# HIV TESTING TOOLKIT

## SELECTING A STRATEGY

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444 North Capitol Street NW, Suite 339
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Phone: (202) 434.8090
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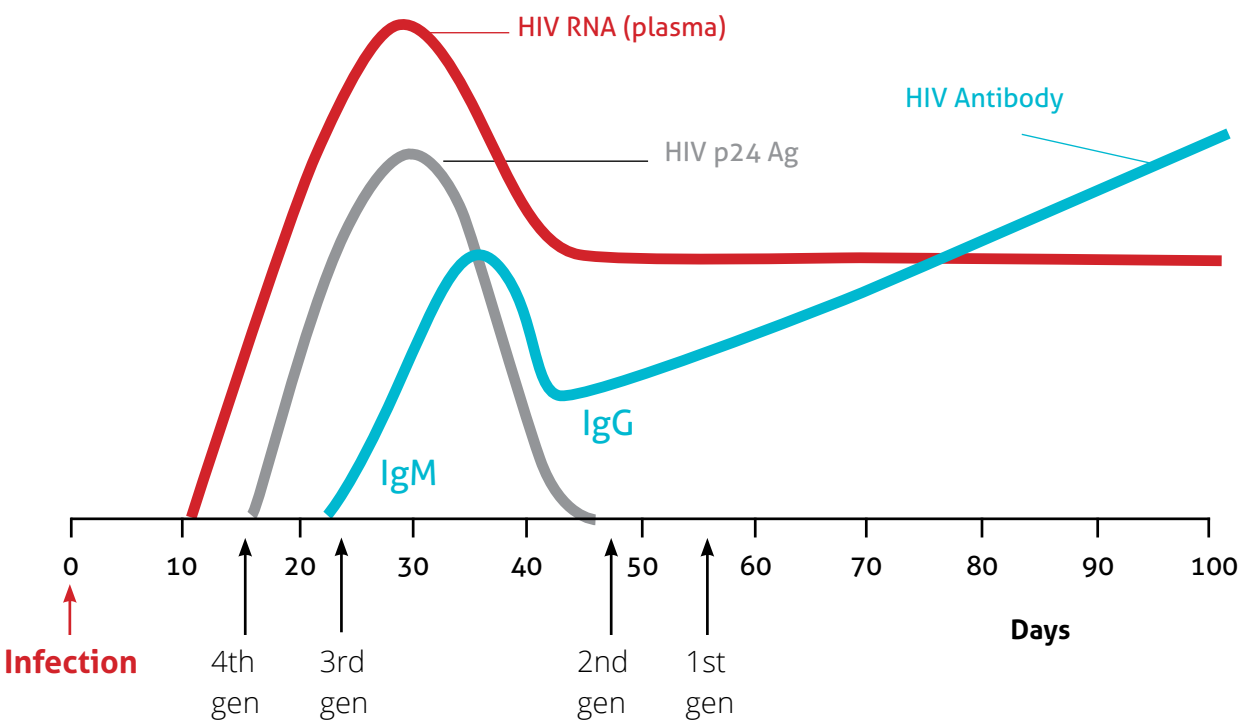
# HIV Test Technologies 101

Recently there has been a great deal of discussion about emerging HIV testing technology. As health departments (HDs) consider which tests to use and where, this primer serves to delineate current options. HIV tests are typically described in terms of their "generation." First and second generation tests detect antibodies which appear later in the course of HIV infection. First generation antibody tests (including the Western blot) have window periods of approximately six weeks. The window period of second generation antibody tests is approximately four to six weeks. Most rapid HIV tests currently used by HD HIV testing programs are considered equivalent to second generation antibody tests. Third generation antibody tests have a window period of approximately three to four weeks. Fourth generation tests detect both antibodies and antigen. The window period of fourth generation tests is approximately two to three weeks. Nucleic acid tests (NAT) directly detect HIV virus. The window period for NAT is approximately seven to 14 days. The approximate window period for detection of HIV infection, by HIV test generation, is illustrated in Figure 1, below.

