



Establishing a Rapid HIV Testing Program: A Guide for Small AIDS Serving Organizations (ASOs)

This guide is designed to assist small and rural community-based AIDS Serving Organizations (ASOs) in building capacity to establish HIV testing programs in their service areas. By their very nature small ASOs tend to be under resourced with inadequate staff. This guide describes a step-by-step process requiring a minimum of resource an HIV to be implemented and sustained. The guide lays out the steps ASOs need to follow to establish an HIV testing program and resources that can provide ASOs with the technical assistance they need to develop successful and sustainable programs.

Step I: Needs Assessment to assess the *need* and the *acceptability* of the proposed testing Service:

By contacting the local health department and/or local health care providers such as hospitals, community health centers/clinics and/or AIDS serving organizations, ASOs can obtain epidemiological data on HIV rates in the community that may inform the decision to provide testing services.

Since ASOs are a part of the fabric of the communities they serve, it is important to assess whether the community wants/needs the proposed HIV testing program. There are various approaches to needs assessment and various resources that can assist ASOs to plan and conduct sound assessments.

Please refer to the Resource List at the end of this document for more information on organizations that provide technical assistance on needs assessment.

At a minimum community assessment efforts should include:

- ☞ Surveying existing ASO clients about the acceptability of the proposed service
- ☞ Seeking input from local HIV prevention and treatment providers
- ☞ Seeking input from other ASOs that already provide testing
- ☞ Review surveillance data to key stakeholders
- ☞

The goals of the community assessment are to ensure that the proposed testing service

- ☞ does not duplicate existing effort
- ☞ is culturally and linguistically acceptable
- ☞ focuses outreach efforts in areas where individuals at the highest risk for HIV are likely to be encountered; and
- ☞ Offers rapid HIV testing with the minimum of barriers (e.g. trained staff, available test kits, waiting time, concerns about confidentiality.).

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SAMPLE NEEDS ASSESSMENT QUESTIONS

What is the HIV prevalence rate in the target community?

Where will outreach efforts be conducted?

Will the ASO conduct in-reach (target clients of existing ASO services)?

How many persons does the ASO expect to test?

What will be the impact on staff's current workload and/or existing client flow?

Which testing approach will be employed?

Where will testing be conducted – a mobile or fixed venue?

What are the outreach and testing approaches/strategies proven to be effective with populations to be targeted?

Step II: Select a testing approach and venue based on the needs assessment data.

The following tables present the options and the pros and cons of each.

TESTING APPROACHES		
	Pros	Cons
Universal testing/screening: testing all persons in a defined population, recommended by the CDC	Most comprehensive approach Useful when HIV prevalence is unknown or if HIV and other STI prevalence is high	<ul style="list-style-type: none"> Most resource intensive approach in terms of staffing and financial costs
Targeted testing: testing members of a subpopulation that is at higher risk for HIV due to their behavioral, clinical and/or demographic characteristics	Useful in settings where the HIV prevalence rate is less than 1 percent Costs less than Universal Testing	<ul style="list-style-type: none"> Outreach staff must be trained to recognize members of the target population May not to identify a substantial number of persons who are HIV infected because they may not recognize that they are at risk for HIV and/or they do not disclose their risks
Diagnostic testing: testing all clients who present with signs and symptoms of AIDS.	Most inexpensive approach since testing focuses on those who are highly likely to be infected	<ul style="list-style-type: none"> Must have clinicians on staff who are trained to recognize the signs and symptoms consistent with HIV infection, opportunistic illnesses, and acute HIV infection Must be able to provide/refer patients to treatment and care services
SERVICE VENUE		
	Pros	Cons
Mobile Testing Unit	Increased access to target population Ability to test interested parties on the spot	Cost Confidentiality concerns particularly if signage indicates services are related to HIV/AIDS
Fixed Venue	Reduced financial costs associated with a fixed location Ease of transitioning persons infected to treatment and care	<ul style="list-style-type: none"> Potential inaccessibility to some members of the target population Delay in testing interested parties encountered during outreach Confidentiality concerns particularly if signage indicates services are related to HIV/AIDS

