- **Request/Distribution Strategy**
- **Support Messaging**

### 3.1.1 CONSENT

Consent must be given by the individual requesting a test regardless of how the test was requested. Consent can be incorporated into online ordering forms and/or verbally. Consent forms and processes should include the following:

- Provide information regarding the HIV test including benefits and consequences.
- Discuss availability and meaning of confidential and anonymous testing, pursuant to Michigan law.
- Discuss and provide assurance of confidentiality, pursuant to Michigan law, as well as anti-discrimination law for PWH.
- Explain Partner Service options.
- Explain that the client has a legal obligation, if found to have acquired HIV, to inform each sexual partner of the client's status prior to engaging in sexual relations with that partner, and the client may be subject to criminal sanctions for failure to inform the partner. This shall take place after all the needs of the client have been addressed.

### 3.1.2 ELIGIBILITY CRITERIA AND ASSESSMENT

Self-testing should be prioritized for people who are members of a priority population, vulnerable to acquiring HIV/STI, not able to access traditional services, or face other barriers such as lack of insurance, transportation, and stigma. Agencies should have specific criteria to determine eligibility based on their priority populations, community resources, and only be distributed to people at high need as determined by the agency. Regardless of program implementation, all people requesting a HIVST kit must be screened for eligibility. Variables for reporting and data collection must be in alignment with MDHHS data requirements. Specifics for data entry can be found in section 6.

| Eligibility must be determined prior to distribution of a test. | | |
|---|---|---|
| | **ELIGIBLE** | **INELIGIBLE** |
| **HIV Self-Testing** | People within MI | People outside of Michigan |
| | Identified as behaviorally vulnerable | Little to no chance of acquiring HIV |
| | Persons who are not currently taking PrEP | Persons taking PrEP must have a 4th generation HIV test. The OraQuick® is not to be used for regular PrEP maintained testing. |
| | Persons who are concerned about an encounter more than 30 days ago | Persons who report an encounter less than 30 days must be tested with a 4th generation test due to window period of the OraQuick®. |
| | People over the age of 18 | People under the age of 18 are not eligible for a rapid self-test kit. The OraQuick® is not FDA approved for people under 18. |

Agencies can add additional eligibility criteria to help prioritize people in need and persons within priority populations.

### 3.1.3 REQUEST APPROACH

Tests can be requested in person, online, or via partner/secondary distribution. Some examples of request approaches are:

- **Online ordering:** Utilizing survey or form platforms (qualtrics, red cap, doxy.me) via QR code or link embedded online and/or printed marketing materials agency chat options on websites or appointment systems.
- **Hotline or call center**: Users call before or after self-testing to obtain psychosocial and/or technical support can also provide referrals and linkage to CTR and other HIV/STI services, as well as to non-medical and social support services.
    - Agencies can utilize 211 link as a resource
- **Partner/secondary distribution or community champion request:** This approach must consider release of information and screening for coercion.
- **Fixed site pick up:** This approach offers tests at fixed sites for individuals to pick up in person.

## 3.2 Request/Distribution

When developing agency protocols, please note that a combined approach for recruitment and distribution can be utilized, as appropriate. There is no one size fits all approach that will work for every agency. Some distribution strategies lend themselves to different requesting and follow-up approaches and the options highlighted in this guide serve as a framework of various public and private sector channels through which self-testing could be distributed, including approaches that are community-based, facility-based, and other venue-based strategies.

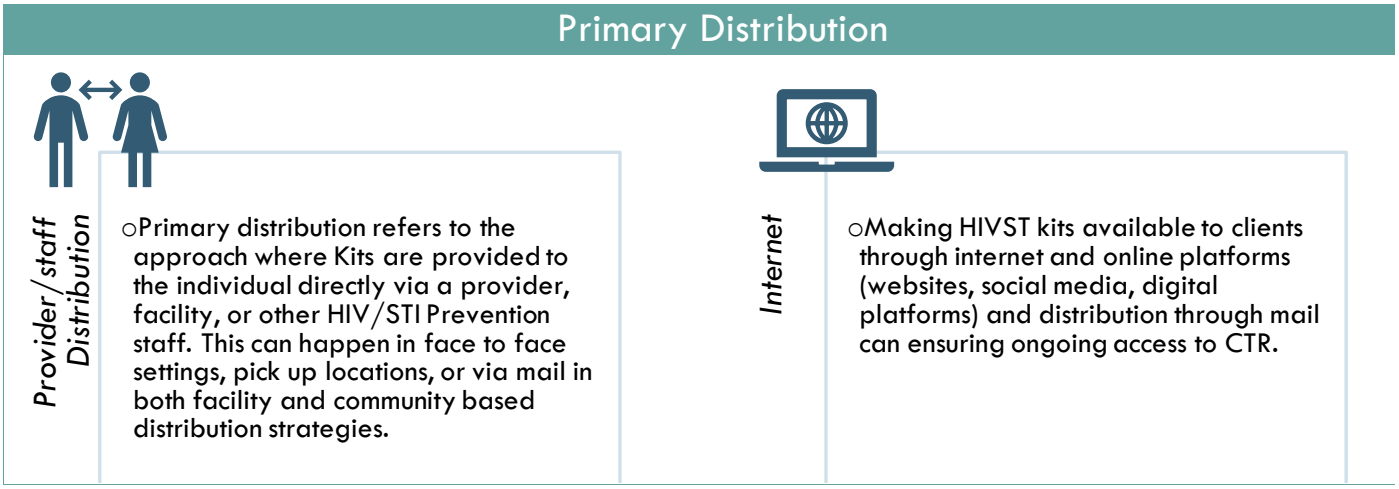
At the most general level, distribution occurs as either direct/primary or indirect/secondary, and testing events can be assisted or unassisted, depending on which options and approaches fit best for your agency. For each approach consider if assisted vs. unassisted, pre/post test counseling, service delivery, and follow up strategies.

> **NOTE**: Budgetary things to consider include – shipping costs, internet platforms for data collection, resources need for testing support and follow ups, and billing reimbursement if applicable.

### 3.2.1 Direct/Primary Distribution

Primary distribution refers to the approach where tests are provided to the individual directly via a provider, facility, or other HIV/STI Prevention staff. This can happen in face to face settings, pick up locations, or via mail in both facility and community-based distribution strategies

- **Internet-Based:** Making HIV self-tests available to clients through internet and online platforms (websites, social media, digital platforms) and distribution through mail can expand access to CTR.




### 3.2.2 Facility Based Distribution

Facility-initiated or facility-based HIV testing approaches allow clients to use HIV self-test kits at home or in a private setting of their choice. This approach employs trained providers, either health professionals (e.g. health care workers, pharmacists, counselors) or lay providers (e.g. community-based distribution agents, peer-educators, community health care workers, expert clients, peer navigator, etc.).

## Facility Based Approach

**Provider ordered Home Specimen Collection Kit**

- A home specimen collection kit can be used to test for HIV and (STI). ordered by physicians and are covered by most insurance plans. Specimen kits are mailed to the participant's home and contain supplies to collect blood from a fingerstick or other appropriate method (e.g. self-collected swabs and urine). The kit is then mailed back to the lab with test results returned to the clinician who acts on results accordingly. This laboratory-conducted test is sensitive enough to detect recent HIV transmission.

**Tele PrEP**

- Telehealth programs providing PrEP use technology to reduce stigma, address privacy concerns, and improve access to resources. Initial patient-to-provider consultations are done remotely through either a (HIPAA) compliant video conferencing platform, telephone call, or a HIPAA-compliant text messaging platform. Clients interact with a PrEP-friendly provider privately and conveniently at a time and setting of their choice.

