

# RAPID HIV TESTING IN NONCLINICAL SETTINGS

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## DESCRIPTION

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Rapid HIV Testing in Nonclinical Settings is HIV antibody testing performed on a sample of fingerstick whole blood or oral fluid. Rapid testing can be done in locations typically accessed by outreach. It offers an opportunity to take advantage of the benefits of outreach testing and ensure that tested persons receive their results. Two rapid tests—the OraQuick Advance Rapid HIV-1/2 Antibody Test and the Uni-Gold Recombigen HIV Test—can be used in selected nonclinical settings and can provide results in 10 to 20 minutes (so clients do not need to schedule a separate visit to get results). It is important to realize that reactive rapid test results must always be confirmed using a second, more specific test (e.g., the Western blot). Therefore, until the reactive result is confirmed, the result is interpreted as preliminary positive.

### Background

Outreach efforts for HIV prevention activities provide access to hard-to-reach populations at high risk for HIV. Bringing HIV prevention counseling, testing, and referral to these outreach sites through the use of mobile vans and HIV tests designed for whole blood and oral fluid has helped to increase knowledge of HIV status among many groups.

CDC is revising its HIV counseling and testing guidelines. Separate guidelines are being developed for HIV testing in health care settings and HIV counseling, testing, and referral in non-healthcare settings. The guidance provided in this document may change, depending on the results of the guideline revision process; however, until that time, the recommendations in this document should be adhered to.

Specifically, Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health Care Settings will be published later in 2006. They will replace CDC's 1993 Recommendations for HIV Testing Services for Inpatients and Outpatients in Acute-Care Hospital Settings; and they will update aspects of CDC's 2001 Revised Guidelines for HIV Counseling, Testing, and Referral that apply to health care settings and the 2001 Revised Recommendations for HIV Screening of Pregnant Women. In addition, the process for updating recommendations for HIV testing in non-healthcare settings is under way, with publication expected in 2007.

### Goals

Rapid HIV Testing in Nonclinical Settings aims to increase knowledge of HIV status among many groups.

### How It Works

By bringing testing into the community and providing test results quickly, rapid HIV tests can be used to reach groups in which HIV infection has been underdiagnosed. HIV infection is

underdiagnosed when people do not recognize that they are at risk for HIV infection or they do not use conventional HIV counseling, testing, and referral services. Testing programs in nonclinical settings are more likely to reach members of some racial and ethnic minorities and persons at increased risk for HIV.

### **Research Findings**

Studies at CDC-funded sites showed that persons tested at nonclinical (outreach) sites were 2 times as likely as persons tested at conventional (CDC-funded) testing sites to report high-risk heterosexual contacts and 3 to 4 times as likely to report injection drug use or male-to-male sex.<sup>1</sup>

In addition, the rate of HIV-positive test results in nonclinical settings is generally high and consistently higher than at conventional testing sites.<sup>1</sup> Unfortunately, many persons tested in nonclinical settings do not return for their test results. CDC's national data from 2000 indicate that of all HIV-positive results from tests performed in nonclinical settings, nearly half were never received. With rapid testing in outreach programs, however, limited experience is encouraging. In a Minnesota program, an outreach worker regularly visited CBOs, homeless shelters, chemical dependency programs, and needle exchange programs to offer rapid HIV testing. When results were provided the same day, 99.9% of those tested received their HIV test results.<sup>2</sup>

Interviews of persons at nonclinical settings reveal features important to the success of this type of testing. For persons at high risk at a needle exchange program and gay bath houses, 36% of those who had never been tested and 28% of those who had delayed testing gave as their reason "not wanting to go to a clinic."<sup>3</sup> Participants in other testing initiatives cited a desire to receive HIV results immediately and a need for testing during expanded hours as important reasons to increase alternative testing opportunities.<sup>4</sup>

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## **CORE ELEMENTS, KEY CHARACTERISTICS, AND PROCEDURES**

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### **Core Elements**

Core elements are those parts of an intervention that must be done and cannot be changed. **Core elements are essential and cannot be ignored, added to, or changed.**

Rapid HIV Testing in Nonclinical Settings has the following 7 core elements:

- Assess the community to determine
  - in which populations HIV is likely to be underdiagnosed (because risk is underestimated or because conventional counseling, testing, and referral services are not used)
  - where and when to reach persons who are at risk, underdiagnosed, or both
- Collaborate (written agreement) with the state health department, a laboratory, or both to ensure compliance with the Clinical Laboratory Improvement Amendments (CLIA) and state and local regulations and policies.
- Delineate a clear supervisory structure to ensure responsibility for training and guidance, oversight for testing procedures, and coordination.

