

“SELF-TESTING” :

A Strategy to Improve
Access to HIV, Viral
Hepatitis, and
STI Testing

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Background

Strategies which allow consumers to control when, where, and how they test for HIV, viral hepatitis, or sexually transmitted infections (STIs) play an increasingly important role in expanding and ensuring access to testing for these infections. Consumers experience a variety of barriers to accessing testing services such as travel distance to testing providers, hours of operation of the clinics or programs offering testing, competing priorities such as work or school, lack of culturally competent providers, stigma, and cost. The “[Diagnose](#)” pillar of CDC’s [Ending the Epidemic](#) initiative highlights the value of leveraging testing strategies and test technologies, in new and creative ways, to make HIV testing easier for consumers to access and promote earlier diagnosis and linkage to care. More recently, the COVID-19 pandemic has resulted in fundamental shifts in our healthcare delivery system and increased the necessity of alternative strategies to in-person health care services, such as the expanded delivery of health care and public health services through telemedicine. In this context, the value of access to testing with minimal intervention or involvement of a healthcare provider has increased. There are several models that allow consumers more control over various components of the testing process (e.g. collecting samples, performing a test). These are distinguished by how a consumer accesses testing services (i.e. point of entry), where and who collects a sample (i.e. sample collection method), and where and who performs the test (i.e. sample testing method). Throughout this document we’ll refer to all of these models by the short-hand of “self-testing”. Each model presents different opportunities to increase access to testing, as well as potential challenges.

Health department HIV, viral hepatitis, and STI programs should be familiar with the landscape of self-testing models as they will need to determine the role(s) that these testing models will play within their broader disease prevention and control efforts, and how each can contribute to achieving public health goals and objectives. Health departments may support or promote one or more self-testing models to increase access to and use of HIV, viral hepatitis, and STI testing services within their jurisdiction. Regardless of how a health department chooses to approach these models it is critical that they are aware of the different self-testing options available to consumers in their jurisdictions including which tests are being performed (i.e. in terms of pathogens and the specific tests or series of tests used), as well as the potential limitations of these tests and associated sample collection methodologies. This information will be important to ensure that health departments are informed about reportable conditions in their jurisdiction, to facilitate linkages to treatment and preventive services, and to enable appropriate contact tracing and partner notification. Additionally, health departments should consider providing information or education regarding the different models and methods of self-testing to help consumers in their jurisdiction make informed decisions.

Intended Audience

This toolkit is targeted to health department program managers and coordinators who have responsibility for HIV, viral hepatitis, and/or STI testing and linkage programs. It provides health departments with information about testing strategies and test technologies that enable consumers to access testing independent of traditional health department testing programs (e.g. testing offered in health department clinics, community-based testing programs, and outreach venues) and/or other healthcare providers. This tool may also be useful to other entities such as public health laboratories, public health agencies, community based organizations, or other stakeholders involved in supporting appropriate testing for consumers. In this way, this toolkit is intended to serve as a resource to increase health department understanding of self-testing models, highlight the benefits and challenges associated with such models, and offer strategies to support health departments in optimizing self-testing strategies within their overall testing and linkage programs. [Additional information and resources for health departments on self-testing strategies are available from the CDC.](#)

Overview of Self-Testing Strategies

This tool provides an overview of the factors that distinguish the different models of testing including point of entry, alternatives for sample collection, and where and by whom testing is performed. Models vary in terms of where they may be available, who is eligible to receive testing, and cost and coverage by health insurers. Consumers should always be advised to check with their health insurance plan to determine coverage. Examples of currently available commercial tests and testing services are available in [Appendix A](#). Health departments may support or promote one or more models of self-testing.

Points of Entry

Consumers may access testing services with or without a healthcare provider involved in a testing event. Direct-access testing is entirely consumer controlled. Healthcare provider-mediated testing involves a consumer engaging with a healthcare provider at one or more points in the testing process (i.e. to have a test ordered, obtain sample collection kits, or receive test results).



DIRECT-ACCESS TESTING

Many states allow consumers to obtain testing without an order from a healthcare provider. In the direct-access model of testing, a consumer accesses testing without the involvement of a healthcare provider to order tests, obtain samples, or deliver results. A consumer may access testing by purchasing tests, test kits, or sample collection kits online, in a pharmacy, or by ordering tests through a company providing direct-access testing services. Test results are delivered directly to the consumer. Assistance with sample collection or test result interpretation is provided through printed materials, a website, video, and/or through consumer support provided e.g. by telephone or computer chat.

Cost: Some health insurance plans may not cover some or all of the costs of testing unless a healthcare provider has ordered tests and/or interpreted results. The cost to a consumer and coverage by health insurance of direct-access testing varies based upon the type and number of tests being performed, and the company providing testing services.

HEALTHCARE PROVIDER-MEDIATED TESTING

In this model, in conjunction with testing, the consumer has a consultation with a healthcare provider, such as through their primary care provider or a commercial testing service. Typically, a healthcare provider consultation is conducted via telemedicine (e.g. video, phone, text message). After a brief assessment/consultation, the healthcare provider submits an order for test(s) at a commercial laboratory, or sends sample collection kits to a location of the consumer’s choice. The consumer then presents at the laboratory to provide samples; or, in the case of self-collected samples, provides the samples, and sends the samples to the laboratory. The extent to which a healthcare provider is involved in delivering results, clinical consultation and/or prescribing treatment or follow-up testing varies by the particular service.

Cost: Cost to a consumer and coverage by health insurance may vary depending on factors such as who provides services (e.g. an individual’s primary care provider or commercial testing service), and how those services are rendered (e.g. in-person or via telemedicine). With respect to commercial testing services, e.g. Nurx or PlushCare, testing costs vary depending on the number and type of tests provided. Consultation with a healthcare provider is usually an additional fee. While commercial testing services may accept health insurance, an individual’s health insurance plan may not cover the costs of tests or clinical consultations, or may cover them at out-of-network rates.



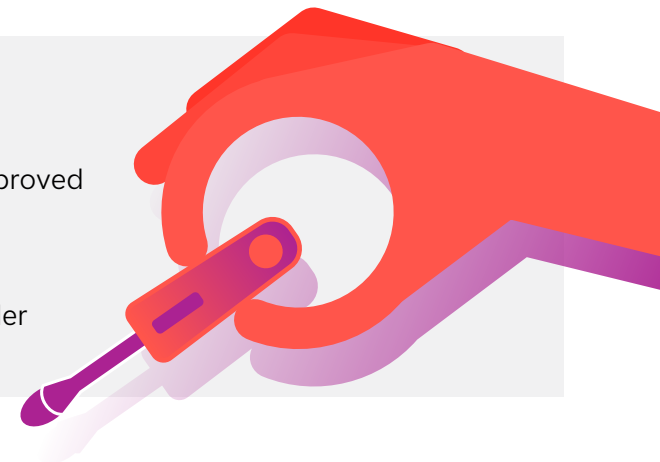
Sample Collection and Testing Method

There are different sample collection and testing methods available to consumers. The different sample collection and testing methods fall into three groups, each of which may be consumer directed or mediated by a healthcare provider.

Self-Collection and Self-Testing

The consumer collects the sample, performs the test, and interprets the test result in their home or other location of their choosing. This is often referred to as “home-testing”. A kit that includes all of the necessary materials may be purchased at a pharmacy, ordered online, or through an app. The consumer follows the directions to collect the sample, performs testing on the sample, interprets the result, and has the option to obtain medical advice, usually by phone, for counseling and appropriate next steps, including linkage to treatment.