**Service Integration**

- Integrating HIVST into the service offerings other venues/programs can expand choice for users and improve efficiency for service provision through increased testing capacity and higher throughput of clients. Examples of integration with other service could include Covid testing/vaccines, SSP programs, STI testing, family planning visits.

### 3.2.3 COMMUNITY- BASED DISTRIBUTION

This approach draws upon outreach best practices and client centered approaches to meet people where they are. This includes prioritizing areas with HIV testing coverage and ART coverage gaps or where priority populations can be found. Methods for distribution includes street outreach, home delivery, site specific pickup locations and/or in other highly utilized areas/social venues.

Alternative venue-initiated or venue-based approaches involve public distribution or sale of HIV rapid diagnostic tests for self-testing through pharmacies, vending machines and other venues –

## Community Based Approaches

**Community Level Targeted Distribution**

- Self- test kit users can also collect kits from the community-based distributors home or from other more permanent distribution points, if preferred. Examples:
  - Community Outreach
  - Community partner organizations

**Mobile Unit Distribution:**

- Is one method to ensure priority populations have access to services particularly in area's with high level of services gaps.

**Pharmacy**

- HIVST is available formally over-the-counter through pharmacies and other retail venues.

**Vending machines**

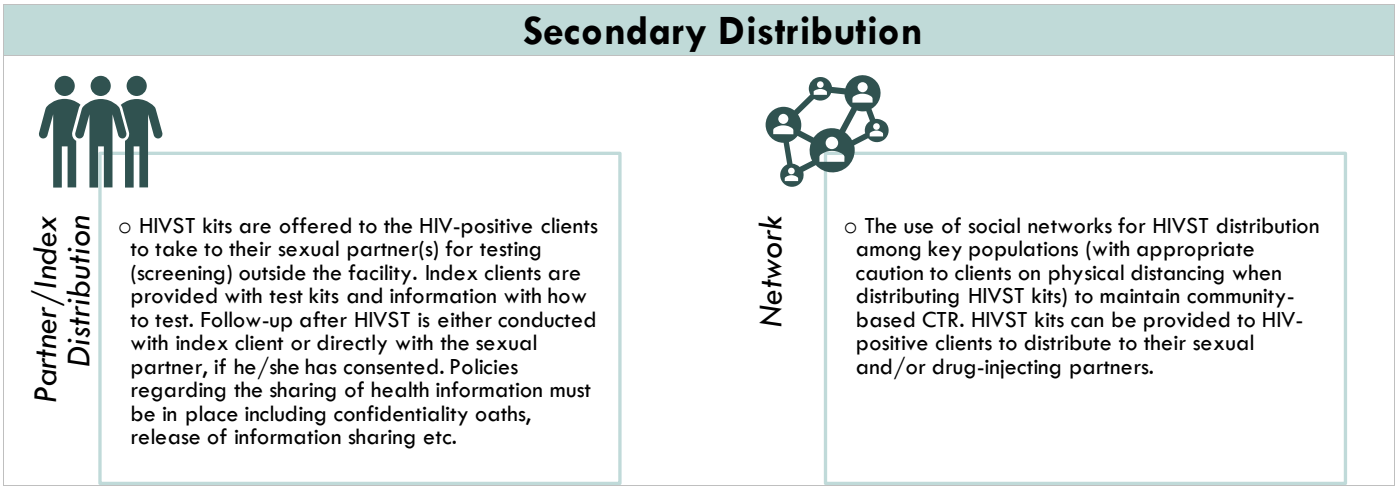
- Vending machine main advantages are the convenience, privacy and confidentiality. vending machine should only be installed in places that could ensure privacy.

### 3.2.4 SECONDARY DISTRIBUTION

This refers to distribution among partners (including sexual and drug injecting partners) and via social networks by a person (either HIV positive or negative), who presents at health care facilities or HIVST distribution points at community level and workplaces, pharmacies, etc. For this approach to be effective, it is important that the initial HIVST distribution include:

- Screening for intimate partner violence (IPV)
- Information on how to self-test
- Information on how to offer and demonstrate a self-test
- Verbiage on the importance of avoiding non-coercive practices
- Information on linkage into confirmative testing, Care and Treatment or HIV prevention
- If indicated: consent for provider follow up with the self-tester directly

This approach can increase testing uptake among people who would otherwise not test and are put at an increased chance of acquiring (e.g. sexual or drug injecting partners of HIV positive index clients) and potentially help facilitate linkages to care and treatment.




## 3.3 Social Marketing

HIV self-testing options can be promoted via agency social media or other communication channels used to market agency services. The keys to effective social media outreach are identifying audience(s) of priority, determining objective(s), knowing outlet(s), and deciding on the amount of resources (time and effort) that can be invested.

Educating the community – including networks of people with HIV, such as communities of focus, trained testers and health workers – about HIVST is critical in order to increase the uptake of self-testing and minimize the likelihood of misuse. It is also important to communicate to providers that HIVST can serve as a tool to create demand for existing services and, thereby, enhance their role in delivering CTR. Information tools such as brochures, job aids and standard operating procedures can also be useful in increasing understanding and raising awareness, especially when combined with training and information sessions.

> **NOTE:** Social marketing can be expensive. It's important to consider this when planning a budget. You can utilize the tool in appendix D to help plan for these costs. See CDC's The Health Communicator's Social Media Toolkit (cdc.gov) for specifics.

### 3.3.1 RECRUITMENT MESSAGING

Agencies should advertise on social media, websites, dating apps, customized agency testing apps, and radio. They also use print advertising strategies by placing information in magazines, at bus stations, on billboards, business cards, and flyers. Some digital platforms, such as Facebook Live®, enable testers to be on a call and to have real-time conversations with clients. This allows demonstration and instruction on how to use a test. Agencies may focus their marketing to populations of priority by utilizing social media and websites that are popular among those populations and by pinpointing specific geographic areas. To ensure marketing materials are tailored to priority populations, agencies can host a virtual focus group to receive community members' feedback.

The standard steps for developing a promotion strategy include:

- Develop communications objectives and key messages.
- Develop a campaign strategy and produce communication assets.

- Identify priority channels.
- Consider pre- and post- communication testing.
- Implement the communication/promotional campaign.

## KEY ADVERTISING AND SOCIAL MARKETING AVENUES

**Internet**

- Promote your HIV self-test program on your homepage.
- Link to a supporting webpage for more information, including:
  - how to request and get a test.
  - link to a questionnaire (if you have eligibility requirements).
  - phone and email for clients to reach out with questions.
- Include wrap around content on HIV testing, plus supporting resources on PrEP and HIV treatment.
- Utilize internet ad banners like google via search engine marketing (SEM) allows you to grow your business in a crowded and competitive marketplace strategically. With search engine ads consisting of the right keyword and quality score, you position your business at the top of SERPs when customers query the search engine.

**Social Media**

- Host a Live event on Facebook/Instagram to answer questions about HIV testing.
- Consider dating and hook up apps for messaging.
- Grindr
- Scruff
- Squirt

**Outreach and Collaboration**

- Consider pop-up or other outdoor testing opportunities in high-traffic areas.
- Think outside the box and consider venues that individuals frequent that are not necessarily a consistent partner.
- Gas Stations
- Rest Stops
- Consider collaborating with other agencies to promote and distribute test kits and other wrap around services.

**TV/Radio/Streaming**

- Radio ads are quite effective if directed at the right audience. With short airtime given, you need to squeeze your ad and have it run several times.

**Print Materials**

- Consider placing information in magazines, restrooms at bus stations, on billboards, business cards, and flyers.

### 3.3.2 TESTING SUPPORT MESSAGES

Pre-test information and post-test counselling messages should be readily accessible and available – for instance, through package inserts or brochures, hotlines, text message services, in-person demonstrations, counselling delivered by trained providers, volunteers or peers, Internet- or computer-based programs, or videos posted on the Internet.