*Figure 1: HIV Infection and Laboratory Markers*




Modified after Busch et al. Am J Med. 1997

Oral fluid tests are **less sensitive** during **acute infection** than laboratory-based screening tests designed for use with blood and have a longer window period than other blood-based laboratory tests. There is one FDA-approved rapid test approved that can be used with either blood or oral fluid samples. The sensitivity and specificity of this test is lower when used with oral fluid when compared with blood specimens.

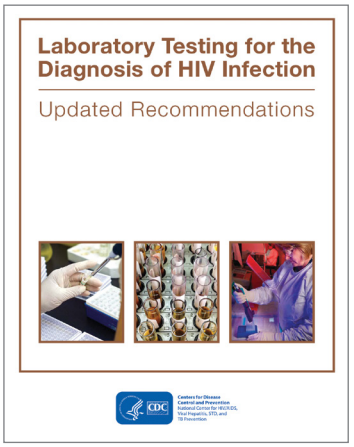
# Testing Strategies 101

There are two basic HIV testing strategies: (1) *laboratory-based* (sometimes referred to as "conventional" testing); and (2) *point-of-care rapid testing.*

## LABORATORY TESTING

Laboratory HIV testing involves obtaining a specimen from a patient and sending it to a laboratory for processing. Most laboratories use several different tests in a sequence (i.e., an "algorithm") to diagnose HIV infection. If the first test result is reactive, one or more tests may be conducted. If testing is performed "in house," such as in a hospital laboratory, results may be available within several hours. If testing is performed elsewhere, such as in a public health or commercial laboratory, test results may be available within several days.

> The CDC published recommendations for **Laboratory Testing for the Diagnosis of HIV Infection**. The CDC recommends an algorithm which begins with a fourth-generation HIV antibody/antigen combination test. A reactive result on the first test is followed by a second antibody test. A negative or indeterminate result on the second test is followed by a NAT. Because this algorithm begins with a fourth-generation test, it enables identification of HIV infection within two to three weeks of infection. The second test in this algorithm allows differentiation of HIV-1 from HIV-2 infections. Use of the NAT in this algorithm enables identification of acute HIV infection. Many public health laboratories currently use the CDC-recommended algorithm, or are in the process of converting to it.




## POINT-OF-CARE RAPID TESTING

There are a number of rapid HIV tests that may be used outside of a laboratory setting, at point-of-care. These tests have been categorized as waived tests under the **Clinical Laboratory Improvement Amendments (CLIA)**. Point-of-care rapid HIV testing is just that: tests conducted where the client receives services and results are typically available on the same day/visit. Reactive test results require supplemental laboratory testing to confirm a diagnosis of HIV. Final results are typically available within several days. Supplemental testing may be performed by the provider that conducted the rapid test or through referral to another provider.

> Most rapid tests that detect HIV antibodies only, are considered equivalent to second generation antibody test, and have a window period of approximately four to six weeks. Many rapid tests detect but do not distinguish between HIV-1 and HIV-2. There is currently only one rapid test, suitable for use at point-of-care, which detects and distinguishes reactivity to antibodies and antigens. The CDC has published an **information sheet** on this test.

A comparison of testing strategies is presented in Table 1, below:

## TABLE 1: COMPARISON OF TESTING STRATEGIES

| | Laboratory-Based Testing (CDC-recommended algorithm) | Point-of-Care Rapid Testing |
|---|---|---|
| *Approximate window period* | 2-3 weeks | 4-6 weeks* |
| *Able to detect acute HIV infection* | Yes | No |
| *Able to distinguish between HIV-1 and HIV-2* | Yes | No |
| *Final results* | From single sample | Requires 2nd sample for supplemental testing if reactive screening result |
| *Integration of STD, viral hepatitis testing* | Yes, multiple tests can be performed on single sample | No, separate samples needed for other tests |
| *Cost* | Relatively low, depending on volume, per test cost typically below $5 | Test devices typically cost between $7 and $20, each; Controls additional cost |
| *Results* | Final result from single sample | Negative results from single sample. Reactive results require supplemental testing with second sample |
| *Timeframe for delivering results* | Several hours to several days to final result, depending on setting and work flow | Negative results delivered same visit/day |
| *Sample type* | Serum or plasma | Whole blood or oral mucosal transudate |
| *Sample collection and processing* | Sample collection via venipuncture. Sample requires centrifuging and possibly temperature controlled shipping | Sample collection via finger stick or oral swab |
| *Quality assurance and monitoring* | Requires limited quality assurance by testing providers. | Requires more extensive quality assurance by testing providers (e.g., temperature and lot control, staff proficiency testing, storage space), especially if multiple rapid tests are to be used in sequence |

**Data regarding the detection of acute HIV infection from whole blood samples is limited.*

# Selecting a Testing Strategy

There are many factors for health departments (HDs) to consider when selecting an HIV testing strategy. In general, HDs should use a testing strategy which ensures accurate and timely results. Optimally, they should use a testing strategy which can identify HIV as early in the course of infection as possible. It's important to note, however, that a single testing strategy may not be appropriate in every situation, setting, or for every population.

Health departments may decide to support different testing strategies for different settings (e.g., clinics or community-based organizations) or populations, or they may decide to support just one strategy across all of their testing programs. In making decisions about testing strategies, HDs should consider population-, client- and program-level factors. The factors are summarized in Table 2, below:

## TABLE 2: FACTORS TO CONSIDER IN SELECTING AN HIV TESTING STRATEGY

### POPULATION-LEVEL FACTORS

- HIV prevalence
- HIV incidence
- Incidence of HIV-2
- Co-morbidity of other STDs, viral hepatitis

### CLIENT-LEVEL FACTORS

- Likelihood of acute HIV infection (i.e., symptomatic, recent exposure)
- Likelihood that clients will return for 2nd visit to receive final result or supplemental testing
- Understanding of accuracy of testing strategy, specific tests
- Acceptability of the testing strategy (e.g., specimen type, length of time for result delivery, method of result delivery)
- Appropriateness to client needs and priorities (e.g., co-morbidity with STDs, HCV)

### PROGRAM-LEVEL FACTORS

- Staff skills and training
- Staff attitudes and perceptions about HIV testing and test strategy
- HD capacity for training and monitoring
- Cost
- Feasibility of introducing strategy into existing workflow or setting
- Laboratory capacity to implement the CDC-recommended testing algorithm
- Collection, processing, and transport of specimens
- Capacity and resources to facilitate linkage to and engagement in HIV medical care
- Capacity and resources to facilitate linkage to and engagement in risk reduction interventions
- Policy and regulatory requirements (e.g., funding requirements, laboratory or licensure requirements, service integration)

A single strategy may not be appropriate or feasible for all HD-supported HIV testing programs, for all populations served by or targeted for testing services, or for all settings in which HIV testing is provided. Health departments may use a combination of both laboratory and point-of-care strategies across their program or within individual testing venues or settings.

For example, an HD may elect to use rapid testing in conjunction with outreach testing activities and laboratory-based testing for testing performed in fixed-site testing programs. Alternatively, an HD may decide to provide HIV testing using point-of-care rapid tests for the vast majority of clients, but for some clients may recommend and/or provide laboratory testing that can identify acute infection.

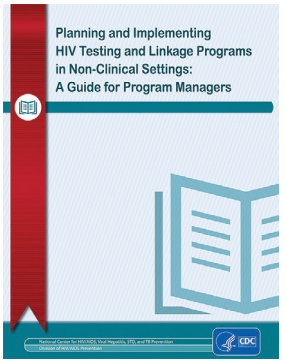
A single strategy may not be appropriate or feasible for all programs, populations, or settings.