- FDA-Approved/Cleared Testing: HIV
- Sample Type: Oral fluid
- Commercially Available Options: OraQuick® In-Home HIV Test is the only FDA-approved device for self-testing.
- Cost: Consumer-purchased OraQuick® costs approximately \$36.00.
- This is only a screening test. Supplemental testing provided through a healthcare provider is necessary to confirm positive or indeterminate results.



Self-collection (non-healthcare setting) and Laboratory Testing

The consumer collects a sample(s), in their home or other location of their choosing, and sends samples to a laboratory for processing. A kit that includes materials for the sample collection is purchased at a pharmacy/store, ordered online, or is provided by a healthcare provider or commercial testing service. The consumer follows the directions to collect sample(s), packages the sample(s) and sends sample(s) to the laboratory for testing. Most kits include pre-paid postage and the materials needed to ship the sample(s)

Sample Collection and Testing Method cont.

to the laboratory. Information is also provided to the consumer on how to receive the test results (usually via an online portal) and how to access further medical information once the testing is complete. If any of the test result(s) are positive for an infection, the consumer is notified of the appropriate next steps, may be provided with resources such as local clinics, and/or in some cases prescriptions for treatment.

- FDA-Approved/Cleared Testing: There are no FDA-approved or cleared methods that allow self-collected samples outside of a healthcare setting (with the exception of the OraQuick® In-Home HIV Test). There are a few STI tests that allow self-collected samples in a healthcare setting (e.g. several FDA-cleared chlamydia and gonorrhea nucleic acid test (NAT) methods include self-collected vaginal swabs as a sample type). Any laboratory that accepts and tests self-collected samples (not included in the FDA-approved or cleared method) must have performed a validation that meets the requirements of the regulatory agency that allows them to perform clinical testing. This type of test is considered a laboratory developed test (LDT).
 - HIV, hepatitis C virus (HCV), chlamydia, gonorrhea, syphilis, and other STIs.
 - In some cases (e.g. HIV or HCV) only screening tests are available. Supplemental or confirmatory testing ordered by a healthcare provider may be necessary.
- Sample Types (varies by company): dried blood spot (DBS), swabs (oral, rectal, and vaginal), and urine.
- Commercially Available Options: Binx Health, Let’s Get Checked, MyLabBox, EverlyWell, My Home STD Test, and iDNA.
- Cost: Testing kits purchased from these companies vary depending on how many tests and which types of tests are included. Tests for individual STIs begin at about \$55, and kits containing tests for multiple infections can cost \$485 or more.



Sample Collection and Testing Method cont.

Sample Collection in Laboratory Associated Facility and Laboratory Testing

A consumer selects and purchases a laboratory test online through a commercial laboratory, or through a third party partnered with a commercial or clinical laboratory. The consumer then goes to a laboratory managed facility (i.e. testing facility or specimen collection site) to provide samples. Samples may be self-collected onsite (e.g. urine), observed (e.g. oropharyngeal swabs), and/or collected by facility staff (e.g. venous blood). The laboratory performs the test(s) and provides the consumer with the result(s). Information is provided to the consumer on how to receive the test results and access to further medical information once the testing is complete, including access to telemedicine consultation in some cases.




- FDA-Approved/Cleared Testing: There are no FDA-approved or cleared methods that allow self-collected samples outside of a healthcare setting (with the exception of the OraQuick® In-Home HIV Test). There are a few STI tests that allow self-collected samples in a healthcare setting (e.g. several FDA-cleared chlamydia and gonorrhea NAT methods include self-collected vaginal swabs as a sample type). Any laboratory that accepts and tests self-collected samples (not included in the FDA-approved or cleared method) must have performed a validation that meets the requirements of the regulatory agency that allows them to perform clinical testing. Commercial laboratories may offer the following testing which will either be an FDA-approved, FDA-cleared, or laboratory developed test (LDT) test depending on the sample type that is used for the specific test.
 - Types of Testing Available: chlamydia, gonorrhea, HIV 1 & 2, HPV, hepatitis C virus, syphilis, Ureaplasma, HSV 2.
- Sample Types (varies by company): whole blood (serum or plasma), swabs (oral, rectal, vaginal, penile), and urine
- Commercially Available Options: CheckMate Healthcare, STD Check, Personalabs, QuestDirect, Pixel by LabCorp, Lemonaid Health.
- Cost: Cost varies depending on number/type of tests ordered. The cost of testing ranges from \$24 for a single test to over \$500 for multiple tests. Some services charge a clinician’s fee for interpretation of laboratory results.



Sample Collection and Testing Method cont.

The table below summarizes different self-testing models according to point of entry, and sample collection and testing methods. Examples of health departments which are employing some of these models are included.

TABLE: TESTING MODELS, BY POINT OF ENTRY AND SAMPLE COLLECTION AND TESTING METHOD

|  SELF-COLLECTED, SELF-TESTED |  SELF-COLLECTED, LAB-TESTED |  LAB-COLLECTED, LAB-TESTED |
|--|---|--|
| DIRECT ACCESS | | |
| <p>OraQuick purchased online or in pharmacy <i>Virginia DOH – HIV Self-Testing Program</i></p> <p><i>TakeMeHome™ national HIV home testing program</i></p> | <p>Commercial kit purchased online (e.g. Binx, My Lab Box)</p> <p><i>Texas Department of State Health Services permits contracted providers to purchase self-collection kits/services for distribution to clients</i></p> | <p>Purchased online (e.g. Pixel by LabCorp, Quest Direct)</p> |
| HEALTHCARE MEDIATED | | |
| <p>OraQuick mailed to patient home from PCP</p> | <p>Service purchased online (e.g. Nurx), or via PCP <i>Iowa TelePrEP Program – bundle of PrEP monitoring tests</i></p> | <p>Service purchased online (e.g. PlushCare)</p> |

Each of the models (or combination of models) described above may facilitate access to and acceptability of testing for HIV, viral hepatitis, and STIs. The cost of these testing strategies, and the extent to and circumstances under which health insurance covers these costs raises the possibility that the services may be cost-prohibitive to populations most in-need of alternative mechanisms for obtaining testing. Typically, health insurance, including Medicaid and Medicare, will cover costs of testing if a healthcare provider has ordered tests and interpreted test results. Health insurance may pay for testing when ordered via a

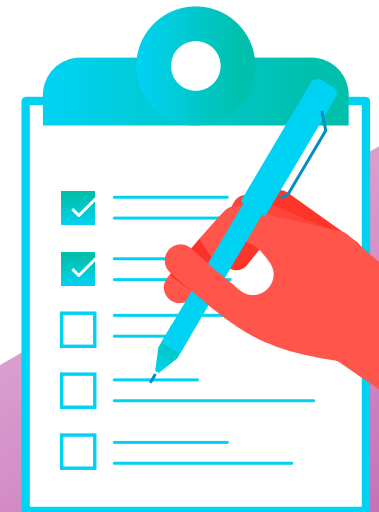
Sample Collection and Testing Method cont.

telehealth provider, including the commercial services described above. Each consumer would be advised to investigate coverage with their health plan, particularly if the healthcare provider ordering the test or the laboratory performing the test is not within the health plan network, or a health plan’s preferred provider. Some commercial testing companies accept payment from Flexible Spending Accounts or Health Savings Accounts. Health department sponsored-programs that facilitate testing by adopting one or more models of self-testing may fill an important gap for some individuals and populations.

Role of HIV, Viral Hepatitis, and STI Programs

Self-testing may contribute to achievement of public health program goals including:

- Providing access to testing services in areas which are medically underserved, or lack HIV, viral hepatitis, and/or STI services;
- Reaching underserved populations, populations who are unlikely to seek out in-person services, or populations who may experience stigma in seeking services in a local program or clinic;
- Stimulating uptake and maintenance of HIV PrEP, especially for individuals for whom repeat clinic visits for screening may be a challenge to retention (CDC has developed [guidance](#) for providing PrEP when facility-based services and in-person patient-clinician contact is limited).
- Reaching populations and individuals who would benefit from testing but who are unable to access services due factors including disruption in health services associated with COVID-19, or because of practical barriers such as lack of transportation to a testing program or clinic; and
- Testing sex and/or needle-sharing partners, who may be encouraged to test if presented with the tools to do so by their partner.



