

until it's over  
**AIDS ACTION**

# Safe, Fast and Reliable

A New Generation of HIV Testing

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AIDS Action is the national voice on AIDS. We are committed to advocating for people affected by HIV/AIDS "Until It's Over" --- until no more people become infected with HIV, until people living with HIV have the care and support they need, and until a cure is found.

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## A New Generation of HIV Testing

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“THE WAITING PERIOD IS ONE OF THE CRUELEST ELEMENTS OF HIV TESTING. IT IS HAVING TO ENDURE TWO WEEKS OF HELL. BECAUSE OF IT, PEOPLE GET LOST. IT IS THE BEST REASON FOR EXPEDITING THIS TECHNOLOGY.”

**Lee Klosinski, AIDS Project Los Angeles**

## The State of HIV Testing

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**During the last several years, powerful new drugs have emerged for treating HIV disease.** These new treatments have dramatically reduced AIDS death rates and improved the health and well-being of tens of thousands of people with HIV.

However, not all people with HIV are benefiting from the treatment revolution. AIDS deaths, which tumbled 42% in 1997, fell only 20% in 1998. For those who can access these treatments and ongoing care with a knowledgeable physician, much of the value of new treatments has been realized. Researchers and physicians at the 1999 Conference on Retroviruses and Opportunistic Infections in San Francisco cited the failure of drug combinations to help all patients. In spite of these findings, the false notion that promising therapies are in effect a cure for AIDS has helped spawn a frightening level of complacency. There continue to be 40,000 new HIV

infections each year, half of them among young people.

Yet, before people living with HIV/AIDS can begin to maximize the benefits of new treatments and exercise risk reduction, they must be aware of their serostatus. Too many people cannot take advantage of treatment opportunities or modify their risk behaviors because they are not even aware they are HIV positive.

According to the Centers for Disease Control and Prevention (CDC), nearly 300,000 Americans living with HIV are unaware of their status. As many as one-third of all HIV-positive people in the U.S. do not know they are infected with the virus.

Moreover, many of those who get tested learn they are HIV-positive late in the course of disease — after the virus has already done extensive damage to the immune system. Consequently, many people first learn they are HIV-positive only after they are hospitalized with an AIDS diagnosis. To care for the nearly one million individuals living with HIV, the U.S. must first ensure that all people who are HIV-positive receive their diagnosis in time for treatment to make the biggest difference. Furthermore, the National Institutes of Health (NIH) has affirmed that early, consistent testing allows for greater modification of risk behavior.

Unfortunately, over 40% of the nearly two million people tested each year in publicly funded counseling and testing sites never receive their HIV test results. In 1997 alone, approximately 10,000 people, or 30% of those who tested positive in publicly funded testing sites, never returned to receive this important news.

There is hope, though, for ensuring that virtually everyone who seeks HIV testing will get his or her test results. New rapid HIV tests enable providers to offer clients pre-test counseling, test results, and post-test counseling — all in a single visit. Rapid testing technology can also save money for testing sites that must otherwise perform expensive follow-up outreach. Such technology will also be useful for perinatal and emergency post-exposure antiviral prophylaxis.

The federal government has already licensed one rapid test, and several others are awaiting approval. The potential for false positives with the use of unconfirmed rapid test results poses a challenge for testing sites.

However, clear, comprehensive pre/post-test counseling and FDA approval of additional rapid tests could help ensure that nearly all HIV-positive testers receive their test results without delay —

empowering them to consider critical treatment options and make safer decisions. Because rapid tests are relatively inexpensive and easy to perform, they offer the

UNFORTUNATELY, OVER 40% OF THE NEARLY TWO MILLION PEOPLE TESTED EACH YEAR IN PUBLICLY FUNDED COUNSELING AND TESTING SITES NEVER RECEIVE THEIR HIV TEST RESULTS.

hope of making testing more accessible by expanding the range of venues where testing services are offered. New testing technologies also save the millions of Americans who test negative each year the anxiety and time associated with waiting for their results.

community-based organizations and their clients. This guide explores current and prospective HIV testing technology and the issues organizations will encounter as they seek to incorporate rapid testing into their HIV testing and counseling programs.

AIDS Action created *Safe, Fast and Reliable — A New Generation of HIV Testing* to help navigate the benefits and challenges rapid testing poses for com-

## Standard (Non-Rapid) HIV Antibody Tests

**Standard HIV antibody tests**, such as enzyme immunoassays (EIA), Western Blots, or immuno-fluorescence assays (IFA), require blood, saliva, or urine samples at the testing site. The samples are normally sent to an outside laboratory because the standard tests use specialized equipment to evaluate the presence or absence of HIV antibodies.

The standard HIV test result comes from a composite of two tests. Specimens for HIV antibody testing first undergo a screening test known as the EIA. If the specimen tests negative with the EIA, no further testing is required. If the EIA detects HIV antibodies, the lab conducts a follow-up confirmatory test — either a Western Blot or an IFA. Only after testing positive on both the EIA and a confirmatory test is the specimen verified as HIV positive.

With the standard test, it normally takes one to two weeks for the lab to return test results to the testing site. Thus, this test requires a second visit to receive results. Clients

often experience anxiety during the one to two week waiting period between visits, and many never return for their test results. A recent AIDS Action survey of AIDS service organizations across the country found that waiting time for test results affects return rates, regardless of testing location or HIV status. Consequently, a critical opportunity for post-test counseling is lost.