Generally, laboratory-based testing using the CDC-recommended testing algorithm is preferred. This test strategy identifies HIV infection early in the course of infection and has the ability to identify acute HIV infection. These features are very important in populations or communities with relatively high rates of transmission and where acute HIV infection may be a concern, such as among men who have sex with men (MSM). This strategy also has the advantage of facilitating integration of STD and viral hepatitis services, by enabling screening for other infections using a single sample. This is an important feature for populations or communities where co-morbidity is a concern, such as gay men and syphilis, or hepatitis C infection among injecting drug users. Laboratory-based testing tends to be less costly than point-of-care testing, especially in high volume settings.

## HOW TO DECIDE?

Table 3, on the following page, presents various factors that health departments should consider in selecting a testing strategy. After each factor, suggestions for how to assess and address those factors are provided. It is strongly recommended to engage the public health laboratory, contracted testing providers, and representatives of target populations in planning efforts. This will ensure that HDs have access to the expertise and perspectives necessary to make a well-informed decision regarding which tests and testing strategies to use, in which settings, and with which populations.

Additionally, HDs may wish to refer to the CDC-produced "**Planning and Implementing HIV Testing and Linkage Programs in Non-Clinical Settings: A Guide for Program Managers**" for more detailed discussion of implementation issues in non-clinical, community-based settings. NASTAD's 2014 webinar, *Update on HIV Testing*, addressed current and near future testing technologies and strategies. A **recording** from the webinar and **slides** are available for download. Finally, CDC's ***Laboratory Testing for the Diagnosis of HIV Infection: Updated Recommendations*** describes the recommended laboratory testing algorithm, including summarizing performance studies, provides sample language for reporting test results, and describes how the laboratory algorithm should be used for supplemental testing associated with reactive rapid tests conducted at point of care.



## TABLE 3: EXAMINING IMPLEMENTATION FACTORS

| POPULATION-LEVEL FACTORS | Considerations |
|---|---|
| ■ **HIV prevalence**<br>■ **HIV incidence**<br>■ **HIV-2 prevalence**<br>■ **Co-morbidity of other STDs, viral hepatitis** | ■ Use epidemiologic data to characterize incidence and prevalence of HIV, STDs, and viral hepatitis. Consider doing this for specific testing providers, geographic areas, and populations to assist with selecting the best testing strategy for a particular setting, area, or population. |
| **CLIENT-LEVEL FACTORS** | **Considerations** |
| ■ **Likelihood of acute HIV infection (i.e., symptomatic, recent exposure)** | ■ Train testing staff to employ a brief set of screening questions to identify patients who have symptoms indicative of acute infection who may benefit from acute testing. |
| ■ **Likelihood that clients will return for 2nd visit to receive final result or supplemental testing** | ■ Make test results available via telephone or electronically. Implement strategies to remind clients to return for results (e.g., text message reminders). Develop simple messages that testing staff can use with clients to help them understand the need for supplemental testing and for returning for test results. Use partner services staff to deliver HIV-positive test results. |
| ■ **Understanding of accuracy of testing strategy, specific tests** | ■ Train testing staff to use simple messages regarding the accuracy of tests, and the approximate window period of tests to optimize client understanding of test limitations. This will be important for clients who may express a preference for point-of-care rapid testing but who would benefit from laboratory-based testing using the CDC-recommended algorithm, including clients who have symptoms indicative of acute HIV infection. |
| ■ **Acceptability of the testing strategy (e.g., specimen type, length of time for result delivery, method of result delivery)** | ■ During program planning, assess client awareness and understanding of various tests and testing strategies. This will help to identify the best testing strategy and also help to craft messages for clients to increase their understanding and acceptance of the tests and testing strategies used by the program. Consider conducting interviews or focus groups with representatives of |