Appropriate, validated, clear and concise instructions for the use of HIVST kits are critical to minimize errors and maximize the performance test devices. Printed instructions – written and/or pictorial – are essential to support correct use and interpretation. In-person demonstrations of how to use HIVST kit, along other support tools, such as telephone-based or Internet-based messaging services, which provide information on HIVST and answer questions about how to perform a self-test and interpret a self-test result.

Clear messages are needed to ensure that users understand their result and what to do next. Specifically the following messages must be included:

- **A reactive result** must be confirmed through further HIV testing. Additionally, messaging on what to do after a reactive self-test result is crucial, including where to go to access stigma-free CTR, HIV prevention, treatment and care and other support services.
- **A negative self-test result** does not always indicate that a person is HIV-negative, information about the window period and other HIV prevention options, such as condoms and PrEP and reduction of vulnerable behaviors should be addressed.
- **Messages and information on tuberculosis, STIs and viral hepatitis.** Brochures and flyers distributed together with HIVST kits, containing information on HIV testing services (CTR) and HIV prevention, treatment and care, as

well as information on other diseases such as tuberculosis, bacterial sexually transmitted infections and viral hepatitis.

# 4 COUNSELING, TESTING AND REFERRAL AND FOLLOW UP

## 4.1 COUNSELING AND TESTING

Per CDC guidance all testing events should include some type of pre- and post-test counseling. Depending on the distribution method, it will vary the level and type of support provided – such as, directly assisted and unassisted methods. Note that all approaches must follow HIPAA compliance and regulations.

- **Directly assisted:** refers to trained providers or peers giving people an in-person or virtual demonstration before or during the test event of how to perform the test and interpret the test result.
- **Unassisted:** refers to when people self-test by themselves and only use with manufacturer-provided instructions.

| SUPPORT TOOLS | DIRECTLY ASSISTED | UNASSISTED |
|---|---|---|
| Brief in-person, one-on-one or group demonstrations on how to correctly use the kitand how to interpret the results | ✔ | |
| Internet-based, virtual, or social media demonstrations on how to correctly use the kitand how to interpret the results | ✔ | ✔ |
| In-person assistance during self-testing procedure | ✔ | |
| Instructions for use:<br>Pictorial/written<br>Brochures or flyers that include information on local HIV services and contact details, for example, health clinic, 24hr hotline<br>Multimedia instructions | ✔ | ✔ |
| Remote support via telephone, social media, text message, QR code, Internet-based or mobile messaging applications | ✔ | ✔ |

Both directly assisted and unassisted may supply additional support tools, such as telephone hotlines, mobile phone text messages, videos, social media and Internet-based applications, which provide technical support, counselling and referrals for further HIV/STI testing services, HIV prevention, care and treatment and other services. Regardless of the strategy/approach tools to support test utilization and linkage to care should be included in the package.

Pre- and post-test counseling can occur virtually, face to face, via chats, etc. If you have access to secure video conferencing, you may consider offering to join the client virtually while they take the test, to walk them through the sample collection, observe the test result, and provide immediate post-test counseling. If clients would prefer to take the test in full privacy, encourage each client to follow up with you with the test result. If you don't hear back from the client, follow up with them in a couple of days. If you are able to connect via secure conferencing please follow your agency's consent protocol. For all test packages delivered, agencies may consider including educational materials on HIV testing, and related prevention and care resources available locally.

**PLEASE SEE BELOW FOR EXAMPLES FROM A LOCAL CBO ON THEIR TESTING AND FOLLOW-UP PROTOCOL:**

"The Project Manager will verify eligibility of all individuals completing the screener, explain the in-home testing pilot project (virtually), and obtain electronic informed consent to enroll them in the project. After agreeing to understanding all components of the project, participants will provide a mailing address where they would like the in-home rapid HIV testing kit sent. Testing materials will be mailed in discreet packaging via United States Postal Service (USPS) priority mail with delivery confirmation to the address requested. The testing materials package will also include safer sex materials such as condoms and lubricant, and educational HIV and brochures containing information about sexually transmitted infections (STIs)."

## 4.2 FOLLOW UP & REFERRALS

Similar to recruitment and distribution strategies, the follow up is dependent on staffing and distribution method and may need to be reevaluated as programs develop. Follow up on results must be conducted, however that may look different between organizations. Some approaches used to date have included live, online two-way text, audio or video counselling services and programs that offer step-by-step instructions on what to do following a reactive self-test result.

**NOTE**: Agencies that chose to have call-in options must ensure that the message indicates this is a secure line, instructions for reporting their result (i.e. provide sticky number and then result) it should also include where they can follow up if they have more questions and any next steps that may be initiated.

## FOLLOW-UP STRATEGIES INCLUDE:

- **Online survey or portal:** either included with the materials via a QR code, sent on a predetermined schedule to client, so that an individual could report a result directly to provider.
- **Two way texting or calls:** Mobile phone text messages services can provide information, reminders, videos and messages that encourage linkage following HIVST. Proactive, community-based follow-up by peer and/or outreach workers (in-person or via telephone/text message/social messaging platforms). Telephone calls, text messages or social media counselling messages and reminders) and digital platforms for self-reporting of outcomes and linkage facilitation: Follow-up counselling, messages and reminders can be used to follow up with self-test users on their individual test results through self-reporting and to facilitate linkage to further testing, prevention and treatment.
- **Champion or partner reporting :** Couples and partner HIVST can promote linkage Follow-up after HIVST is either conducted with index client or directly with the sexual partner, if he/she has consented. Partners are invited to return to the health facility for confirmatory testing and referral/linkage into care and treatment. Follow up of index clients and referral/linkage facilitation can also be done at community level via peer navigator, expert client, community health care workers, etc.
- **Result/appointment post cards:** that are pre addressed and stamped: cards should have the sticky number and confidential way of designating results given to clients may facilitate linkage by including the day and time of an appointment or the name and phone number of a contact person and facility where services can be sought. Distributing referral/appointment cards together with HIV self-tests – with information materials and brochures and contact details on where to access further HIV testing, prevention and treatment can help facilitate linkages. These materials should be adapted to the local context and ideally directly link to existing health care facilities in the catchment areas of HIVST distribution. provided as supplementary materials by implementing partners.
- **Financial or in-kind incentives:** can be utilized to encourage users to report and share information about their HIV self-testing experience. Vouchers, coupons or rebates may facilitate linkage, particularly among populations facing structural barriers to accessing services, such as long distance and costly transportation .
- **Community outreach and follow-up:** Follow-up community health care workers, peer educators, peer navigators, referral facilitators and other community-based cadres can be a useful strategy for facilitating linkage to further testing, prevention and treatment. This approach is in particular important for follow up of sexual partners of index clients, who received HIV self-tests through their HIV positive partners and for male sexual partners who received HIV self-tests through secondary distribution. This can include offering community-based confirmatory testing, prevention and treatment while HIV self-tests are distributed or on an ad hoc basis. Community workers and peer navigators may also accompany those with a reactive self-test result to receive further testing and care in a facility.

### PLEASE SEE BELOW FOR EXAMPLES FROM A LOCAL CBO ON THEIR TESTING AND FOLLOW UP PROTOCOL

Participants will have the option to be connected to a virtual counselor during the in-home testing and follow-up process. Whether they choose to schedule with a virtual counselor and collect testing specimens in real-time or inform project staff that they have received the in-home test kit and complete testing without assistance, they will complete a pre-testing assessment on HIV knowledge, HIV testing experience and influence of the COVID-19 pandemic on their health choices. Participants will also complete a 90-day post testing follow-up assessment about their sexual health practices since completing in-home testing. Finally, they will complete a program evaluation.