Because self-testing for HIV, viral hepatitis, and STIs can facilitate achievement of public health program goals and may mitigate some important barriers to testing, health departments may consider supporting or promoting self-testing strategies, or if already doing so, expanding their involvement in supporting self-testing. Health departments may consider greater or lesser levels of involvement in supporting or promoting self-testing strategies depending on factors such as health department program capacity and financial resources to support such efforts. Health department programs may consider directly offering self-testing,

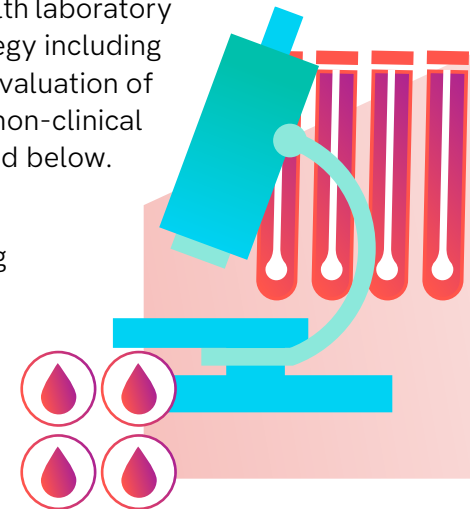
Role of HIV, Viral Hepatitis, and STI Programs cont.

potentially through collaboration with their public health laboratory. Alternatively, health departments may also purchase testing kits for distribution, procure commercial testing services, or partner with other entities or organizations to expand the availability of self-testing. In the section [Considerations for Establishing or Evaluating Self-Testing Approaches](#) a number of challenges and considerations are presented that the health department will need to work through in determining whether and how self-testing may advance public health goals.

Role of the Public Health Laboratory

The role of the public health laboratory (PHL) in self-testing for HIV, viral hepatitis, and STIs varies by jurisdictional regulations, capacity, and the health department approach. The public health program(s) should collaborate with the PHL to identify and implement strategies to provide access to HIV, viral hepatitis, and/or STI testing services through new delivery models such as self-testing. The public health laboratory may collaborate with the health department for various aspects of the testing strategy including creating self-collection kits and developing instructions, as well as participating in evaluation of self-collected samples and/or validating self-collected samples (from clinical and non-clinical settings as needed). A list of [considerations for public health laboratories](#) is included below.

Alternatively, if the public health laboratory is not involved in creating kits or performing testing associated with implementation of self-testing programs, their expertise could be invaluable to the health department as they evaluate alternative strategies that rely on commercially available collection kits and clinical or commercial laboratories. In the section [Considerations for Establishing or Evaluating Self-Testing Approaches](#) a number of challenges and considerations are presented that the public health program will need to work through. By working with laboratory staff at the public health laboratory they can collectively review what options are available through alternative mechanisms. As mentioned above, the public health program should evaluate various self-testing models for awareness as well if they are going to pursue working with or using any of the commercially available third-party entities. The public health laboratory can provide subject matter expertise to help provide context or information on what testing is being offered, appropriate



Role of the Public Health Laboratory cont.

validation specifications, interpretation of available performance data, and reporting language. The PHL can also assess other potential challenges or considerations that might arise with the different strategies that are being examined.

Evaluating Self-Testing as a Public Health Strategy

Self-testing is a tool to reach individuals who are hesitant or unable to attend traditional healthcare facilities or public health testing and linkage programs. Health departments may consider implementing self-testing programs to strengthen their testing and linkage programs. In determining whether to implement a self-testing program and which model(s) are most appropriate, health departments should consider several factors, presented below in Table 1.

TABLE 1: BENEFITS AND DRAWBACKS OF IMPLEMENTING A SELF-TESTING PROGRAM




|  POPULATION-LEVEL FACTORS |  Benefits |  Drawbacks |
|--|--|--|
| <ul style="list-style-type: none"> • HIV, viral hepatitis, and STI incidence and prevalence • HIV, viral hepatitis, and STI co-morbidity | <ul style="list-style-type: none"> • May increase uptake of testing in priority populations • May enhance access to and utilization of testing in medically underserved populations, or populations who would not otherwise be able to access testing • May enable access to testing services where health care and public health services have been disrupted, e.g. due to pandemic COVID-19 • Some test kits/services offer multiple or bundled tests appropriate for co-occurring conditions • Some test kits/services are available to minors ages 13 years and above | <ul style="list-style-type: none"> • Certain available tests may not be able to diagnose acute HIV infection • Available test kits/services may not provide the tests best aligned with population needs to identify potential co-infections • Supplemental testing, ordered by a healthcare provider and conducted by a laboratory, may be required to diagnose current infection (e.g. HIV, HCV, syphilis) • Test results may not be available to public health surveillance program, e.g. HIV self-test results may be known only to the consumer |

TABLE 1: BENEFITS AND DRAWBACKS OF IMPLEMENTING A SELF-TESTING PROGRAM cont.




|  CONSUMER-LEVEL FACTORS |  Benefits |  Drawbacks |
|---|--|--|
| <ul style="list-style-type: none"> Ease of Access, Convenience | <ul style="list-style-type: none"> Consumers do not need to e.g. wait for an appointment with a healthcare provider, secure transportation to a clinic or agency, or request time off from work Consumers have the option for “home testing” (HIV only), or to self-collect samples for testing in the location of their choice Some testing services provide consumers with the option to receive medical consultation via video, phone, text, and/or email. This may be beneficial for repeat screening necessary for PrEP monitoring | <ul style="list-style-type: none"> Internet access and mailing address usually required Consumers may be required to present to a healthcare provider for additional testing to diagnose an infection, and/or for treatment |
| <ul style="list-style-type: none"> Sample Collection, Packaging and Shipping | <ul style="list-style-type: none"> Test kits and testing services offer different options for samples that can be tested Consumers can elect to self-collect samples in a location of their choice, or may present to a laboratory managed facility to self-collect and/or have a blood draw | <ul style="list-style-type: none"> Consumers may not understand or be able to correctly follow instruction(s) for sample collection, packaging, or shipping, which may lead to inaccurate test results |
| <ul style="list-style-type: none"> Cost to Consumer | <ul style="list-style-type: none"> Some testing services may accept health insurance (including Medicaid and Medicare), or FSA/HSA Health department-sponsored programs may offer certain test kits or services at reduced or no cost to consumers | <ul style="list-style-type: none"> Test kits/services may not be covered by health insurance causing consumers to incur out-of-pocket costs. Testing not ordered by healthcare providers may not be covered by health insurance The cost of consultation by healthcare providers offered by some testing services may not be covered by health insurance, or may be covered at out of network rates |
| <ul style="list-style-type: none"> Decreased Stigma | <ul style="list-style-type: none"> Consumers do not have to present to a clinic or agency where they may feel stigmatized Consumers may avoid discussions with a healthcare provider about sexual or drug using behaviors which they may find uncomfortable Consumers may be able to encourage testing by their sex- and needle-sharing partner(s) | <ul style="list-style-type: none"> Identifying and accessing a clinic or healthcare provider where a consumer is not stigmatized may be needed to accomplish additional testing and/or treatment (depending on the infection and what clinical services may be provided by the testing service) |

TABLE 1: BENEFITS AND DRAWBACKS OF IMPLEMENTING A SELF-TESTING PROGRAM cont.