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| | the target population(s) to explore different testing methods. This will help in understanding which factors are likely to be a barrier or facilitator to using particular testing methods. |
| ■ **Appropriateness to client needs and priorities (e.g., co-morbidity with STDs, HCV)** | ■ Testing strategies should optimally enable screening for relevant co-infections thereby facilitating treatment for these infections, regardless of HIV status. Testing staff should employ simple messages to help clients understand the value of being tested for multiple infections. |
| **PROGRAM-LEVEL FACTORS** | Considerations |
| ■ **Staff skills and training** | ■ During program planning, consider the knowledge, skills, and proficiencies that testing staff will need to perform testing using the selected strategy. |
| ■ **Staff attitudes and perceptions about HIV testing and test strategy** | ■ During program planning, assess testing staff awareness and understanding of various tests and testing strategies. This will help craft education and training for staff to increase their understanding and acceptance of the employed tests and testing strategies. Consider conducting interviews or focus groups with representatives of the target population(s). |
| ■ **Health department capacity for training, monitoring** | ■ The health department (the public health laboratory and/or the HIV/AIDS program) will need to have adequate capacity to support the necessary and ongoing training for staff performing testing. During planning staff will need to determine whether the health department (the HIV/AIDS program and/or the public health laboratory) has adequate resources and needed expertise to support the number of testing agencies and providers of testing with training, technical assistance, and programmatic monitoring. |
| ■ **Cost** | ■ The health department should perform a cost analysis to determine the cost of the proposed testing strategy relative to available resources. The cost analysis should address laboratory costs such as reagents or kits, sample collection supplies, storage of reagents or kits, specimen transport, and staff costs. |

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| ■ **Feasibility of introducing strategy into existing workflow or setting** | ■ Conduct a work flow analysis to determine where in an existing workflow the various components (e.g., sample acquisition, sample preparation) testing can feasibly be introduced. Integrating HIV testing into an existing workflow (e.g., at the time that blood is drawn for other tests) will be more sustainable and efficient than implementing a parallel process.<br><br>■ Conduct an analysis of the setting or venue in which testing is to be performed. The setting must allow for client privacy and confidentiality, and compliance with legal and regulatory requirements for laboratory quality and safety. Certain settings may preclude use of certain test technologies (e.g., those that require a blood sample). |
| ■ **Laboratory capacity to implement the CDC-recommended testing algorithm** | ■ Contact the public health laboratory to determine the HIV testing algorithm that is currently used and to discuss future plans for changing the algorithm. Some HD-supported testing programs use clinical or commercial laboratories that should be contacted to determine the testing algorithm being used by that laboratory. If they are not currently using the CDC-recommended algorithm, the public health laboratory may be able to provide the laboratory with training and technical assistance to adopt the CDC-recommmended algorithm. |
| ■ **Collection, processing, and transport of specimens** | ■ Work with the public health laboratory to identify the requirements for collection, processing, and transport of specimens. For laboratory-based testing or point-of-care rapid testing, they can provide the necessary expertise to develop protocols, procedures, and training for testing providers. They may also be able to provide technical assistance to providers using clinical or commercial laboratories. |
| ■ **Capacity and resources to provide clients with results** | ■ Assess the resources that the testing program has for providing clients with test results in a timely manner. Do they, for example, have the capacity (or could capacity be developed) to provide results via telephone (e.g., can the agency implement a protocol that requires clients to call-in and have staff to verify client identity? Do they have adequately trained staff to provide this service during regular business hours?)? Timely return of results is particularly important in the case of clients identified with acute HIV infection. |

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| ■ **Policy and regulatory requirements (e.g., funding requirements, laboratory or licensure requirements, service integration)** | ■ During program planning, assess the policy, legal, and regulatory considerations that impact HIV testing. There may be different regulatory and legal requirements for clinics and community-based organizations, as well as for clinical and lay providers. Work with state and/or local government entities responsible for licensing clinics and clinical providers, and for regulating laboratories. |


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