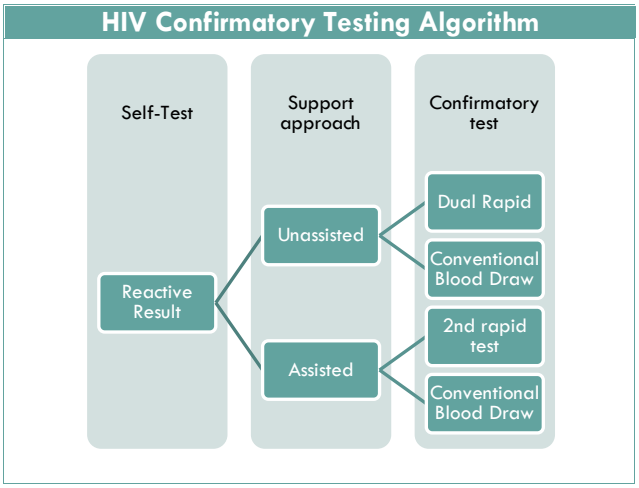
## 4.3 Linkage to Care & Referrals

### Reactive Results/Preliminary Positive

Follow up protocols for reactive results should continue regardless of how result was reported. Confirmatory testing and linkage to care must be conducted. Have tools available that support testers' links to counseling, treatment, and/or prevention after a self- test. Tools should allow the tester to opt-in, use the highest level of technology available to the populations of priority (e.g., phone, Internet, smartphone), offer the option of speaking to a human and direct community follow-up, and protect the privacy and confidentiality of the self-testing experience. Assure treatment for clients who test positive in accordance with the Centers for Disease Control and Prevention's Treatment Guidelines.

#### Confirmatory Testing

If an individual reports a reactive result confirmatory testing must be done. If the person refuses to get confirmatory testing with your agency encourage the person to go to the LHD or provider and follow up with client to confirm linkage. If the initial reactive result was self reported, a dual rapid or conventional blood draw will be required as confirmatory. See diagram to the right for more information.




#### Follow-Up For Confirmatory Test Results

If a client has tested confidentially with a rapid test at point of care, has a reactive result for HIV, and fails to return for their test confirmatory results, the agency must refer this client to the appropriate local public health agency for follow-up, notification of results, and prevention counseling. Similarly, if a client receives a reactive result in an agency with referral to LHD for confirmatory testing, the agency must follow up with the LHD to record confirmatory test result.

**Partner Services:** Regardless of if agency is diagnosing or reporting a preliminary reactive result Partner Services should be notified via the case report form.

#### Disease Reporting

All reactive results must be reported to MDHHS surveillance via the Adult Case Report Form. Pursuant to state law, HIV positive tests results are to be reported to the LHD within seven (7) days after receiving the test result from the laboratory of individual. Information is to be submitted on the Adult HIV/AIDS Confidential Case Report (DCH #1355).

- Reference: Act 489 of 1988, MCL 333.5114.

LHD PS staff are mandated to follow up with all diagnosed individuals and their partners.

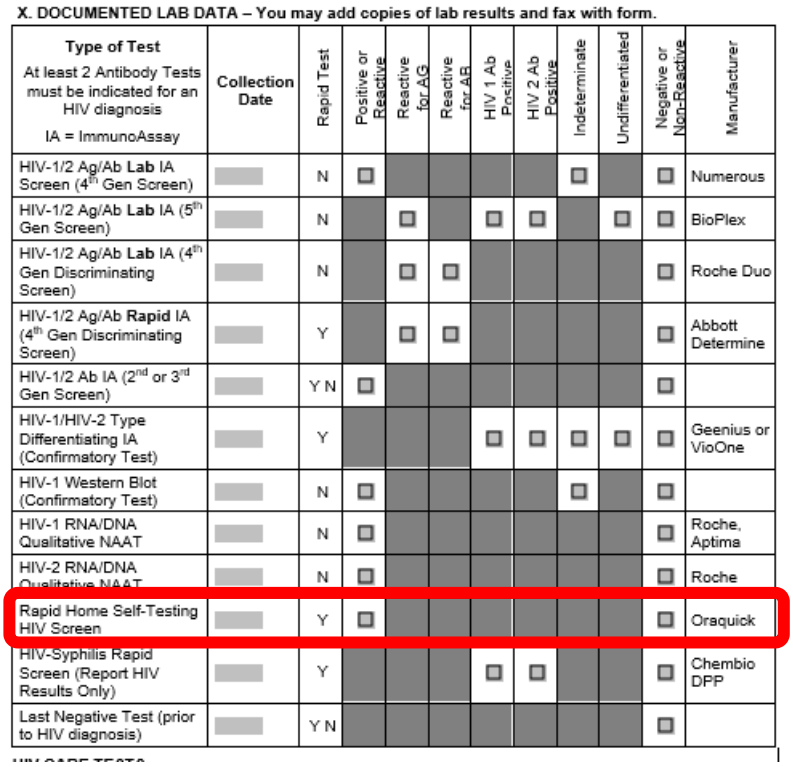
- Reference: Public Act 489 333.5114a

Note: See Health Professional's Guide to Disease Reporting in Michigan: A Summary of the Michigan Communicable Disease Rules (rev. April 2015) When a dual rapid is utilized to confirm diagnosis, the case report form must be completed noting confirmation status and the different devices utilized

#### Case Report Form

The Michigan Adult HIV Confidential Case Report Form (ACRF) is Michigan's version of the Centers for Disease Control (CDC) 50.42A/50.42C and, as of the date of its release, replaces all prior HIV and AIDS case report forms for age 13 and over. (A separate form, DCH-1402, is used for reporting HIV/AIDS in persons under age 13.) Instructions for each section of the form are described below.

**EXAMPLE OF CASE REPORT FORM**



**X. DOCUMENTED LAB DATA – You may add copies of lab results and fax with form.**

| Type of Test<br>At least 2 Antibody Tests must be indicated for an HIV diagnosis<br>IA = ImmunoAssay | Collection Date | Rapid Test | Positive or Reactive | Reactive for AG | Reactive for AB | HIV 1 Ab Positive | HIV 2 Ab Positive | Indeterminate | Undifferentiated | Negative or Non-Reactive | Manufacturer |
|---|---|---|---|---|---|---|---|---|---|---|---|
| HIV-1/2 Ag/Ab **Lab** IA Screen (4th Gen Screen) | | N | ☐ | | | | | ☐ | | ☐ | Numerous |
| HIV-1/2 Ag/Ab **Lab** IA (5th Gen Screen) | | N | | ☐ | | ☐ | ☐ | | ☐ | ☐ | BioPlex |
| HIV-1/2 Ag/Ab **Lab** IA (4th Gen Discriminating Screen) | | N | | ☐ | ☐ | | | | | ☐ | Roche Duo |
| HIV-1/2 Ag/Ab **Rapid** IA (4th Gen Discriminating Screen) | | Y | | ☐ | ☐ | | | | | ☐ | Abbott Determine |
| HIV-1/2 Ab IA (2nd or 3rd Gen Screen) | | Y N | ☐ | | | | | | | ☐ | |
| HIV-1/HIV-2 Type Differentiating IA (Confirmatory Test) | | Y | | | | ☐ | ☐ | ☐ | ☐ | ☐ | Geenius or VioOne |
| HIV-1 Western Blot (Confirmatory Test) | | N | ☐ | | | | | ☐ | | ☐ | |
| HIV-1 RNA/DNA Qualitative NAAT | | N | ☐ | | | | | | | ☐ | Roche, Aptima |
| HIV-2 RNA/DNA Qualitative NAAT | | N | ☐ | | | | | | | ☐ | Roche |
| Rapid Home Self-Testing HIV Screen | | Y | ☐ | | | | | | | ☐ | Oraquick |
| HIV-Syphilis Rapid Screen (Report HIV Results Only) | | Y | | | | ☐ | ☐ | | | ☐ | Chembio DPP |
| Last Negative Test (prior to HIV diagnosis) | | Y N | | | | | | | | ☐ | |

- Michigan Adult HIV Confidential Case Report
- Instructions to Complete Michigan Adult HIV Confidential Case Report

## NON REACTIVE RESULTS/UNKNOWN RESULTS

### REFERRALS

As with all HIV/STI testing, users who receive a non-reactive result should be encouraged to retest at least every year dependent on their individual engagement in behaviors that may increase the chance of HIV. Prevention options should also be recommended including condom use and PrEP.