- Train, or ensure training of, providers in nonclinical settings to perform rapid HIV testing. Include the following essential elements on how to
  - perform the test, including procedures done before, during, and after testing
  - integrate rapid testing into the overall counseling and testing program
  - develop and implement a quality assurance program (Guidelines are available at [www.cdc.gov/hiv/rapid\\_testing/materials/QA-Guide.htm#qc](http://www.cdc.gov/hiv/rapid_testing/materials/QA-Guide.htm#qc).)
  - collect and transport specimens for confirmatory testing
  - ensure specimen integrity
  - document and deliver confirmatory test results to persons whose rapid test results had been preliminary positive
  - comply with universal and biohazard safety precautions
  - ensure confidentiality and data security
  - ensure compliance with relevant state or local regulations
- In conjunction with health departments (state, local, or both) and community mental health providers, establish clear and easy guidelines and sobriety standards to help counselors determine when clients are not competent to provide consent. Although it is important to assess sobriety level, every person who has been drinking or using other substances should not be excluded from testing. Some persons will be active substance abusers who use substances on a daily basis; these persons are generally at high risk for infection and should not be excluded from testing if they are still capable of providing informed consent. In situations where a client's sobriety and ability to provide informed consent is questionable, some counselors have found it helpful to ask the client what he or she would do in the event of a preliminary positive result. This may be 1 of several questions that counselors could use to assess an individual's ability to provide informed consent.
- Ensure confirmatory testing of preliminary positive test results.
- Provide clients who have a confirmed HIV-positive diagnosis with, or refer them to, medical evaluation, partner counseling and referral services, and other appropriate prevention services.

### **Key Characteristics**

Key characteristics are those parts of an intervention (activities and delivery methods) that can be adapted to meet the needs of the CBO or target population.

Rapid HIV Testing in Nonclinical Settings has the following key characteristics:

- Arrange appropriate referral agreements (for medical and social services), and develop strategies for follow-up.
- Obtain detailed locating information for clients whose test results are preliminary positive so that the clients can be contacted and encouraged to come in for care if they fail to return for their follow-up appointment. The health department and the testing program should specify who is responsible for follow-up of clients who fail to return for confirmatory test results.
- Assemble the testing supplies for easy storage and transportation to each testing site. Individually packaged rapid test kits include all the supplies and materials needed to facilitate single-client testing in nonclinical settings.

## **Procedures**

Procedures are detailed descriptions of some of the above-listed elements and characteristics.

Procedures for providing Rapid HIV Testing in Nonclinical Settings are as follows:

### **Assessing the Community**

CBOs considering the use of rapid testing in nonclinical settings should begin by assessing their community. They should seek input from community planning groups, other community-based service providers, staff from similar programs within the CBO (e.g., needle exchange or screening for sexually transmitted infections), and representatives of their target populations. They should find out where persons at high risk for HIV are likely to spend time and where rapid testing services could be delivered without an appointment, with little waiting time, and with no barriers such as transportation.

### **Ensuring Regulatory Compliance**

If the needs assessment indicates that Rapid HIV Testing in Nonclinical Settings is both appropriate and feasible, the CBO must ensure an understanding of, and compliance with, CLIA and all state and local regulations and policies. This is done through a written agreement with the state or local health department, laboratory, or both.

The agreement delineates

- responsibility for training and guidance
- oversight for testing procedures
- coordination of services
- assurance that confirmatory testing of preliminary positive results is provided

### **Training Staff**

Training on the essential elements of delivery of the HIV rapid test is available from CDC. CDC recommends that any persons who are responsible for the delivery of the rapid test should be trained in and familiar with

- client-centered HIV prevention counseling
- performing the rapid test
- providing and interpreting test results (including the meaning of negative, preliminary positive, and invalid test results)
- referring clients for services (social and medical)
- reporting positive test results to the state or local health department

### **Handling and Tracking Specimens and Materials**

Rapid HIV Testing in Nonclinical Settings differs from standard counseling, testing, and referral in that rapid testing materials must be carried to the testing site. Individually packaged rapid test kits include all the supplies and materials necessary for single-client testing in nonclinical settings, but CBOs must devise a means for easy storage and transport of testing materials. In addition, specimens collected for confirmatory testing must be transported to a laboratory for analysis. Specimen handling and tracking procedures must be devised to ensure the safety and integrity of the specimen and to comply with Occupational Safety and Health Administration regulations for handling of infectious waste. An exposure control plan must be devised for potential occupational exposures.

### **Locating Clients**

Detailed locating information must be obtained for all persons with a preliminary positive test result so that they can be contacted to come in for care should they fail to return for their follow-up appointment. The state or local health department and CBO must specify who is responsible for following up with clients who fail to return for confirmatory test results. In some states, preliminary positive results cannot be given to clients. Consideration should be given, where appropriate, to eliminating such barriers to rapid testing.