|  CONSUMER-LEVEL FACTORS |  Benefits |  Drawbacks |
|---|---|---|
| <ul style="list-style-type: none"> • Appropriateness of Tests | <ul style="list-style-type: none"> • Consumers select test(s) to be performed | <ul style="list-style-type: none"> • Consumers may request tests that are not well aligned with their risk or need, either in terms of the infection(s) for which they are tested, or the test methods. This may result in missed or inaccurate diagnoses • Without provider input, the consumer may test themselves at inappropriate times, such as before a virus is detectable, leading to a missed diagnosis • Test manufacturers and testing services provide relatively limited information on the tests they perform and the performance of those tests. Consumers may not know how to evaluate information about tests and their performance, and as a result select tests which are not appropriate to identifying infection, use a sample type which is not ideal to identifying infection, or which yield inaccurate results |
| <ul style="list-style-type: none"> • Test Results and Engaging in Treatment or Support Services | <ul style="list-style-type: none"> • Results are given directly to consumers via an online portal, text, email, or similar means • Test kit manufacturers/testing services may provide information and support in accessing local treatment or support services | <ul style="list-style-type: none"> • In the case of “home testing” (HIV tests only), consumers may not understand or be able to correctly follow instructions for performing a test or interpreting results • Consumers may not have the knowledge necessary to correctly interpret results, understand their meaning, or the actions they should take in response to test results • Needed supplemental testing and engagement in treatment may be delayed because a consumer does not understand the need for, is not motivated, or does not otherwise have access to supplemental testing and/or treatment • The testing service or manufacturer may not provide information about local prevention, treatment, and support services; the information available from the testing service may not be comprehensive or up-to-date; or the consumer would benefit from more support in accessing support services than is available from the testing service or test manufacturer |

TABLE 1: BENEFITS AND DRAWBACKS OF IMPLEMENTING A SELF-TESTING PROGRAM cont.

|  PROGRAM LEVEL FACTORS |  Benefits |  Drawbacks |
|---|--|--|
| <ul style="list-style-type: none"> Health Department Capacity and Resources to Operationalize and Support Self-Testing | <ul style="list-style-type: none"> The health department has control over the tests, sample collection methods used, and selection of the laboratory performing testing to ensure high quality testing, and promote or facilitate integrated testing The health department may be better able to ensure that test results are reported to the health department surveillance program The health department may provide information and assistance to consumers to select and acquire tests appropriate to their need; or implement screening criteria to facilitate the “right” match of tests to the consumer’s situation The health department can arrange for “bundles” of tests appropriate to the consumer’s needs, and to support programmatic objectives The health department can develop and provide information to facilitate linkage to treatment and other support services, and tailor this information to local needs and resources The health department can collect data from consumers regarding demographics, risk, testing history and other information of value to understanding testing need, testing patterns, and to ensure complete data for surveillance, and program evaluation | <ul style="list-style-type: none"> Health department procurement and contracting mechanisms may not offer sufficient flexibility to engage needed laboratory services, kit manufacturers, or other elements of self-testing program operations or supplies. Health departments will also want to ensure they have contingency plans for disruptions to supply chains and/or delays in laboratory testing Promotion of self-testing programs requires resources and expertise needed to e.g. effectively use social media, and other health communication strategies to ensure populations are aware of self-testing opportunities and how to access them Preparing and delivering kits requires infrastructure and staff support; and/or adequate resources to support fulfillment vendor Consumers may not use tests/sample collection kits; or may only use some of them Follow-up with consumers to obtain test results and linkage to treatment may be time and resource intensive Optimizing resources requires striking the right “balance” between self-testing programs and traditional testing programs |

Considerations for Implementing Self-Testing Programs

As a health department evaluates implementing or otherwise supporting self-testing, there are a number of issues that must be considered in order for self-testing efforts to be successful. In this section, we present some of these issues, in the form of questions, along with some recommended strategies to support implementation of self-testing. These questions should serve as a reference and resource to determine whether the various aspects of the approach will meet the needs of their jurisdiction. This can be used to help evaluate commercial products or services, or to set up health department self-testing programs, or a hybrid of the two. If a health department decides to implement a self-testing program, you will need the capacity, expertise, and resources to address such issues.

Is self-testing an appropriate strategy to help improve access to and utilization of testing?

- Populations prioritized by health department HIV, viral hepatitis, and STI programs may not be accessing testing services or may be testing at sub-optimal levels. Individuals in these populations may not be aware of the value of testing, or may lack the motivation, self-efficacy, or resources to access testing.
- State and local laws and regulations vary regarding self-testing. In many jurisdictions, consumers can obtain testing for a health condition without an order from a licensed healthcare provider.



Health departments should:

- Collaborate with advisory groups, testing and linkage providers, and community gatekeepers to determine their awareness/interest in testing services, current barriers to testing, and whether self-testing is an appropriate strategy to increase uptake of testing, what model(s) of self-testing may be most appropriate, and what strategies should be used to support implementation.
- Identify which testing kits and testing services are available in the jurisdiction and may already be used by the target population(s). There may be opportunities to build off of existing campaigns or distribution programs.
- Consider how to incorporate self-testing in health communications campaigns or other health department program initiatives, such as expansion of HIV PrEP.

[TakeMeHome™](#) is a partnership between [Building Healthy Online Communities](#), NASTAD, and Emory University. Through this program, health departments can offer free self-testing and self-collection to eligible community members. Coordination with dating apps to promote self-testing resources through messaging and advertisements is a component of this program. Participating health departments receive a minimum of two messages per month for the first four months of participation. Users of geospatial social networking apps, like Grindr, can order test kits by clicking on a link embedded in HIV-related content of their apps. Public health departments can also include the ordering links in their health communications materials.

Considerations for Implementing Self-Testing Programs cont.

How well does the test(s) perform?

- The performance characteristics of any individual test varies based on a number of factors including the type of sample tested, the quality of the sample, the test method, and the laboratory practices. FDA-approved or cleared assays are evaluated in a clinical trial to determine the performance characteristics as well as diagnostic sensitivity and specificity.
- There are no FDA-approved or cleared tests for samples self-collected outside of a healthcare setting. Test methods that are not FDA approved or cleared must be validated by each laboratory performing the test, for each sample type that is tested, and for each different analyte (e.g. antibodies, antigen) the test is detecting to determine the performance of the test method.
- It may be difficult for consumers to find information about the specific tests being used, including their performance characteristics, and to determine which laboratory is performing tests associated with commercially available self-collection kits. Information regarding test performance may not be readily available and can be difficult to interpret if insufficient data is provided.

Diagnostic Sensitivity is the ability of a test to detect a true positive, that is, the ability of a test to correctly identify all individuals tested who actually have the condition in question.¹

Diagnostic Specificity is the ability of a test to detect a true negative, that is, the ability of a test to correctly identify all individuals tested who truly do not have the condition in question.¹

Validation is a process to establish the performance characteristics and limitations of laboratory test which includes evaluations for accuracy, precision, analytic sensitivity and analytical specificity. **Analytic sensitivity** is the smallest amount of substance in a sample that can be measured or the limit of detection for the method. **Analytical specificity** is the ability of the method to identify the particular organism you are testing for.



Health departments should collaborate with their public health laboratory to:

- Investigate the specific test(s) that are being performed by testing services and/or laboratories,

The Texas Department of State Health Services (DSHS) permits agencies funded by its TB/HIV/STD section to use program resources to purchase and distribute in-home HIV tests and HIV/HCV/STI and creatinine self-collection kits. The goal is to promote access to testing for HIV, sexually transmitted infections, and viral hepatitis through use of self-testing strategies, and tests required for HIV PrEP. To support implementation, DSHS has issued [Interim Guidance on Home Self-Collection and Testing Kits](#). The guidance aims to provide agencies with information needed to select appropriate tests for the client population(s), evaluate the tests and laboratory providing testing services, and to operationalize home testing and home self-collection strategies.