# 5 QUALITY ASSURANCE

## 5.1 MATERIALS AND RESOURCES

One of the hallmarks of a QA program is comprehensive documentation. Sites using waived rapid HIV tests must have policies and procedures describing what QA records are required and how and when they are reviewed, stored, and destroyed.

### REQUIRED DOCUMENTATION

#### STAFF TRAINING REQUIREMENTS:

Staff responsible for providing direct prevention services must receive appropriate and culturally competent training to ensure they have the knowledge, skills, and abilities necessary to deliver high quality prevention services.

Specifically:

- Staff must successfully complete all training, certifications, and updates relevant and/or required to perform roles and responsibilities associated with their position. Training and certification requirements are described in the relevant sections of this document.
- Staff must be provided with copies of relevant programmatic guidelines and standards, including a professional boundary policy.
- Staff must receive training appropriate to implementation of the intervention(s).
- Staff must be provided with and oriented to program plans, including objectives, work plans, and timelines. Opportunities to periodically review and discuss progress toward meeting objectives should be provided.
- Staff must be provided with and oriented to all forms (e.g., consent forms), data collection tools, agency-specific procedural documents (e.g., record keeping, referral protocol), and data management systems (e.g., Aphirm) and trained regarding their use.
- Staff must be provided with regular educational and skills-enhancement opportunities, appropriate to performing roles and responsibilities associated with their position.
- Staff must be knowledgeable about confidentiality laws and agency-specific confidentiality policies and procedures.
- Staff must also be knowledgeable about available resources and strategies to support them in their role. This can include but is not limited to, employee self-care, employee assistance programs, professional development opportunities, and continuing education programs.

#### SUPPLY DOCUMENTATION

- **Temperature Logs**: these must include a daily record of the refrigerator and/or room temperature where test kits and external controls are stored and the temperature of the testing area. Thermometers must be placed in each location. Laboratory grade thermometers, which can be purchased from medical or laboratory supply houses, are recommended and their accuracy checked periodically (e.g., every six months) by comparison with another thermometer.
- **Client and Kit Logs**: these must include the date and time of testing, an identifier for the person being tested, a test kit lot number and expiration date, test result, action taken if the result was invalid, identification of the person who performed the test, whether confirmatory testing was requested, including the type of specimen sent for confirmation (e.g., oral fluid, blood), and the confirmatory test results when they are available. If more than one person is conducting testing, there should be a mechanism to chronologically link the test record log sheets to detect problems, such as invalid results occurring repeatedly with the same test kit lot number. See Appendix D.
    - Logs should be sent to MDHHS staff monthly per QA standards
- When necessary, contact the manufacturer for assistance and/or to report defective test system components.
    - OraSure: 1-866-436-6527

# 6 APHIRM REPORTING: RAPID HIV SELF-TESTING

ALL rapid HIV self-testing kits that have been **requested and distributed must be documented** into MDHHS data systems and reported per MDHHS disease reporting processes. Funded HIVST programs must follow contractual data reporting requirements (Aphirm/MDSS/QPR's*) and report the following measures:

**Quarterly Progress Reports:** Specific data requirements are outlined in your agency's approved workplan. Self-testing events will not be adversely counted towards program objectives but rather it is a supplement to an existing testing program.

**NOTE:** If HIV Prevention staff are involved (time and effort) in any part of the self-testing process, the test must be reported, regardless of how tests were acquired (donated or purchased).

Agencies will not be held to a positivity goal (e.g., 1%) for self-testing, but should continue to focus on populations of priority as was done for non-clinical testing activities prior to COVID-19.

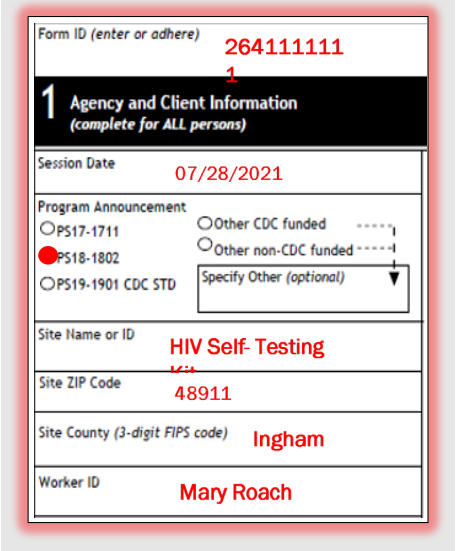
| *QUARTERLY PROGRESS REPORTS (CBO'S ONLY) REQUIRED REPORTING BY FUNDING ANNOUNCEMENT |
|---|
| • PS18-1802<br>○ total number of HIV self-test kits distributed<br>○ total number of people who received at least one HIV self-test kit<br>○ all required APHIRM fields |
| • PS20-2010<br>○ total number of HIV self-test kits distributed<br>○ total number of people who received at least one HIV self-test kit<br>○ total number of newly diagnosed HIV-positive persons<br>○ total number of previously diagnosed HIV-positive persons<br>○ tests with unknown results stratified by:<br>▪ demographics<br>▪ population group<br>▪ testing history |

## 6.1 DATA ENTRY: RAPID HIV SELF-TESTS

An example of how to complete the testing template for rapid HIV self-tests and description of the fields is outlined below. The information on the form is for a fake client and does not represent a real testing event. This information must be completed regardless of how a test is requested and distributed.

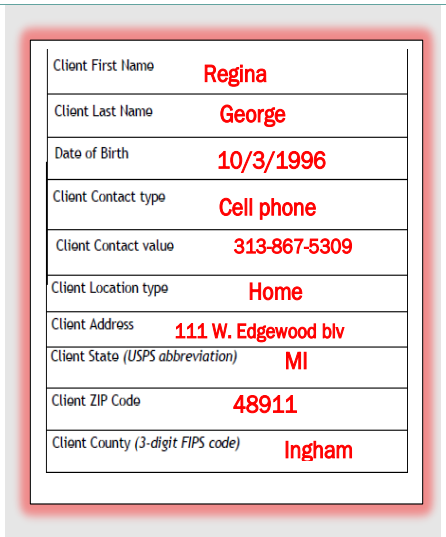
**Variables REQUIRED in Aphirm for All HIV Self-Test Kits Distributed**

Agency Information



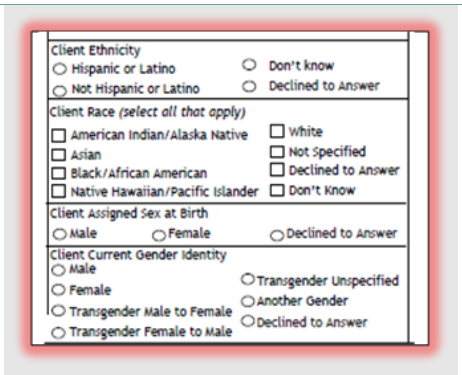

- Form ID: 10-digit sticky number. Sticky number should be placed on any materials that are associated with the self-test kit and for reporting of results.
- Session Date: Date of intake or day the self-test kit was requested.
- Program Announcement: select appropriate funding source (e.g., 1802, 2010, etc.) even if self-test kit was donated.
- Site Name:
  - HIV self-test
    - (OraQuick® rapid HIV self-test)
- Site Zip Code: Zip code of agency
- Site County: County of agency
- Worker ID: The person distributing and/or following up on the test