Another decision that needs to be made is on the brand of rapid test that will be used. The following tables develop by the CDC present the brands and pricing options. (See reference 8)

FDA-Approved Rapid HIV Antibody Screening Tests

February 4, 2008

	FDA Approval Received	Specimen Type	CLIA Category*	Sensitivity** (95% CI)	Specificity** (95% CI)	Manufacturer	Approved for HIV-2 Detection?	List Price Per Device^	External Controls
OraQuick ADVANCE Rapid HIV-1/2 Antibody Test	Nov 2002	Oral fluid	Waived	99.3% (98.4-99.7)	99.8% (99.6-99.9)	OraSure Technologies, Inc. www.orasure.com	Yes	\$17.50	Sold Separately (\$25 each)
		Whole Blood (finger stick or venipuncture)	Waived	99.6% (98.5-99.9)	100% (99.7-100)				
		Plasma	Moderate Complexity	99.6% (98.9-99.8)	99.9% (99.6-99.9)				
Uni-Gold Recombigen HIV	Dec 2003	Whole blood (fingerstick or venipuncture)	Waived	100% (99.5-100)	99.7% (99.0-100)	Trinity Biotech www.unigoldhiv.com	No	\$15.75 \$8.00*	Sold Separately (\$26.25 each)
		Serum & Plasma	Moderate Complexity	100% (99.5-100)	99.8% (99.3-100)				
Reveal G-3 Rapid HIV-1 Antibody Test	Apr 2003	Serum	Moderate Complexity	99.8% (99.2-100)	99.1% (98.8-99.4)	MedMira, Inc. www.medmira.com	No	\$14.00	Included
		Plasma	Moderate Complexity	99.8% (99.0-100)	98.6% (98.4-98.8)				

* "Public health" price for public health programs that are recipients of CDC funds for expanded HIV testing

* Clinical Laboratory Improvement Amendments: CLIA regulations identify three categories of tests: waived, moderate complexity, or high complexity

** Sensitivity is the probability that the test result will be reactive if the specimen is a true positive; specificity if the probability that the test result will be nonreactive if the specimen is a true negative. Data are from the FDA summary basis of approval, for HIV-1 only. For HIV-2 information, see package inserts.

^ Actual price may vary by purchasing agreements with manufacturers

Note: Trade names are for identification purposes only and do not imply endorsement. This information was compiled from package inserts and direct calls to manufacturers.



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MultiSpot HIV-1/HIV-2 Rapid Test	Nov 2004	Serum	Moderate Complexity	100% (99.94-100)	99.93% (99.79-100)	BioRad Laboratories www.biorad.com	Yes – differentiates HIV-1 from HIV-2	\$25.00	Included
		Plasma	Moderate Complexity	100% (99.94-100)	99.91% (99.77-100)				
Clearview HIV 1/2 STAT-PAK	May 2006	Whole Blood (finger stick or venipuncture)	Waived	99.7% (98.9-100)	99.9% (99.6-100)	Inverness Medical Professional Diagnostics www.invernessmedical.com	Yes	\$17.50	Sold Separately (\$50/set)
		Serum & Plasma	Non-waived	99.7% (98.9-100)	99.9% (99.6-100)			\$8.00*	
Clearview COMPLETE HIV 1/2	May 2006	Whole Blood (finger stick or venipuncture)	Waived	99.7% (98.9-100)	99.90% (99.6-100)	Inverness Medical Professional Diagnostics www.invernessmedical.com	Yes	\$18.50	Sold Separately (\$50/set)
		Serum & Plasma	Non-waived	99.7% (98.9-100)	99.9% (99.6-100)			\$9.00*	

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FDA-Approved Rapid HIV Antibody Screening Tests – Purchasing Details