- Evaluate performance data on each test regarding clinical performance of the test methods and to ensure the tests are properly validated for each sample type and analyte in the method (i.e. if a service is offering HIV Ag/Ab testing, they should have validated that both antigen and antibody can be detected and be able to provide that data for review.)

Considerations for Implementing Self-Testing Programs cont.

What is the right test?

- Consumers may not understand which tests are appropriate for their situation (e.g. type of test, timing relative to exposure, sample type, pathogens, etc.) without advice from a healthcare provider or public health professional.
- For example, an HIV test that detects antibody only (not antigen) would not be appropriate for an individual with recent exposure to HIV when there may be a chance of acute HIV infection. An individual with history of injecting drug use may be interested in learning their HIV status, but would also benefit from testing for HCV infection as well. An individual wanting to initiate HIV PrEP should also be tested for STIs, as well as creatinine level.



Health Departments involved in ordering tests and sending or distributing collection kits to consumers should implement strategies to ensure that the test(s) performed are appropriate to an individual’s situation (e.g. risk, recency of exposure). This may include:

- Collaboration with your public health laboratory or other laboratory or testing service to offer a “bundle” of tests (including appropriate supplemental tests to confirm infection) appropriate for your target population(s) or program e.g. HIV and HCV testing for persons who use injection drugs, or HIV, STI, and creatinine panels for PrEP programs.

The Iowa TelePrEP program is a collaboration between the Iowa Department of Public Health (IDPH) and the University of Iowa. In lieu of presenting to a clinic or clinic-associated laboratory, individuals receiving HIV PrEP have the option of using “home kits” for monitoring tests. Self-collected samples for a panel of tests are shipped to a central laboratory for processing. The panel of tests performed includes HIV, syphilis, creatinine, gonorrhea, and chlamydia. IDPH, through its public health laboratory, is considering developing the capacity to conduct testing on self-collected samples, including validating dried blood spots for HIV, syphilis, HCV, and creatinine; and extra-genital swabs for gonorrhea and chlamydia testing.

- Implementing a screening strategy to ensure that the tests requested and provided are the “right” match to a consumer’s situation.

Through its Home HIV Test Program, the Virginia Department of Health (VDH) distributes OraQuick® In-Home HIV Test kits, free of charge, to individuals who register with the program by completing an [on-line confidential survey](#). The program is currently available to all residents of Virginia and Maryland. Individuals may request test kits at 90-day intervals. Program promotion is through social media, with Facebook as the primary platform. VDH leveraged images and content from previous statewide HIV campaigns. VDH administers the Home HIV Test Program in collaboration with the Maryland Department of Health.

Considerations for Implementing Self-Testing Programs cont.

- Providing supplemental information or educational materials to consumers regarding appropriate tests (e.g. by publishing information on your program’s webpages or other social media outlets, including in health communication campaign messaging).

What is the best sample type?

- Consumers may not know or understand which sample type is appropriate for a particular infection or test method.
 - For example, an individual that wants to be tested for gonorrhea should collect and test samples from multiple anatomic sites (e.g. rectal sample, oral/pharyngeal) so that infections are not missed. In order to do this, a consumer would need to swab each anatomic site rather than just submit a single urine test.
 - Alternatively, if a consumer wants to be tested for HIV based on a recent exposure, the at-home HIV test is not appropriate as it uses an oral fluid sample which is not the preferred sample type for detecting a recent HIV infection and detects HIV antibody only (not antigen). Additionally, a dried blood spot would have a lower chance of identifying recent infection as compared to a whole blood sample drawn by a phlebotomist.^{2,3}



Health Departments should be aware of the sample types used by testing laboratories and the different commercially available testing services and should implement strategies to ensure that sample types requested are appropriate for the test method and the infection(s) of concern. This may include:

- Collaboration with your public health laboratory or other laboratory/testing service to offer testing on the types of samples that are appropriate to your target population (e.g. rectal and oropharyngeal swabs to enable multi-site sample collection for gonorrhea testing among men who have sex with men).
- Implementing a screening strategy to ensure that the tests requested and provided are the “right” match to a consumer’s situation.

TakeMeHome™ provides flexibility for health departments to select the configuration of testing options appropriate to their program and needs of priority populations. Health departments can elect to implement distribution of kits for HIV self-testing using the OraQuick® In-Home HIV Test kit, or for self-collection for laboratory-based testing for STIs (using extra-genital swabs) and HIV (using dried blood spots).

Considerations for Implementing Self-Testing Programs cont.

- Health departments may consider providing supplemental information or educational materials to consumers regarding appropriate tests (e.g. by publishing information on your program’s webpages or other social media outlets, including in health communication campaign messaging).

Are the instructions for sample collection simple, clear, and easy to follow?

- Consumers may not understand the importance of carefully following instructions and may deviate from those instructions in ways that impact the accuracy of test results. Additionally, consumers with low levels of literacy may have difficulty following written instruction.
 - For example, if too much or too little sample is collected, it may not be possible to perform one or more tests (e.g. if several are requested), or if first-stream urine is collected rather than mid-stream, this too may impact test accuracy.
 - If the filter paper for a dried blood spot is not properly dried before packaging or multiple swabs are combined or not placed back in the appropriate container the laboratory may not be able to test the samples.
 - If samples are not returned to the laboratory within a specified time frame, the sample may not be able to be tested, or it may yield inaccurate results.



Some people may find self-collection of blood samples more challenging than other sample types. It may be helpful to provide “tips” such as “drink water to hydrate” or “run your hands under warm water” to help them get a better sample. It may also be helpful to include extra lancets or filter cards with sample collection kits in the event that consumers are unsuccessful in getting a sample on their first attempt.



Health Departments should implement strategies to ensure that instructions are clear and easy to follow and include information for correctly collecting, packing, and transporting samples. Consumers may also require instruction in languages other than English. Videos, infographics, or other pictures may be helpful to provide clear instruction. Health departments may also consider virtually supervised collection sessions to improve self-collection, or consumer “help” lines (e.g. via telephone, text messaging, or email).

Emory University developed written information regarding collection and submission of samples developed that was lengthier and more detailed than informational material typically included by commercial or clinical laboratories/test manufacturers. This was due to feedback from study participants who indicated a preference for more detailed informational materials.

Considerations for Implementing Self-Testing Programs cont.

Are instructions for self-testing simple, clear and easy to follow?

- For true self-testing (i.e. the consumer collects the sample, performs the test, and interprets the result), it is critical that instructions for reading (e.g. time period for test to process) and interpreting results are clear and easily understood. Consumers may not understand the importance of carefully following instructions and may deviate from those instructions in ways that impact the accuracy of test results. Additionally, consumers with low levels of literacy may have difficulty following written instruction.
- Information regarding next steps that the consumer should take should be clearly described (e.g. see a healthcare provider for treatment, re-test), and appropriate local prevention, treatment, and support resources are made available to the consumer.



Health departments should implement strategies to support consumers in accurately performing the test, and reading and interpreting results. This may include:

- Developing information or education supplemental to what is provided in the test kits. Consumers may require information and instruction in languages other than English. Videos or graphics, or virtually supervised testing may assist consumers in correctly performing self-testing.

Are the test results and interpretation stated in plain language?