## Client Contact Information



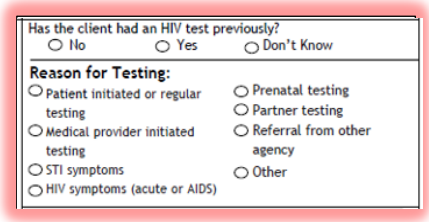

- Client First Name: full first name (do NOT put numbers, symbols, or single letters).
- Client Last Name: Full Last name
  ***Attention*** An actual name is preferred. If you have someone that is resistant, then use J DOE.
- Date of Birth: HIV self-tests should not be distributed to anyone under the age of 18.
- Client Contact Type/Value: Possible options include cell phone, social media handle, dating app profile name, etc.
- Client Location Type: Place test is sent to or where test is being administered.
- Client Address, State, Zip Code, and County: Where the client lives or where you are sending the HIV self-test. This is important in the event there is a recall or some error with the test, as follow-up can be conducted.

## Client Demographics



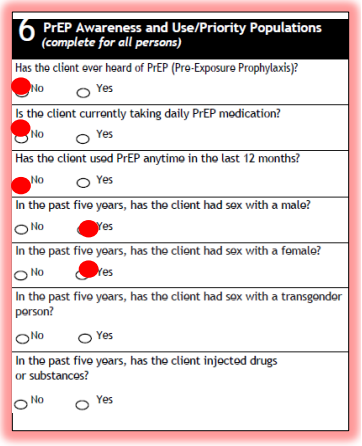

- Client Ethnicity: If the client is Arab or Chaldean document AC in *Local Field 1*.
- Client Race: Please mark what the client identifies.
- Client Assigned Sex at Birth: Please mark the sex the client was assigned at birth.
- Client Gender Identity: Please mark the gender the client identifies.

## Reason for Testing




- Has the client had an HIV test previously?
  - People who have never been tested should be prioritized.
- Reason for Testing: Choose patient initiated or regular testing unless otherwise specified.

## PrEP Awareness/Use and Priority populations




- Has the client ever heard of PrEP?
- Is the client currently taking PrEP?
- Has the client used PrEP anytime in the last 12 months?

People who report yes to the following should be prioritized

- In the past five years, has the client has sex with a male?
- In the past five years, has the client has sex with a female?
- In the past five years, has the client has sex with a transgender person?
- In the past five years, has the client injected drugs or substances?

Test Election


- HIV Testing Election: Select *Test Not Done* for all self-tests that have been distributed.

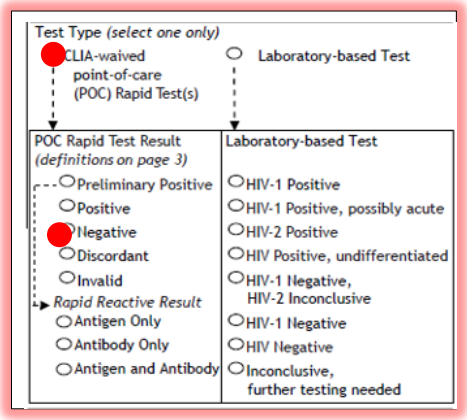
**NOTE**: At this point the rest of the form can be left blank until the result is received move on to 6.2 once the result is received.

## 6.2 Follow-up has been completed by client and/or tester and the result is now known.

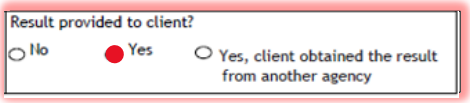
**NOTE:** DO NOT enter duplicate entries for the same test event. Search by name and wait patiently for the record search. That is, if a client's self-test result is initially entered in Aphirm as a point-of-care (POC) preliminary positive but then the client goes to a CDC-funded agency for confirmatory testing, update the final test information under the same test event (i.e., FORMID). Do not create a new test event (i.e., FORMID) for the confirmatory test. Aphirm will tell you there are no results while it is still searching. Please be patient.

### Editing Results in Aphirm When an HIV Self-Test Result is Reported

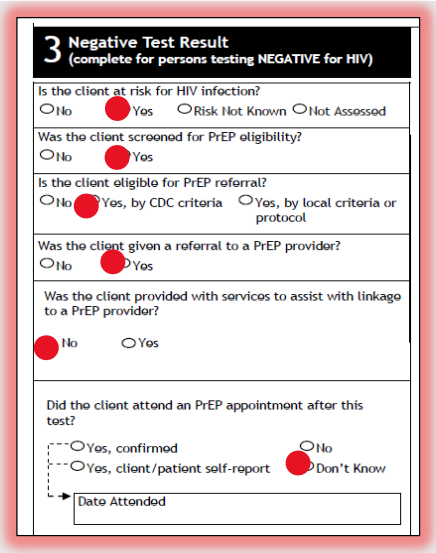

- HIV Test Election: Edit from test not done to confidential once test is completed.




- Test Type: For HIV self-testing, select CLIA-waived point-of-care (POC) rapid test(s).
- POC Rapid Test Result: This is the only selection that needs to be completed for an HIV self-test.
  - If confirmatory testing is conducted, update the final test information under the same test event (i.e., FORMID). Do not create a new test event.




- Result provided to client: Select Yes



**3 Negative Test Result**
**(complete for persons testing NEGATIVE for HIV)**

Is the client at risk for HIV infection?
○ No ● Yes ○ Risk Not Known ○ Not Assessed

Was the client screened for PrEP eligibility?
○ No ● Yes

Is the client eligible for PrEP referral?
○ No ● Yes, by CDC criteria ○ Yes, by local criteria or protocol

Was the client given a referral to a PrEP provider?
○ No ● Yes

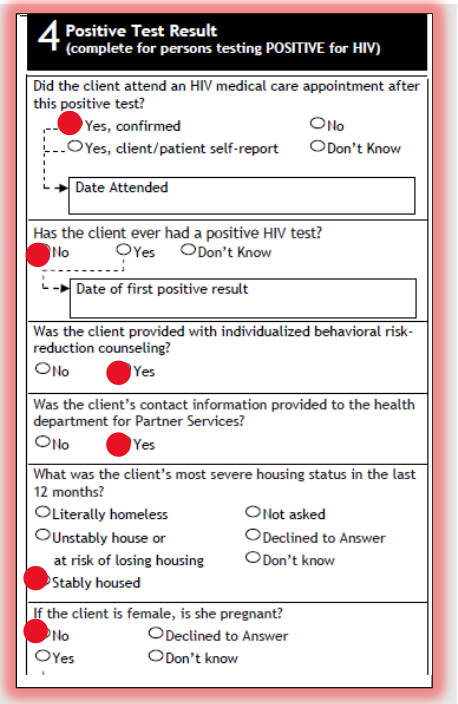
Was the client provided with services to assist with linkage to a PrEP provider?
● No ○ Yes

Did the client attend an PrEP appointment after this test?
○ Yes, confirmed ○ No
○ Yes, client/patient self-report ● Don't Know
→ Date Attended

- Is the client at risk for HIV infection?
  - This should be asked during intake as an eligibility criteria

PrEP questions need to be completed. Rapid HIV self-tests CANNOT be used for routine testing with persons already taking PrEP. A 4th generation test must be utilized for clients taking PrEP.

- Was the client screened for PrEP Eligibility?
- Is the client eligible for PrEP?
- Was the client given a referral to a PrEP provider?
- Was the client provided services to assist with linkage to a PrEP provider?
- Did the client attend a PrEP appointment after this test?