### **Staying Current**

CBOs should frequently review the package insert for the rapid HIV test to note any recommended changes related to test delivery and use.

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## **RESOURCE REQUIREMENTS**

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### **People**

Rapid HIV Testing in Nonclinical Settings needs staff members who are trained in HIV counseling, testing, and referral and in the delivery of rapid HIV testing. Training should include all topics noted under Quality Assurance, below. The number of staff needed will vary according to the number of tests to be done. The number of tests completed per hour depends on the needs of the clients and the abilities of the counselor. Each counselor may provide between 1 and 3 tests per hour. Explaining positive results will take longer. CBOs should staff their programs according to the projected need for rapid testing in their area. This information can be obtained from an appropriate needs assessment and a review of the local epidemiologic profile (the HIV prevention community plan and other sources of relevant information).

Rapid HIV Testing in Nonclinical Settings also needs trained staff members to conduct outreach activities, follow-up and linkage to care activities, and to provide security (if testing is offered in unsafe areas or during the evening or nighttime hours).

### **Space**

Rapid HIV Testing in Nonclinical Settings can be done anywhere that confidentiality of clients can be assured (e.g., private area or room) and where a specimen can be collected according to minimal standards as outlined by the Occupational Safety and Health Administration. The setting must have a flat surface, acceptable lighting, and ability to maintain temperature in the range recommended by the test manufacturer for performing the test. Clients must be able to stay long enough to be counseled and tested and to receive their results.

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## **RECRUITMENT**

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Review Recruitment in this document to choose a recruitment strategy that will work in the setting in which the CBO plans to implement Rapid HIV Testing in Nonclinical Settings.

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## POLICIES AND STANDARDS

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Before a CBO attempts to implement Rapid HIV Testing in Nonclinical Settings, the following policies and standards should be in place to protect clients, the agency, and the test provider:

### **Confidentiality**

A system must be in place to ensure that confidentiality is maintained for all participants in the program. Before sharing any information with another agency to which a client is referred, signed informed consent (for release of information) from a client or his or her legal guardian must be obtained.

### **Cultural Competence**

CBOs must strive to offer culturally competent services by being aware of the demographic, cultural, and epidemiologic profile of their communities. CBOs should hire, promote, and train all staff to be representative of and sensitive to these different cultures. In addition, they should offer materials and services in the preferred language of clients, if possible, or make translation available, if appropriate. CBOs should facilitate community and client involvement in designing and implementing prevention services to ensure that important cultural issues are incorporated. The Office of Minority Health of the Department of Health and Human Services has published the *National Standards for Culturally and Linguistically Appropriate Services in Health Care*, which should be used as a guide for ensuring cultural competence in programs and services. Please see Ensuring Cultural Competence in the Introduction of this document for standards for developing culturally and linguistically competent programs and services.

### **Data Security**

To ensure data security and client confidentiality, data must be collected and reported according to CDC requirements.

### **Informed Consent**

CBOs must have a consent form that carefully and clearly explains (in appropriate language) the CBO's responsibility and the client's rights. In some states informed consent is not required to be written and can be given orally. Client participation must always be voluntary, and documentation of this informed consent must be maintained in the CBO's records. Clients offered HIV testing at nonclinical settings may be under the influence of alcohol or drugs or may have chronic mental health conditions, any of which may interfere with their ability to provide informed consent for voluntary HIV testing and to understand test results. CBOs should work with their state or local health department and with community mental health providers to establish clear and easy guidelines and sobriety standards to help counselors determine when clients are not competent to provide consent. Because regulations vary by state, CBOs should be familiar with informed consent requirements in their state.

### **Legal and Ethical Policies**

Rapid testing in nonclinical settings requires specialized training and deals with private client medical information. CBOs must know their state laws regarding who may implement counseling, testing, and referral and rapid testing and about disclosure of a client's HIV status (whether positive or negative) to sex partners and other third parties. Additionally, some state laws prohibit the disclosure of preliminary positive test results. CBOs must also know, and adhere to all CLIA regulations for testing, documentation, and use of logs relating to test implementation. CBOs also must inform clients about state laws regarding the reporting of child abuse, sexual abuse of minors, and elder abuse, or imminent danger or harm to a specific person.

### **Referrals**

CBOs must be prepared to refer clients as needed. Follow-up procedures for clients with preliminary positive rapid test results must be in place. A follow-up visit must be scheduled so these clients can receive confirmatory test results and referrals for care (within or outside the CBO). HIV counselors from the nonclinical setting may accompany clients to the medical center to provide support and ensure continuity of care. For clients who need additional help decreasing risk behavior, providers must know about referral sources for prevention interventions and counseling, such as partner counseling and referral services and health department and CBO prevention programs for persons living with HIV.