- Laboratory reports, including results and interpretations, are technical documents that are typically read, reviewed, and acted upon by trained healthcare or public health professionals. Additionally, different laboratories may use different terminology (e.g. ‘reactive’ vs. ‘detected’ vs ‘positive’) to refer to the same thing. The way that test results are presented in laboratory reports and the terminology used to explain results may be unfamiliar to and not easily understood by a consumer. In some self-testing models, consumers receive results directly from a laboratory or testing service and need to be able to understand the meaning of the results so that they may take appropriate action, including obtaining treatment for an infection or obtaining additional testing needed to confirm an infection.



Health Departments should implement strategies to ensure that consumers are able to understand their test results, and take necessary next steps. This may include:

- Collaborating with your public health laboratory to review the laboratory reports from commercial testing services to become knowledgeable about the test result reports and terminology.

Considerations for Implementing Self-Testing Programs cont.

- Developing supplemental informational materials for consumers to assist them in understanding test results, and in taking appropriate follow-up action. Consumers may require information in languages other than English. Health departments may also consider a consumer “help” line to assist consumers in understanding results reports, and any needed follow-up actions.
- Implementing a process to follow-up with consumers after distribution of In-Home HIV Test kits to ascertain test results. Follow-up engagement may also be used to assess needs for additional services, and support for linkage to treatment.

Does the self-testing approach include appropriate linkages to additional services?

- The extent to which local prevention and health care resources are communicated to consumers by test kit manufactures and testing services, and the support that is provided to consumers to access such resources may be variable.



Health Departments should implement strategies to ensure that linkage to treatment, prevention services, and partner notification services are provided, as needed. This may include:

- Publishing information (e.g. agencies, locations, hours of service, cost) on your program’s webpages or other social media outlets, or including in health communication campaign messaging regarding local resources for treatment, prevention services, and other support services.

Test kits distributed by the Virginia Department of Health include information to support individuals in correctly conducting the test and accessing prevention and treatment resources. Each kit is labeled with OraSure’s Home Testing Hotline, the CDC HIV Hotline, VDH’s Prevention Hotline, as well as local prevention resources. The kit also includes condoms, lubricants, and informational resources on HIV pre-exposure prophylaxis.

- Developing supplemental informational/educational materials for consumers to assist them in understanding the benefits of treatment, prevention services including PrEP or immunization for viral hepatitis, and other support services (e.g. substance use treatment, housing benefits). Resources should be responsive to the specific population(s) needs and be culturally relevant.
- Establishing a consumer telephone or chat “help” line to assist consumers in accessing needed services.
- Implementing a process to follow-up with consumers after distribution of sample collection and/or test kits to ascertain linkage to care and identify support needs.

Considerations for Implementing Self-Testing Programs cont.

What data will be available to the health department?

- Self-testing poses challenges for public health surveillance, including contact tracing and partner notification. In particular, self-testing performed entirely by a consumer (i.e. consumer collects a sample, performs the test, and interprets the results) is essentially anonymous testing in that the results are known only to the consumer. Incident infections may only be reported to public health if and when the individual presents to a healthcare provider for additional testing and/or treatment. Self-testing kits or services which provide only screening tests may make case classification and public health follow-up challenging, absent results from supplemental tests.
- Self-testing also presents a challenge from the perspective of evaluating the extent to which self-testing, including programs implemented by a health department, is contributing to achievement of public health objectives e.g. in terms of increasing testing uptake in priority populations, identifying infections, or linking individuals with treatment.



Health Departments should implement strategies to ensure complete and timely surveillance reporting, and to facilitate evaluation of the contribution of self-testing to achievement of public health goals and objectives. This includes:


- Becoming familiar with the manufacturers, testing services, and affiliated laboratories providing self-testing in the jurisdiction or testing individuals in the jurisdiction to confirm they are reporting appropriately to public health authorities for public health action and surveillance purposes. The health department may also be able to obtain data from these manufacturers, testing services, and affiliated laboratories regarding utilization (e.g. volume of kits ordered/purchased, tests performed, demographics of consumers).
- If the health department is implementing a self-testing program, establishing mechanisms, such as with the kit manufacturer, testing service, or fulfillment center to collect data from program participants relevant to evaluating utilization and achievement of public health objectives.

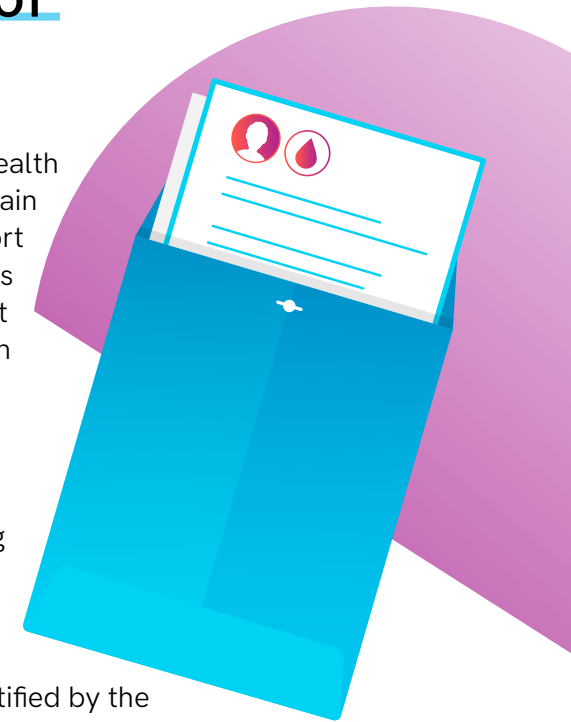
All individuals that receive an In-Home HIV Test from the Virginia Department of Health receive a follow-up survey (automatically generated and sent to the registered email address) two weeks after the test kit is shipped. This enables collection of data regarding test results, linkage to treatment, or other tests that the individual may have received.

Considerations for PHLs Implementing Testing of Self-Collected Samples


For health departments implementing self-testing programs, collaborating with the public health laboratory to perform testing on self-collected samples may be possible and may have certain advantages. These advantages may include the ability to provide a custom bundle of tests, report test results in plain language, and efficiently collect data regarding self-testing program participants and test results, both for program evaluation and disease surveillance. In this section, we present some of these considerations, and recommended strategies, for PHLs evaluating implementation of testing on self-collected samples.

Does the PHL have the capacity to perform the testing?


- The PHL along with the health department program will need to address the following questions and then determine if the PHL will have the necessary resources to perform the validations including but not limited to staff time and the necessary samples but also the funding to procure the collection and test kits for the validation and the program itself.
 - What pathogens should be tested for to address the needs of priority populations identified by the health department program?
 - What sample types would be ideal and what sample types will be accepted?
 - What is the best test to perform given the sample type?
 - Are there any restrictions, exclusions, or special requirements for specific target populations?
-  The public health laboratory should assess what may already be validated (i.e. self-collection in a healthcare setting for certain specimen types) in their laboratory and what else may need to be validated to offer testing in-house. This will include determining the various aspects that will need to be validated. This may include:
 - Shipping of collection supplies (to consumers)
 - Time/temperature of returned collection materials/samples
 - Minimum volume of sample required to perform testing




Considerations for PHLs Implementing Testing of Self-Collected Samples cont.

-  The public health laboratory will also need to assess if they have sufficient staff time and resources to conduct the necessary validations and maintain the proposed volume of testing to support the testing program, including funding as needed.

How will collection kits be handled and by whom?

- A key component of a self-testing approach is providing collection kits and any ancillary materials such as documentation to help the consumer with self-collection itself, other prevention materials, and/or educational material. Depending on the testing that will be performed there may need to be some manual kit making if more than one type of collection device (e.g. urine cup and swabs) will be used and/or if ancillary materials are being provided.
-  Public health laboratories, in collaboration with the health department, should clearly establish roles and responsibilities for the procurement of materials, packaging and storage of collection kits including collection devices, shipping and/or distribution of collection kits to the consumer, and tracking inventory.