**4 Positive Test Result**
**(complete for persons testing POSITIVE for HIV)**

Did the client attend an HIV medical care appointment after this positive test?
● Yes, confirmed ○ No
○ Yes, client/patient self-report ○ Don't Know
→ Date Attended

Has the client ever had a positive HIV test?
● No ○ Yes ○ Don't Know
→ Date of first positive result

Was the client provided with individualized behavioral risk-reduction counseling?
○ No ● Yes

Was the client's contact information provided to the health department for Partner Services?
○ No ● Yes

What was the client's most severe housing status in the last 12 months?
○ Literally homeless ○ Not asked
○ Unstably house or at risk of losing housing ○ Declined to Answer ○ Don't know
● Stably housed

If the client is female, is she pregnant?
● No ○ Declined to Answer
○ Yes ○ Don't know

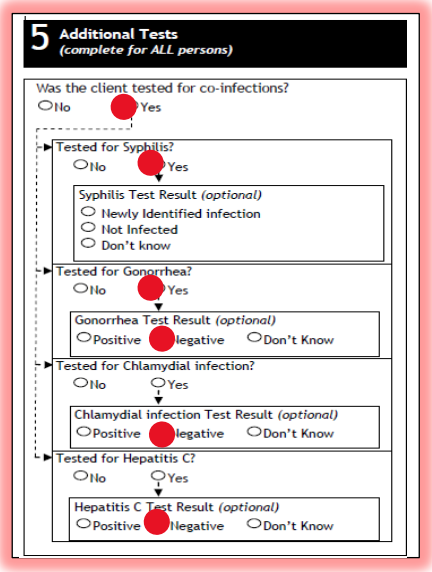
- Did the client attend an HIV medical care appointment after this positive test?
  - Date attended: CDC requirements are that linkage occurs within 30 days.
- Has the client ever had a positive HIV test?
- Was the client provided with individualized behavioral risk-reduction counseling?
  - CDC guidance is that everyone should receive 3–5-minute risk reduction counseling to reduce possible exposures.
- Was the client's contact information provided to the HD for PS?
  - This is required by state law.
- What was the client's most severe housing status in the last 12 months?
- Is the client pregnant? Pregnant people are a CDC priority population. State law requires pregnant people be tested in the first and third trimester
  - If Yes, are they in prenatal care?
  - If Yes, was the client screened for need of perinatal service coordination?
  - If Yes, was the client referred for need of perinatal service coordination?

**NOTE:** If a client self-reports a positive result, encourage them to get a confirmatory test. If the client is willing to come in for confirmatory testing, they must be tested via a dual rapid algorithm (see procedure) or via a blood draw. A single rapid POC test should not be used for confirmation. Do not create duplicate testing events for the client if you know the 10-digit sticky number.

The Case Report Form will need to be completed regardless of the status of a confirmatory test (i.e., if the client went to their provider or came to your facility). Please select self-test as the preliminary positive test.

**Sections to be Completed in Aphirm for all tests regardless of result. Please fill in all sections to the best of your ability, do not leave anything blank.**

## Additional Tests for Co Infections

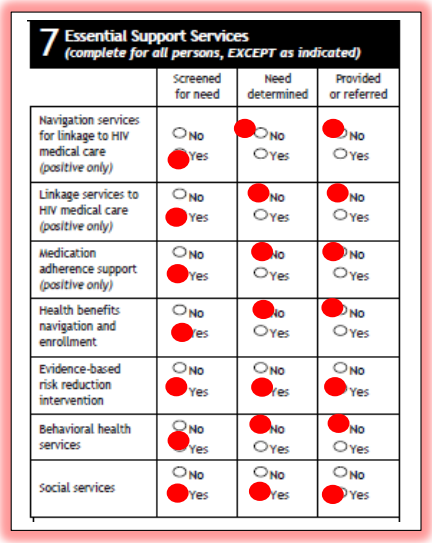



Agencies that do not provide STI testing: Select No.

Agencies that do provide STI testing: Complete for all tests regardless of results. Do not leave anything blank.

- Negative HIV test results can be entered once STI results are received.
- Reactive HIV test results still need to be entered within 48 hours. Do not wait for results from STI testing. This section will need to be edited to reflect the STI results once they are received.

## Essential Support Services




Essential Support Services: Complete this section for all persons, EXCEPT as indicated.

# 7 MONITORING & EVALUATION, AND QUALITY IMPROVEMENT

Monitoring and evaluation (M&E) are a critical part of any public health intervention, including HIVST. The M&E framework has a core function as part of the implementation process to ensure that the program is proceeding as planned; it provides routine information for decision making at all levels; and help to highlight areas where there are challenges or unexpected delays so that these can be identified and resolved quickly.

- It is recommended that your agency conduct on-going assessments regarding access, acceptance, and uptake of home testing kits. Please discuss this consideration with your designated DSHS consultant(s).
- Engage in ongoing QI activities focusing on specific processes that will improve the delivery and quality of HIV care and prevention services to persons who have an increased chance of exposure to HIV and PWH.
- Focus on the consumer. Understanding clients' experiences will help identify areas that are important for improving services.
- Collect and use data to improve services.
- Encourage participation in teams by those who implement the processes being evaluated.

## MONITORING AND EVALUATION

Internet and mobile phone surveys and tools can be used to encourage users to provide feedback on their experiences, including test failures and social harm or adverse events.

HIVST monitoring may require data collection across this HIVST delivery cascade, including:

- HIVST kit distribution.
- HIVST use and results.
- linkage to appropriate services following HIVST.

Improving data quality is a long-term task and should be a priority from the start of the implementation process. Some of the data quality improvement measures which you might need to adopt as part of your implementation process are:

# 8 Resources and References

Any HIV RDT for self-testing, either oral or blood, which is procured or used for HIVST should be approved by the relevant regulatory authority, or the results of an international regulatory review may be used.

Laws and regulations permitting the sale, distribution, advertisement, and use of in vitro diagnostics for HIVST will generally need to be adapted or developed. Countries must provide clear pathways for national validation and registration of HIVST kits. Countries where RDTs for HIVST are informally available may need to develop additional resources.

The following are additional resources:

A Summary of HIV Self-Testing Program Models and (cdc.gov)

NASTAD Self-Testing Toolkit: A Strategy to Improve Access to HIV, Viral Hepatitis, and STI Testing

CDC HIV Self-Testing Overview

The Health Communicator's Social Media Toolkit

HIV-Self-Testing-Ops-Guide.pdf (psi.org)

Telehealth for Health Centers: Telehealth Resource and Innovations for HIV Pre-Exposure Prophylaxis (PrEP) (ymaws.com)

Increasing Access to HIV Testing Through Direct-to-Consumer HIV Self-Test Distribution — United States, March 1, 2020–March 30, 2021 (cdc.gov)

MDHHS Regional Laboratory Manual and Resources

# 9 APPENDICES

## 9.1 APPENDIX A: HIVST READINESS ASSESSMENT

Complete the following tables as thoroughly as possible. Use this document to inform the creation of an agency- specific policy. The readiness assessment filled out does not need to be shared with MDHHS but your final policies and procedures for self-testing programs will need to be shared with us. Please DO NOT begin activities until your policy has been approved by MDHHS. The table below is fillable so you will not have to shorten your answers to fit the box size.