February 4, 2008

	<u>Price For Device*</u>	<u>External Controls</u>	<u># of Tests per Case</u>	<u>Catalog numbers</u>	<u>Storage Temperature</u>	<u>Operating Temperature</u>	<u>Shelf life of Test**</u>	<u>Shelf Life of Control**</u>	<u>Total Time Required to Conduct Test***</u>	<u>Window Period for Reading Results****</u>
OraGulek ADVANCE Rapid HIV-1/2 Antibody Test www.oralguite.com	\$17.50	Sold Separately (\$25)	25 or 100	#1001-0079 (25 tests) #1001-0078 (100 tests) #1001-0077 (controls)	2-27°C (tests)	15-37°C	6 months	12 months	<5 minutes (<10 min. for plasma)	20-40 min
					2-8°C (controls)				21 days (after opening)	
Uni-Gold Recombigen HIV www.unigoldhiv.com	\$15.75 \$8.00-	Sold Separately (\$25.25)	20	#1206506 (tests) #1206530 (controls)	2-27 °C (tests)	15-27°C	12 months	12 months	<5 minutes	10-12 min
					2-8 °C (controls)				1 month (after opening)	
Reveal G-3 Rapid HIV-1 Antibody Test www.reveal-hiv.com	\$14.00	Included	20 or 60	B1057-6 (20 test kits) B1057-7 (60 test kits)	2-30°C (tests)	15-27°C	12 months	12 months	3-5 minutes	Result must be read immediately
					2-8°C (controls)				7 days (after reconstituting)	

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** From date of manufacture, unless otherwise noted

***First time listed is estimated time required to set up test. The second time is the required wait time before reading results. Times listed exclude time needed to draw/obtain sample

****As measured from last step of testing process

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Multispot HIV-1/HIV-2 Rapid Test www.biorad.com	\$25.00	Included	50	#72269 (test kits)	2-8 °C Or 20-30 °C (tests and controls)	20-30°C	12 months (@ 2-8 °C) 3 months (@ 20-30 °C)	12 months	10-15 minutes	Can be read immediately or anytime up to 24 hours
									No add. wait time	
Clearview HIV 1/2 STAT-PAK www.invernessdiagnostics.com	\$17.50 \$9.00-	Sold Separately (\$50/set)	20 per kit	92110 (tests) 92112 (controls)	8-30°C or 46-86°F	18-30°C or 64-86°F	24 months	24 months	< 5 minutes	15-20 minutes
									+ 15 min wait time	
Clearview COMPLETE HIV 1/2 www.invernessdiagnostics.com	\$18.50 \$9.00-	Sold Separately (\$50/set)	25 per kit	92111 (tests) 92112 (controls)	8-30°C or 46-86°F	18-30°C or 64-86°F	24 months	24 months	< 5 minutes	15-20 minutes
									+ 15 min wait time	

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Step III: Determine staffing needs

A quality HIV testing program must have:

- ☞ A *supervisor* who is responsible for overseeing the program and ensuring that it meets all federal, state, local and/or tribal standards of care and that the staff has the ongoing training and support needed to administer the testing services.
- ☞ *Outreach worker(s)* trained to recruit clients for testing in accordance with informed consent protocols.
- ☞ *Counselors* trained to *conduct testing* and to provide pre and post-test *counseling* and *referral* to prevention, medical care and ancillary services, such as partner counseling and substance abuse counseling. ASOs can determine the number of counselors needed based on the projected number of persons to be tested, as indicated by the needs assessment, and using the CDC¹ recommendation of a maximum of 3 tests per hour per counselor while factoring in additional time to provide pre and post test counseling and referral and the individual capacity of each counselor.