How will the PHL report results?

- The public health laboratory typically reports results back to the submitter or healthcare provider rather than a consumer. If the self-testing model includes direct delivery of results to the consumer, consideration should be given to ensuring the reporting format and language is plain, easy to read, and includes appropriate actions the consumer should take based on the results.
-  The public health laboratory should discuss with the public health program how results will be conveyed to the consumer—directly to the consumer or through the public health program. Additionally, particularly in the case of direct delivery, the mechanism for result reporting should also be addressed and would likely need to be electronic in nature (e.g. a web-based portal with text or email notifications).

Summary

Self-testing promises to expand access to testing for HIV, viral hepatitis, and STIs. Alternative models of testing are urgently needed to overcome barriers to testing for individuals who do not have access to more traditional models of testing offered by healthcare providers and public health programs which typically require in-person encounters between clients and healthcare providers. While there are many benefits to self-testing, there are also important challenges to ensuring quality testing, supporting individuals in accessing needed prevention and treatment resources, and ensuring availability of data necessary for public health surveillance and disease control activities. Health department HIV, viral hepatitis, and STI programs, in collaboration with public health laboratories, have important roles to play relative to effectively advance self-testing methods. Health departments considering supporting and/or promoting self-testing should learn more about the tests and testing services to make best use of these resources, and to support consumers in using them appropriately and safely.

Appendix A: Examples of Currently Available Commercial Tests and Testing Services

This is a summary of a number of commercial providers of tests and testing services grouped by point of entry and sample collection and testing method but may not be comprehensive and not all methods may be available in all jurisdictions. Inclusion in this table is not an endorsement of any of the products or approaches.

| Point of Entry | Sample Collection and Testing Method | Commercial Providers ^a | Tests Offered ^b | Sample Types (May vary by kit) | Insurance/Cost |
|----------------|--------------------------------------|-------------------------------------|--|--|---|
| DIRECT ACCESS | Self-testing | Consumer-purchased OraQuick | HIV-1/2 | Oral swab | No insurance accepted (FSA may be accepted) Cost: ~\$36-48 |
| | Self-collection | Binx Health ^{5,6} | Chlamydia, Gonorrhea, HBV, HCV, HSV-2, HIV, HPV, Syphilis, Trichomoniasis | Dried blood spot; genital, throat, rectal swabs; urine | No insurance accepted Cost: \$69 - \$485 |
| | | CheckMate Healthcare ⁶⁻⁸ | Chlamydia, Gonorrhea, HCV, HSV-2, HIV-1/2, Syphilis, Trichomoniasis | Dried blood spot; vaginal swabs; urine | HSA/FSA accepted Cost: \$63-\$269 |
| | | EverlyWell ^{6,9} | Chlamydia, Gonorrhea, HCV, HSV-2, HIV-1/2, Syphilis, Trichomoniasis | Dried blood spot; vaginal swab; urine | No insurance accepted Cost: \$69-\$199 |
| | | iDNA ¹⁰ | Chlamydia, Gonorrhea, HCV, Herpes Virus 2, HIV-1/2, HPV, <i>Mycoplasma genitalium</i> , Syphilis, Trichomoniasis, Ureaplasma | Dried blood spot; vaginal swab; urine | No insurance accepted Cost: \$78-\$298 |
| | | Let's Get Checked ^{6,11} | Chlamydia, Gardnerella, Gonorrhea, HSV-1/2, HIV-1/2, HPV, <i>Mycoplasma genitalium</i> , Syphilis, Trichomoniasis, Ureaplasma | Dried blood spot; urine | No insurance accepted Cost: \$55.30-\$349 |
| | | My Home Tests (MTL) ¹² | Chlamydia, Gonorrhea, HCV, HSV-2, HIV, HPV, <i>Mycoplasma genitalium</i> , Syphilis, Trichomoniasis, Ureaplasma | Dried blood spot; vaginal, oral, rectal swabs; urine | No insurance accepted Cost: \$79-\$399 |
| | | My LAB Box ^{6,13} | Bacterial Vaginosis, Chlamydia, Gonorrhea, HBV, HCV, HSV-2, HIV-1/2 HPV, <i>Mycoplasma genitalium</i> , Syphilis, Trichomoniasis | Dried blood spot; rectal, throat, vaginal swabs; urine | HSA/FSA accepted Cost: \$79-\$369 |

| Point of Entry | Sample Collection and Testing Method | Commercial Providers* | Tests Offered# | Sample Types (May vary by kit) | Insurance/Cost |
|---|---|-------------------------------------|--|---|---|
| DIRECT ACCESS | Sample collection in a laboratory-managed facility | CheckMate Healthcare ⁶⁻⁸ | Chlamydia, Gonorrhea, HCV, HSV-2, HIV-1/2, Syphilis, Trichomoniasis | Varies | No insurance accepted (FSA may be accepted) Cost: ~\$36-48 |
| | | Lemonaid Health ¹⁵ | Chlamydia, Gonorrhea | Urine | No insurance accepted Cost: \$73.16 |
| | | Personalabs ^{6,14} | Chlamydia, Gonorrhea, HBV, Herpes Simplex Virus (1&2), HIV-1/2, Syphilis, Trichomoniasis | Blood; urine | HSA/FSA accepted Cost: \$46-\$522 Consult: \$70-\$125 |
| | | Pixel by LabCorp ¹⁶ | Chlamydia, Gonorrhea, Trichomoniasis | Urine | No insurance Cost: \$164 |
| | | QuestDirect ¹⁷ | Chlamydia, Gonorrhea, HBV, Herpes Simplex Virus (1&2), HIV-1/2, Syphilis, Trichomoniasis | Blood; urine | No insurance accepted Cost: \$49-\$379 |
| | | STD Check ^{6,18} | Chlamydia, Gonorrhea, Hepatitis A, HBV, HCV, Herpes Simplex Virus (1&2), HIV-1/2, Syphilis | Blood; urine | No insurance accepted Cost: \$24-\$349 |
| HEALTHCARE PROVIDER-MEDIATED TESTING | Self-collection | Nurx ^{6,19} | Chlamydia, Gonorrhea, HCV, HIV, Trichomoniasis, Syphilis | Dried blood spot; rectal, throat, vaginal swab; urine | Private insurance accepted Cost: With insurance: \$15 consult + \$75 testing Without insurance: \$150-\$220 |
| | Sample collection in a laboratory-managed facility | PlushCare ^{6,20} | At discretion of provider | Varies | Private insurance accepted Cost: With insurance: varies Without insurance: \$165-\$235 |
| | | Personalabs ^{6,14} | At discretion of provider | Varies | HSA/FSA accepted Cost: \$46-\$522 Consult: \$70-\$125 |

Information is current as of July 1, 2020. Information on the table is from test providers’ website or relevant articles as referenced.

^aCommercial providers may use one or more laboratories to perform testing.

^bThere are no FDA-approved or cleared methods that allow self-collected samples outside of a healthcare setting (with the exception of the single FDA-approved HIV Home Test). There are a few STI tests that allow self-collected samples in a healthcare setting (e.g. several FDA-cleared chlamydia and gonorrhea NAT methods include self-collected vaginal swabs as a sample type). Any laboratory that accepts and tests self-collected samples (not included in the FDA-approved or cleared method) must have performed a validation that meets the requirements of the regulatory agency that allows them to perform clinical testing. Commercial laboratories may offer testing which will either be an FDA-approved, FDA-cleared, or laboratory developed test (LDT) test depending on the sample type that is used for the specific test.

Tip Sheet: Implementing HD Self-Testing

This tip sheet summarizes key issues and strategies that health departments should address as they consider implementation of self-testing.



