Rapid HIV Testing

What is “rapid” HIV testing, and why do we need it?

Rapid HIV testing involves use of disposable HIV antibody tests that can detect HIV antibodies in a person’s blood or oral fluid, usually within 10-20 minutes. They do not require a full microbiology laboratory to be accurately run, and therefore rapid HIV tests can be provided in locations most likely to reach people with undiagnosed HIV, and offer same-day results in those locations.

Rapid HIV testing in non-clinical settings is important, because research has shown that people who test for HIV in non-traditional venues are twice as likely as those in conventional 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. Community-based organizations and other non-clinical settings often have established relationships with people at high risk for HIV, and offering testing in those locations can facilitate access to testing and ensure that HIV-positive individuals learn their status and are linked to care. Even more importantly, while the rate of HIV positive tests is generally higher in non-clinical settings than at medical test sites, the data show that many people in non-clinical settings do not return for their test results. Rapid testing allows people to receive their results on the same day they go for testing, making the rate of results disclosure nearly 100%.

What types of rapid HIV tests are currently on the market?

In order for a non-clinical setting to provide rapid HIV testing, they need to obtain a CLIA certificate of waiver. “CLIA” stands for the Clinical Laboratory Improvement Amendments of 1988, which established quality standards for laboratory testing to ensure that patients receive accurate, reliable, and timely results. Some tests are considered “CLIA-waived.” CLIA-waived tests must use unprocessed specimens (whole blood or oral fluid), be very easy to use, and have little risk of an incorrectly interpreted result. There are many types of certifications that laboratories can receive under CLIA; however, in order to run CLIA-waived tests, a testing site must apply for a CLIA certificate of waiver, or establish an agreement to work under the CLIA certificate of an existing laboratory. Holding a CLIA certificate of waiver means the agency is considered a clinical laboratory, only for the purpose of waived tests. For more information about how to obtain a CLIA certificate, see www.cdc.gov/hiv/topics/testing/resources/factsheets/roltclia.htm.

As of May 2012, there are 4 CLIA-waived rapid HIV tests on the market in the United States*

**OraQuick Advance Rapid HIV-1/2 Antibody Test**
- Can use oral fluid or whole blood
- Can detect HIV-1 and HIV-2
- Results take 20-40 minutes
- Sold by OraSure Technologies, Inc.

**Clearview HIV 1/2 STAT-PAK**
- Can be used with whole blood
- Can detect HIV-1 and HIV-2
- Results take 15-20 minutes
- Sold by Alere, Inc.

**Uni-Gold Recombigen HIV Test**
- Can be used with whole blood
- Can only detect HIV-1
- Results take 10-12 minutes
- Sold by Trinity Biotech

**Clearview COMPLETE HIV 1/2**
- Can be used with whole blood
- Can detect HIV-1 and HIV-2
- Results take 15-20 minutes
- Sold by Alere, Inc.

*This information is included purely for educational purposes and is not intended as an endorsement of any specific product.
What is a “preliminary positive”?  

All FDA-approved rapid HIV tests are currently approved as screening tests. Screening tests are designed to “cast a wide net” and miss the fewest number of true HIV-infections possible. However, this also means that screening tests sometimes have false positive results. While this is rare, the only way to rule out a false positive result is to run a second “confirmatory” HIV test using a different HIV test technology. Since all rapid HIV tests are considered screening tests, all positive results on rapid HIV tests are considered “preliminary positive.” Once a preliminary positive occurs, another test approved for confirmation must be done before the result is considered confirmed. Sometimes this requires a second visit to the test site to find out confirmatory results.

Setting up a Rapid HIV Testing Program

Whether an organization has provided conventional HIV testing in the past, or whether they are new to HIV testing, planning and implementing a rapid HIV testing program can be challenging. Here are some tips about how to successfully set up rapid HIV testing in your organization.

Talk to your local health department. Before you implement a rapid HIV testing program, you need to make sure you are adhering to all local, state, and federal requirements for testing. Because your site is functioning as a laboratory and providing results directly to clients, it is extremely important that services are well-planned and frequently evaluated. Your health department will help you determine what support is available to you in your area, can put you in touch with other organizations successfully doing rapid HIV testing, and may even have tools specific to your jurisdiction that can help you plan and implement a high-quality program.