### **Safety**

Counseling, testing, and referral and rapid testing services that are provided in outreach settings may pose potentially unsafe situations (e.g., the risk of transmitting bloodborne pathogens). CBOs should develop and maintain written detailed guidelines for ensuring personal safety and security in outreach settings; minimal safety standards with regard to specimen collection as outlined by the Occupational Safety and Health Administration; and the security of the data collected, client confidentiality, and the chain of custody for testing supplies and collected client specimens. Agreements with law enforcement agencies, owners of social locations such as bathhouses or sex clubs, neighborhood associations, and other key partners should be established before testing activities begin.

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## **QUALITY ASSURANCE**

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The following quality assurance activities should be in place when implementing Rapid HIV Testing in Nonclinical Settings:

### **Counselors**

#### **Training**

CBOs should have a training program in place for all new and existing employees providing rapid HIV testing services. This program should ensure that all providers receive adequate training, annual training updates, continuing education, and appropriate supervision to implement rapid testing services, including training with regard to

- providing client-centered HIV prevention counseling
- providing information to persons before they are tested

- understanding HIV transmission and prevention of HIV and other sexually transmitted diseases
- understanding the history of HIV
- understanding partner counseling and referral services
- understanding comprehensive risk counseling and services
- knowing about prevention and support services in the area
- using gloves for personal protection
- disposing safely of biohazardous waste, including used lancets
- maintaining sufficient supplies and unexpired test kits and control kits (including proper storage and performance checks for new lots of test kits and shipments with external controls)
- maintaining and documenting the temperature of the room and refrigerator where the test and control kits are stored and testing is performed
- performing quality control testing and taking action (e.g., contacting the supervisor or manufacturer) if controls do not work
- collecting specimens
- performing the steps in the test procedure
- reporting results
- referring specimens or persons being tested for confirmatory testing and managing confirmatory test results
- recording test and quality control results
- conducting external quality assessment. (Please refer to [www.cdc.gov/hiv/rapid\\_testing](http://www.cdc.gov/hiv/rapid_testing).)
- reviewing records and storing and destroying them when they are outdated (how long test result records are kept as part of a medical record may be subject to state or other requirements)
- troubleshooting and taking corrective action when things go wrong

### **Protocol Review**

The training should ensure that providers are skilled and competent in the provision of services by watching them practice counseling skills integrating the rapid HIV test and watching them perform all steps of the rapid test. Quality assurance reviews can include direct observation of sessions as well as role-playing demonstration of skills. The reviews should focus on ensuring that the protocol is delivered with consistency and responsiveness to expressed client needs and should help counselors develop skills for delivering the intervention.

Control kits, available from the test kit manufacturer, should be used to ensure reliability and validity of the test process and materials. CDC also offers the Model Performance Evaluation Program to ensure accurate testing (available at [www.phppo.cdc.gov/mpep/for\\_enrl\\_form.asp](http://www.phppo.cdc.gov/mpep/for_enrl_form.asp)).

### **Record Review**

Reviews of selected intervention records should focus on ensuring that consent is obtained and documented for all clients and that all process and outcome measures are completed as required.

### **Clients**



Clients' satisfaction with the services and their comfort should be assessed periodically. Process monitoring systems should also track the number of referrals made and completed as well as responses to the service.

### **Setting**

Supervisors should periodically review the settings to ensure that they are private and confidential, that the requirements of the test are met, and that the waiting time for a test at this setting does not create a barrier to testing.

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## **MONITORING AND EVALUATION**

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At this time, specific guidance on the collection and reporting of program information, client-level data, and the program performance indicators is under review and will be distributed to agencies after notification of award.

General monitoring and evaluation reporting requirements for the programs listed in the Procedural Guidance will include the collection of standardized process and outcome measures as described in the Program Evaluation and Monitoring System (PEMS). PEMS is a national data reporting system that includes a standardized set of HIV prevention data variables, web-based software for data entry and management, data collection and evaluation guidance and training, and software implementation support services.

Funded agencies will be required to enter, manage, and submit data to CDC using PEMS. Furthermore, agencies may be requested to collaborate with CDC in the implementation of special studies aimed at assessing the effect of HIV prevention activities on at-risk populations.

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## **KEY ARTICLES AND RESOURCES**

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CDC. CDC model performance evaluation program for rapid HIV testing. Available at: [http://www.phppo.cdc.gov/mpep/for\\_enrl\\_form.asp](http://www.phppo.cdc.gov/mpep/for_enrl_form.asp).

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