| Staffing | |
|---|---|
| **Questions for Consideration** | **Agency Answers** |
| Describe your staffing plan to implement rapid HIV self-testing | |
| What training will be required for staff (e.g., explaining testing and/or collection processes to persons requesting tests, reading/interpretation of results, documentation of activities)? | |
| Which staff will be utilized for follow-up communication? | |
| What staff will make appropriate referrals (on how to prevent the transmission of HIV/STIs/HCV including information on local prevention resources, including PrEP) as needed to those who receive test kits? | |

| Strengths of readiness | Barriers to implementation |
|---|---|
| • | • |

| Eligibility | |
|---|---|
| **Questions for Consideration** | **Agency Answers** |
| Describe your test kit eligibility criteria (e.g., geographic area, priority population, demographics, HIV/STI history or contacts, etc.)? | |
| How do you plan to screen for eligibility? | |
| How will you conduct behavioral assessments to determine what tests should be ordered for a client (i.e., online, video conference, phone)? | |
| Describe how the agency will ensure that only appropriate tests are provided to people based on medical history and/or assessment (e.g., GC/CT extragenital sites, persons with a prior HIV diagnosis should not receive an HIV test, persons with a history of syphilis should not receive a syphilis treponemal test)? | |
| What is the process for someone to request a test (i.e., agency website, phone contact or both)? | |
| How often can someone be given the test kit(s)? | |

| Strengths of readiness | Barriers to implementation |
|---|---|
| • | • |

| Marketing & Contact | |
|---|---|
| **Questions for Consideration** | **Agency Answers** |
| How will the new testing services be marketed and tailored specifically to the eligible focus populations? | |
| How will you evaluate the reach of the marketing plan to eligible focus populations? | |
| For kits sent out, what information will be given about how and when to contact your agency with questions? | |
| What strategic partnerships do you have or plan to make that will allow you to broaden the reach of your self-testing programs? | |

| Strengths of readiness | Barriers to implementation |
|---|---|
| • | • |

| Data Collection & Analysis | |
|---|---|
| **Questions for Consideration** | **Agency Answers** |
| How will relevant data (e.g., demographic information, priority population group, test result(s), result notification, referrals for confirmatory testing, referral to and confirmation of medical care/treatment, and referrals for other prevention services) be documented and tracked? | |
| What system(s) will be used? Be specific about how data will be entered and by whom. | |
| How will your agency obtain and document informed consent (e.g., to receive test kits, to be contacted by a staff member of your agency, for counseling, and medical services as applicable to the encounter)? | |
| How will your agency use the collected data to measure the success of your self-testing program? | |

| **Strengths of readiness** | **Barriers to implementation** |
|---|---|
| • | • |

| Follow-Up & Linkage to Care and/or Prevention Services | |
|---|---|
| **Questions for Consideration** | **Agency Answers** |
| Will staff members schedule time with those who have received an HIV self-test and conduct the process together or will persons collect the specimens on their own with the written instructions included with the kit? | |
| If persons will have a scheduled time with a staff member, what HIPAA compliant platform will be used to communicate with the person (e.g., video chat, phone, other telemedicine software or platform)? | |
| How will referrals for PrEP be handled for persons testing negative for HIV? | |
| What information will be provided to clients on how to prevent the transmission of HIV/STIs/HCV including information on local prevention resources, including PrEP? | |

| Strengths of readiness | Barriers to implementation |
|---|---|
| • | • |

| Privacy & Security | |
|---|---|
| **Questions for Consideration** | **Agency Answers** |
| How will you ensure that client information is kept private and confidential? | |
| What plan do you have in place for transferring collected data to MDHHS? Will data be transferred or manually inputted? | |
| Once data is delivered to MDHHS, how will your agency store/destroy original copies of PII? | |

| Strengths of readiness | Barriers to implementation |
|---|---|
| • | • |

## 9.2 APPENDIX B: EXAMPLE HIVST PRE-TESTING ASSESSMENT

(Table 1) HIV In-Home Pilot Pre-Testing Assessment EXAMPLE

| HIV KNOWLEDGE | TRUE | FALSE |
|---|---|---|
| Coughing and sneezing can spread HIV to others. | | |
| Having sex with multiple partners decreases your chance of getting HIV. | | |
| There is a vaccine that can prevent you from getting HIV. | | |
| HIV is spread through semen, breast milk, vaginal secretions, and blood. | | |
| HIV can be cured. | | |

| EXPERIENCE WITH HIV HOME TESTING | YES | NO |
|---|---|---|
| Taking an HIV test at home was easier than I thought. | | |
| Taking an HIV test at home was harder than I thought. | | |
| I would choose HIV testing at home over testing in a clinic. | | |
| I chose to test virtually with a counselor. | | |

| PANDEMIC INFLUENCE | YES | NO |
|---|---|---|
| If there was no pandemic, I would go to a clinic for an HIV test. | | |
| I chose home testing because of the privacy. | | |
| I chose home testing because of HIV stigma. | | |
| I am willing to go to a clinic for an HIV test. | | |
| I chose home testing because I can't get to a clinic. | | |

(Table 2) HIV In-Home Pilot Post-Testing Assessment EXAMPLE

| HIV KNOWLEDGE | TRUE | FALSE |
|---|---|---|
| Coughing and sneezing can spread HIV to others. | | |
| Having sex with multiple partners decreases your chance of getting HIV. | | |
| There is a vaccine that can prevent you from getting HIV. | | |
| HIV is spread through semen, breast milk, vaginal secretions, and blood. | | |
| HIV can be cured. | | |

| EXPERIENCE WITH HIV HOME TESTING | YES | NO |
|---|---|---|
| Taking an HIV test at home was easier than I thought. | | |
| Taking an HIV test at home was harder than I thought. | | |
| I would choose HIV testing at home over testing in a clinic. | | |
| I chose to test virtually with a counselor. | | |

| PANDEMIC INFLUENCE | YES | NO |
|---|---|---|
| If there was no pandemic, I would go to a clinic for an HIV test. | | |
| I chose home testing because of the privacy. | | |
| I chose home testing because of HIV stigma. | | |
| I am willing to go to a clinic for an HIV test. | | |
| I chose home testing because I can't get to a clinic. | | |

## 9.3 APPENDIX C: EXAMPLE HIVST EVALUATION

(Table 3) HIV In-Home Pilot Evaluation EXAMPLE

Thank you for taking the time to provide feedback on the in-home HIV testing program you participated in. Your anonymous and honest opinion is very important to us. This survey should take no longer than ten minutes.

Please select the date you are completing this survey: (*will have calendar*)

---

Please enter the zip code where your test was mailed:

---

How long after receiving your in-home test did you use it? (*select 1*)

Within a day

Within a week

Within a month

Did you schedule an appointment with virtual test counselor? *(If no, then skip next 3 questions)*

Yes No

The virtual test counselor was friendly agree disagree

The virtual test counselor answered my questions agree disagree

The virtual test counselor boosted my confidence agree disagree

Why did you choose not to take the test with a virtual counselor?

_____

Please let us know how much you agree or disagree with the following questions:

| | Agree | Disagree | Not Applicable |
|---|---|---|---|
| My in-home test kit materials arrived discreetly | | | |
| The testing instructions were easy to follow | | | |
| Scheduling with a virtual counselor was easy | | | |
| I would take an HIV test in-home in the future | | | |

Is there anything else about the in-home testing program or process you would like to share?

_____

## 9.4 APPENDIX D: EXAMPLE HIVST CLIENT CONTROL LOG

# OraQuick® Rapid self-testing HIV 1/2 Assay Client Log

For each self-testing distributed please complete the following information. Use one log for each diagnosis.

| | | | | |
|---|---|---|---|---|
| **Agency:** | | **Kit Lot Number** | | **Shipment was received Date** |
| **Distribution site:** | | **Kit Expiration Date** | | |
| **Date kit was sent** | **Client ID** | **Date Result reported** | **Results[3]** | **Initial or Counselor ID #** |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| **Site Coordinator Signature:** | | | | |
| **Date:** | | | | |

3. Record test results as: R=Reactive; NR=Non-Reactive UK= unknown