HIV Testing Counselor Responsibilities²

- provide client-centered HIV prevention counseling
- provide pre-testing information to persons before they are tested
- understand HIV transmission and prevention of HIV and other sexually transmitted illnesses
- understand the history of HIV
- understand partner counseling and referral services
- understand comprehensive risk counseling and services
- know about prevention and support services in the area/region
- use gloves for personal protection
- dispose safely of bio-hazardous waste, including used lancets
- maintain 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)
- maintain and document the temperature of the room and refrigerator where the test and control kits are stored and testing is performed
- perform quality control testing and taking action (e.g., contacting the supervisor or manufacturer) if controls do not work
- collect specimens
- perform the steps in the test procedure
- report results to patient as much as referring clinician
- refer specimens or persons being tested for confirmatory testing and manage confirmatory test results
- record test and quality control results
- conduct external quality assessments
- review records, store and destroy them in harmony with state or other requirements for storing medical record data
- troubleshoot and take corrective action when things go wrong

¹ Centers for Disease Control and Prevention (CDC) (2006) *Rapid HIV Testing in Nonclinical Settings*
http://www.cdc.gov/hiv/topics/prev_prog/AHP/resources/guidelines/pdf/pro_guidance_RT.pdf

² Adopted from the Centers for Disease Control and Prevention (CDC 2006)

- ☞ *Additional staff to follow-up on referrals*, provide *security* if testing is performed after hours and/or in unsafe areas, *coordinate the delivery of preliminary positive specimens* to the laboratory for confirmatory testing, *client tracking* and *client notification*, if the latter is not handled by counselors. Malignant

The *minimum staff training needs*³ relate to:

- ☞ client-centered HIV prevention counseling including
 - pre-test counseling** that addresses informed consents, the risks associated with HIV/AIDS, explains the rapid HIV test to be used, including the fact “rapid” refers to the time the test takes to yield results, the risks and benefits of testing, the implications of test results, and how test results will be communicated
 - post-test counseling** covering interpretation of test results, the process of confirmatory testing of preliminary positive results. Prevention counseling for clients with negative results. This also includes advising patients that if they have been exposed to HIV in the past three months, it may be too soon to detect infection.
- ☞ perform the rapid test
- ☞ provide and interpret test results – specifically the meaning of “negative”, “preliminary positive” and “invalid” test results
- ☞ client referral to medical and ancillary services
- ☞ report positive test results to the state, local and tribal health department

Step IV: Ensuring adequate space

The entire testing encounter including pre and post counseling, must occur in designated areas that preserve client confidentiality, e.g. a private room within an ASO office or a private space within a mobile unit. In addition, the space must allow for specimens to be collected in accordance with Occupational Safety and Health Administration (OSHA) standards⁴, such as:

- ☞ Flat surface
- ☞ Good lighting
- ☞ Temperature controlled within the range specified by the test manufacturer

Step V: Creating and documenting program policies

A testing program must have guidelines for

- ☞ ensuring *compliance* with all relevant *federal, state, and local regulations*⁵ including *Clinical Laboratory Improvement Amendments (CLIA) requirements*⁶

³ ASOs may contact the AIDS Education and Training Center (AETC) [see Resource List] or local Health Department for Assistance with initial and follow-up staff training.

⁴ Adapted from the Centers for Disease Control and Prevention (CDC, 2006)

⁵ The National HIV/AIDS Clinicians Consultation Center provides a summary by state of all laws relevant to HIV testing <http://www.nccc.ucsf.edu/StateLaws/Index.html>

⁶ Refer to the National HIV/AIDS Clinicians Consultation Center HIV law summary <http://www.nccc.ucsf.edu/statelaws/index.html>