Accessing Target Populations

- Identify which testing kits and testing services are already available in the jurisdiction, and which populations may be accessing them.
- Collaborate with community advisory groups and other stakeholder groups to identify and adopt the models of self-testing appropriate to addressing community needs and priorities.
- Leverage health communications campaigns or other social media to increase awareness of the value of testing and resources for obtaining low- or no-cost testing, including self-testing.



Alignment with Public Health Priorities and Population Needs

- Coordinate across health department programs to identify areas self-testing may enhance program initiatives (e.g. integration) and contribute to achievement of program objectives.
- Consult with test kit manufacturers, or testing services to help consumers obtain the tests and samples appropriate to their risk and circumstance.
- Collaborate with the public health laboratory, test kit manufacturers, or testing services to design a “custom” test bundle, including sample types and supplemental tests.
- Identify and implement strategies to assist consumers to access local resources to link to treatment, prevention, partner notification, and other support services. This may include coordination with test kit manufacturers or testing services.



Quality Testing

- Identify the specific tests performed by testing services or laboratories.
- Confirm that tests are validated for each sample type.
- Evaluate performance data for each test, and for each sample type.

- Develop and provide materials and resources that assist consumers in sample collection and submission, and performing a test.
- Identify and implement strategies that ensure consumers obtain and accurately interpret test results, including need for follow-up and supplemental testing. This may include coordination with test kit manufacturers or testing services.



Disease Surveillance and Program Monitoring

- Communicate and collaborate with your public health laboratory, test kit manufacturers, or testing services and their affiliated laboratories, to obtain data about consumers using test kits or testing services, including test results.
- Support or establish electronic reporting of test results (e.g. via laboratory reporting).
- Implement a process to follow-up with consumers after distribution of In-Home HIV Test kits to ascertain test results to support disease surveillance and partner notification.



Feasibility

- Investigate state and local laws and regulations that impact self-testing.
- Negotiate with test kit manufacturers or testing services for reduced costs to consumers, or purchase kits or services on behalf of consumers at reduced costs, as part of a self-testing program.
- Collaborate with your public health laboratory to provide services for self-testing, possibly at a lower cost than commercial providers.
- Coordinate across health department programs to leverage resources and expertise needed to implement a self-testing program including kit assembly and distribution, data collection and evaluation, health communications, and consumer support.

Additional Resources for Health Departments

1. Telemedicine in Sexual and Reproductive Health (Kaiser Family Foundation)
<https://www.kff.org/womens-health-policy/issue-brief/telemedicine-in-sexual-and-reproductive-health/>
2. Dear Colleague Letter: HIV Self-Testing Guidance (Centers for Disease Control and Prevention)
https://www.cdc.gov/nchhstp/dear_colleague/2020/dcl-042820-HIV-self-testing-guidance.html
3. HIV Testing: Guidance and Implementation Resources (Centers for Disease Control and Prevention)
<https://www.cdc.gov/hiv/guidelines/testing.html>
4. Sexually Transmitted Diseases Treatment and Screening (Centers for Disease Control and Prevention)
<https://www.cdc.gov/std/treatment/default.htm>
5. Recorded Webinar: Challenges in HIV and HCV Diagnostic Testing (Association of Public Health Laboratories)
<https://aphl.wliinc23.com//events/Challenges-and-Developments-in-HIV-and-HCV-Diagnostic-Testing-588-641-20-1135/details>

References

1. Trevethan R. Sensitivity, Specificity, and Predictive Values: Foundations, Plausibilities, and Pitfalls in Research and Practice. *Front Public Health* [Internet] 2017 [cited 2020 Nov 4];5. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5701930/>
2. Luo W, Davis G, Li L, et al. Evaluation of dried blood spot protocols with the Bio-Rad GS HIV Combo Ag/Ab EIA and Geenius™ HIV 1/2 Supplemental Assay. *J Clin Virol* 2017;91:84–9.
3. Stefic K, Guinard J, Peytavin G, et al. Screening for Human Immunodeficiency Virus Infection by Use of a Fourth-Generation Antigen/Antibody Assay and Dried Blood Spots: In-Depth Analysis of Sensitivity and Performance Assessment in a Cross-Sectional Study. *Journal of Clinical Microbiology* [Internet] 2019 [cited 2020 Aug 31];58(1). Available from: <https://jcm.asm.org/content/58/1/e01645-19>
4. Oral HIV Testing at Home | OraQuick [Internet]. [cited 2020 Sep 10]; Available from: <http://www.oraquick.com/>
5. binx boxes - binx health [Internet]. [cited 2020 Sep 10]; Available from: <https://app.mybinxhealth.com/binx-boxes/>
6. Weigel G, Frederiksen B, Ranji U, 2019. Telemedicine in Sexual and Reproductive Health [Internet]. KFF. 2019 [cited 2020 Sep 10]; Available from: <https://www.kff.org/womens-health-policy/issue-brief/telemedicine-in-sexual-and-reproductive-health/>
7. CheckMate Healthcare [Internet]. CheckMate Healthcare. [cited 2020 Sep 10]; Available from: <https://checkmatehealthcare.com/>
8. New App Lets Consumers Order STD Tests and Get Treatment via Telemedicine [Internet]. MPR. 2018 [cited 2020 Sep 10]; Available from: <https://www.empr.com/home/news/new-app-lets-consumers-order-std-tests-and-get-treatment-via-telemedicine/>
9. Everlywell - Innovative at-home Health Testing [Internet]. [cited 2020 Sep 10]; Available from: <https://www.everlywell.com/>
10. Details - Kit Contents [Internet]. [cited 2020 Sep 10]; Available from: https://www.idna.com/details-kit-contents?utm_term=idna%20std%20test&utm_medium=cpc&utm_source=Google&utm_content=ETA4220&utm_campaign=STD+Terms+Exact+Top+Terms&gclid=EAlaIqobChMI5_uYjtSB6wIVA6SzCh3Llwa0EAAYASAAEgLPW_D_BwE
11. Home STD Test, Confidential At Home Testing Kit, Results Online [Internet]. LetsGetChecked. [cited 2020 Sep 10]; Available from: <https://www.letsgetchecked.com/us/en/home-std-test/>
12. At Home Sexual Health and General Wellbeing Testing [Internet]. My Home Tests. [cited 2020 Sep 10]; Available from: <https://myhometests.com/>
13. At Home STD Tests | Test Kits For All Common STDs | myLAB Box™ [Internet]. At Home Tests | myLAB Box™. [cited 2020 Sep 10]; Available from: <https://www.mylabbox.com/>
14. Online Blood Testing Labs | Bloodwork Labs [Internet]. Personalabs. [cited 2020 Sep 10]; Available from: <https://www.personalabs.com/>
15. STD lab testing for chlamydia and gonorrhea and treatment for chlamydia [Internet]. [cited 2020 Sep 10]; Available from: <https://www.lemonaidhealth.com/services/std-testing>
16. Pixel by LabCorp [Internet]. Pixel by LabCorp. [cited 2020 Sep 10]; Available from: <https://www.pixel.labcorp.com/>
17. QuestDirect Test Catalog [Internet]. <https://questdirect.questdiagnostics.com/products>. [cited 2020 Sep 10]; Available from: <https://questdirect.questdiagnostics.com/products>
18. Fast, Private, Confidential STD Testing | How it Works [Internet]. [cited 2020 Sep 10]; Available from: <https://www.stdcheck.com/how-std-testing-works.php>
19. STD Test Kit: Order Online with Free Delivery - Nurx™ [Internet]. [cited 2020 Sep 10]; Available from: <https://www.nurx.com/sti-testing/>
20. How It Works [Internet]. PlushCare. [cited 2020 Sep 10]; Available from: <https://plushcare.com/how-it-works/>