Network with other organizations doing rapid HIV testing. There are organizations in the U.S. that have been doing rapid HIV testing since as early as 2003. Whether you are the first site in your area to do rapid HIV testing or not, there are organizations with vast experience who can support you in this process and offer advice. Use any networking tools you have to contact these organizations, and ask whether you can observe their services or borrow any of their written documents for adaptation in your own setting.

Identify staffing needs and train staff. The amount of staff you need for your rapid HIV testing program will depend on your clinic flow, the number of clients you expect to see, and more. At a minimum, you will need test counselors as well as people to run the test and provide results (these may be the same people or different people). It is often helpful to role-play the testing flow to determine how many staff you need to complete necessary tasks and remain client-focused. Once staff have been identified, you will need to make sure they are trained in counseling and/or the rapid test(s) you will be using. Each state has different training requirements; your local health department can help you understand your training needs and what opportunities are available for training your staff.

Obtain a CLIA waiver. Before any testing can begin you will need to obtain a CLIA certificate of waiver for your site, as described on page 1 of this information sheet. This process can be lengthy, so you should submit your application as early as possible in your planning process.

Look at options for funding the test kits. Test kits can be expensive. Start by talking with your local health department to see if there are any options to obtain free test kits from them, or from your state health department. If free kits are not available, talk to the manufacturer’s sales representative for your area to see what pricing plans they have; smaller agencies sometimes share orders to obtain bulk discounts.

Develop written policies and procedures. It is very important that you have a comprehensive set of written policies and procedures before you begin rapid HIV testing. Policies and procedures should address everything from testing inventory to universal precautions to clinic flow. One example of a policies and procedures document you could adapt for your own organization is available at: [http://sfhiv.org/documents/CTLTemplate3-21-10.pdf](http://sfhiv.org/documents/CTLTemplate3-21-10.pdf).

Set up a comprehensive quality assurance plan. As part of your written policies and procedures, you will need to have a plan for ensuring that your tests are working correctly, and your technicians are using them properly and providing accurate results.
Quality Assurance for Rapid HIV Testing

With rapid HIV testing, people with little to no laboratory training are responsible for providing an HIV result to their clients. It is imperative that an agency providing rapid HIV testing in a non-clinical setting has a robust quality assurance program, so that any issues with accuracy or reliability of the test results will be immediately caught and addressed. Many tasks related to rapid HIV testing require skills not typically required of staff in non-medical social service agencies.

Any non-clinical rapid HIV testing site should have the following quality assurance activities in place:

1. A training program for all new and existing employees, about safety and effectiveness in counseling and testing
2. Written records of inventory, as well as temperature of storage areas where tests and control kits are kept
3. Written records of the test each time it is performed, with the time and temperature when the result was read
4. Use of external control kits, provided by the manufacturer, on a regular basis to ensure test kit accuracy
5. Regular review of counselor performance, including role-playing, shadowing of sessions, and in-services
6. Regular review of test technician performance, including competency assessment testing at least annually
7. Regular review of selected client records to ensure that informed consent is being obtained appropriately

Additional Resources

Here are some additional resources that provide more specific guidance about rapid HIV testing:


- CLIA Certificate of Waiver Fact Sheet: [www.cdc.gov/hiv/topics/testing/resources/factsheets/roltelia.htm](http://www.cdc.gov/hiv/topics/testing/resources/factsheets/roltelia.htm)

- One example of a policies and procedures document you could adapt for your own organization is available at: [http://sfhiv.org/documents/CTLTemplate3-21-10.pdf](http://sfhiv.org/documents/CTLTemplate3-21-10.pdf)

- A 3 part Online Training series on High Impact HIV Testing is available on the Capacity 4 Health Online Resource Library at [http://library.capacity4health.org](http://library.capacity4health.org)

- Capacity for Health offers individualized capacity-building assistance. For more information, contact Capacity for Health at 415-568-3308 or [c4h@apiahf.org](mailto:c4h@apiahf.org).

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