- ☞ *maintaining staff and specimen safety* in outreach settings that are not under the control of the ASO offering the testing service
- ☞ *informed consent procedures* that meet *state/tribal requirements*⁷ and mention the *voluntary* nature of *testing*, enforce *sobriety standards* to assess client competency to give informed consent, and explain the *Client's rights* and *ASO's rights*
- ☞ *ordering, storing, and transporting test kits* and related materials and supplies and ensuring that outdated test kits and supplies are discarded appropriately
- ☞ conducting *pre and post test counseling* including compliance with the state law on disclosure of client's HIV status to sex partners and/or other third parties; disclosure of preliminary positive results; reporting of child abuse; sexual abuse of minors; elder abuse; or imminent danger or harm to a specific individual⁸
- ☞ establishing and maintaining a relationship with a *laboratory* to conduct *confirmatory tests* of preliminary positive results
- ☞ *collecting and transporting specimens* for confirmatory testing of preliminary positive results
- ☞ *universal precautions* and *biohazards* in accordance with OSHA⁸ regulations including plans for handling accidental exposure to specimens and ensuring that specimens are handled and transported to the laboratory correctly
- ☞ documenting and *delivering results of confirmatory tests to individuals* whose rapid test results were preliminary positive including a tracking system to minimize the number of clients with preliminary positive tests who are lost to follow-up
- ☞ *confidentiality* and *data security* in accord with the Health Insurance Portability and Accountability Act (HIPAA)⁹
- ☞ *referral* of clients with a confirmed HIV-positive diagnosis to *treatment care and support services* including clearly executed agreements between partner agencies
- ☞ conducting *quality assurance* including the delivery of *culturally competent* services in the preferred language(s) of clients

Step VI: Quality Assurance

Quality assurance¹⁰ efforts must address the following:

- ☞ The quality of the *staff*, specifically their *ability to carry out the duties* outlined earlier in the section entitled "Staffing." The program supervisor and/or staff trainers should periodically observe the staff as they conduct testing and counseling to ensure that they carry out all procedures correctly.
- ☞ The *reliability of the testing kits* and the *validity of the testing process* by ensuring that the tests are stored and used in accordance with the manufacturer's guidelines
- ☞ The *reliability, validity, and security of client records* as evidenced by the completeness of the records including signed informed consent, client locator information, test results, referrals and follow-up data

⁷ Refer to the National HIV/AIDS Clinicians Consultation Center HIV law summary

<http://www.nccc.ucsf.edu/StateLaws/Index.html>

⁸ The NMAETC provides minority serving ASO's with free quality assurance training and technical assistance.

⁸ Occupational Safety and Health Administration (OSHA) (The NMAETC provides minority serving ASO's with free quality assurance training and technical assistance.)

⁹ Health Insurance Portability and Accountability Act (HIPAA)

<http://aspe.hhs.gov/admsimp/pL104191.htm> and main page is <http://aspe.hhs.gov/admsimp/H3103SUM.HTM>

¹⁰ The NMAETC provides minority serving ASO's with free quality assurance training and technical assistance.

- ☞ *Client satisfaction* with the testing program through periodic client assessments as well as monitoring the confidentiality of the testing venue; waiting times; the delivery of culturally competent services; and the number of referrals made and completed
 - ☞ *Staff satisfaction* with the workload and the overall process of service delivery should be assessed.
 - ☞ Basic process and outcomes data should also be collected. The following indicators form the basis of a sound *monitoring and evaluation system* for a testing program:
 - * Number of persons offered a test
 - * Number of persons accepting a test
 - * Number of persons who receive test results
 - * Number of reactive tests
 - * Number of reactive tests that are submitted for confirmatory testing
 - * Number of clients with preliminary positive tests receiving results of confirmatory tests
 - * Number of patients who are HIV positive who are referred to follow-up care
 - * Number of patients who are HIV positive who access medical treatment and other services
- Additional indicators of interest that may aid in the allocation of scarce resources include
- * Testing outcomes at different times of the day, days of the week, and venues
 - * Testing outcomes by counselor

Resource List

• Needs Assessment Tools:

- **Community Readiness Model Interview Questions** (www.happ.colostate.edu)
- **Native American HIV/AIDS Education Toolkit** (www.nnaapc.org/resources/toolkit/index.htm)

• Training Resources:

BESAFE: A Cultural Competency Model Towards the Prevention and Treatment of HIV/AIDS developed by the National Minority AIDS Education and Training Center (www.nmaetc.org)

- African American
- Hispanics/Latinos
- Native Americans/American Indians, Alaska Natives, and Native Hawaiians
- Asian Pacific Islanders

• Counseling Tools:

- **Risk Reduction Notepad** To begin discussion about prevention topics and agree to specific risk reduction strategies with their patients.
http://www.ihs.gov/MedicalPrograms/HIVAIDS/docs/risk_reduction_pad.pdf
- **Let's Start Talking** A risk reduction, patient education pamphlet. www.mpaetc.org
- **Native American HIV/AIDS Prevention Guidelines**
- **Red Talon STD/HIV Resource Directory / Media Campaign / Tribal Advocacy Materials**
http://www.npaihb.org/epicenter/project/project_red_talon

Organizations Providing Technical Assistance and Training

AIDS Education and Training Centers:

- ☞ Delta Region AETC www.deltaaetc.org
- ☞ Florida/Caribbean AETC www.faetc.org
- ☞ Midwest AIDS Training and Education Center www.matec.org
- ☞ Mountain Plains Regional AIDS Education and Training Center www.mpaetc.org
- ☞ National Clinician Consultation Center (NCCC)
- ☞ National Evaluation Center (NEC)
- ☞ National Minority AIDS Education and Training Center (NMAETC) www.nmaetc.org
 - Charles Drew University
 - Colorado State University
 - Meharry Medical College
 - Morehouse School of Medicine
 - Navajo AIDS Network, Inc.
 - University of Texas
 - Xavier University
- ☞ National Resource Center (NRC)
- ☞ New England AETC <http://www.neaetc.org>
- ☞ New York/New Jersey AETC www.nynjaetc.org
- ☞ Northwest AIDS Education and Training Center www.nwaetc.org
- ☞ Pacific AETC www.ucsf.edu/paetc
- ☞ Pennsylvania/MidAtlantic AETC www.pamaaetc.org
- ☞ Southeast ATEC www.seatec.emory.edu
- ☞ Texas/Oklahoma AETC www.aidseducation.org
- ☞ National Native American AIDS Prevention Center (NNAAPC) <http://www.nnaapc.org/>
- ☞ Center for Applied Studies in American Ethnicity (CASAE) Advancing HIV/AIDS Prevention in Native Communities www.happ.colostate.edu
- ☞ The Northwest Portland Indian Area Health Board <http://www.npaihb.org/>
- ☞ The National HIV Testing Database <http://www.hivtest.org/> available 24 hours a day lists testing locations across the country

Local Health Department, health center, health station, or health clinic **might** be able to provide

- * Free or low-cost rapid test kits
- * Laboratory services for confirmatory tests
- * Assistance in interpreting public health codes in such areas as consent and counseling requirements
- * HIV counseling training for ASO staff
- * Training for ASO staff in administering HIV tests
- * Training in and use of information systems to collect and track data from the program
- * Placing HIV counselors in the ASO to provide testing and counseling
- * Equipment, such as mobile carts
- * Partner notification and referral services
- * Referral resources
- * Assistance with patient follow-up and tracking
- * Providing needs assessment data
- * Assistance and support in linking with other community resources

Planning Checklist

This list contains some, not all, of the key questions that need to be answered as a testing program is being established.

Step	Decision Made	Responsible Party
Has needs assessment been conducted?		
What brand of HIV test will be used?		
Where will tests will be conducted?		
Is the venue compliant with OSHA standards?		
Who will supervise the program?		
How will test kits be obtained and stored?		
Who will conduct outreach?		
Where will outreach be conducted?		
Who will administer tests?		
When and by whom staff will be trained?		
Which laboratory will handle confirmatory tests of preliminary positives?		
How will specimens be transferred to the lab?		
Has the program obtained its CLIA certification?		
Have informed consent procedures and forms been developed?		
What referral linkages to medical treatment and ancillary care are in place?		
Are the arrangements to store client records HIPAA-compliant?		
Are the testing services culturally competent?		
What arrangements are in place to track clients who need to return for follow-up or who have been referred for other services?		
What universal precaution/ biohazard, and security protocols are in place		
Is there a quality assurance plan for the program?		
Is there a program manual documenting all of the planning decisions and the protocols that will guide the program?		