### Saliva and Urine Tests

The non-invasive nature of saliva and urine tests not only makes them safer alternatives to blood testing, but also provides incen-

tive for those who avoid HIV testing because they don't like having blood drawn. In a Michigan study, a clinic that began using a saliva-based standard test tripled the

A RECENT AIDS ACTION SURVEY OF AIDS SERVICE ORGANIZATIONS ACROSS THE COUNTRY FOUND THAT WAITING TIME FOR TEST RESULTS AFFECTS RETURN RATES, REGARDLESS OF TESTING LOCATION OR HIV STATUS.

number of people tested. An EIA produced by Organon Teknika Corporation and a Western Blot manufactured by Epitepe both screen oral fluid for HIV-1 antibodies. Researchers have also determined urine tests accurately screen for HIV-1. Calypte Biomedical Corporation produces EIAs and Western Blots that screen urine for HIV-1 antibodies.

### Home Tests

The Home Access HIV-1 Test System manufactured by Home Access Health Corporation is the

only FDA-approved home testing kit. The test cost ranges from \$44 to \$55. The user pricks a finger to collect a dried blood spot sample in the home that is then

sent to a laboratory for processing. Results are available between three to seven business days later. The convenience and confidentiality of the Home Access System have the potential to boost testing rates overall, but the absence of pre- and post-test counseling raises serious concerns about lost opportunities for support and education. The kit can be purchased over the counter or ordered directly from the manufacturer. Mail delivery takes anywhere from two days to three weeks, meaning a month may pass before the client learns of her or his serostatus.

## The Rapid Test

### *Single Use Diagnostic System (SUDS)*

**Rapid tests detect HIV antibodies within five to 30 minutes**, enabling results to be given during the same visit at which the sample is drawn. Because the rapid test does not require specialized laboratory equipment to evaluate the sample, it can easily be conducted on site.

One rapid HIV test — the Single Use Diagnostic System for HIV-1 (SUDS), manufactured by Abbott Diagnostics — has already received federal approval from the Food and Drug Administration (FDA). The SUDS test is a blood test. There is currently no saliva or urine-based *rapid* test approved by the FDA. At present, the SUDS test is being used primarily in hospitals to obtain HIV results immediately following needlestick injuries.

Rapid testing technology has been underutilized due in part to United States Public Health

Service (USPHS) recommendations that require confirmation of reactive test results before they are given to clients. A recent CDC study determined that if publicly funded testing programs gave clients unconfirmed screening results from rapid HIV tests, it would substantially increase the number of people receiving positive and negative HIV test results, but also increase those receiving false positive results. However, studies have demonstrated that two different rapid tests used in tandem virtually eliminate false positives. A major barrier to the

implementation of rapid testing is the lack of a second FDA-approved rapid test that could be used as a confirmatory test instead of a Western Blot or IFA.

In addition to the SUDS test, other nations are already using several rapid HIV tests, including some that are saliva based. The CDC is currently evaluating rapid testing in Uganda, Malawi, Botswana, and South Africa. Clinical trials of non-SUDS rapid tests are also being conducted in Los Angeles, Chicago, and Phoenix. Several such products are currently await-

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Laboratories' conference demonstrating that Determine, Hemastrip, Quix, Unigold, and Medmira are rapid tests as accurate as standard EIAs. New York state's newborn HIV screening program presently relies on unconfirmed SUDS results to make postpartum treatment decisions, illustrating the need for expedited FDA approval for additional rapid tests (S. Kline, personal communication, March 2000).

## Accuracy of the Rapid Test

### **Predictive Value of Rapid HIV Test Combinations**

**The sensitivity and specificity of the rapid HIV test are just as good as the EIA.** As with the EIA, rapid tests are only screening tests, and a reactive screening test must be confirmed by a follow-up test. If, as expected, the federal government approves one or more additional rapid HIV tests in the future, a second rapid test could be done on site to validate the initial result. Studies by the CDC and others have repeatedly documented that combinations of various different rapid tests can be as accurate as the current standard EIA and Western Blot/IFA — virtually 100%. Once the FDA approves a second rapid test, false positive results can be virtually eliminated, unleashing the full potential of rapid testing technology (see Appendix B).

### **Predictive Value of a Single Rapid HIV Test Result**

The chance that a reactive rapid test result is erroneous depends in part on the level of HIV infection in the community in which the test occurs. In a high-prevalence area — where one in 10 people is infected — a reactive result on a single rapid test predicts infection

96% of the time. There, a counselor should tell a person whose test is reactive that he or she is probably infected, although a small chance exists that the test result could be false.

By contrast, there is only a 50% chance that a reactive result on a single rapid test truly indicates infection in an area of moderate

HIV prevalence — where one in 200 people is infected. Here, the counselor will need to help the person understand that there is a likelihood he or she is *u n i n f e c t e d*, despite having received a reactive test result.

In low-prevalence areas — where, say, only one out of every 1,000 people is HIV positive — a reactive

IN A HIGH-PREVALENCE AREA — WHERE ONE IN TEN PEOPLE IS INFECTED — A REACTIVE RESULT ON A SINGLE RAPID TEST PREDICTS INFECTION 96% OF THE TIME.

result on the rapid test probably does not indicate actual infection. Indeed, a reactive rapid test is only 18% predictive of infection in areas with such low prevalence. Thus, a sin-

gle rapid test can be most useful in emerging and current “hot-spots” of the epidemic — areas with high HIV prevalence — and in targeting hard-to-reach populations. See Appendix C.

## Issues for Community-Based Organizations

### **Meeting Infrastructure Requirements**

**The feasibility of rapid testing by smaller community organizations** may largely depend on which of the rapid tests are ultimately approved by the FDA. Although all of the rapid tests currently under consideration by the FDA are far simpler to administer than standard antibody tests, some are more complicated than others.

The sophistication of laboratory infrastructure required for institutions to perform a diagnostic test depends on how the test is classified under the federal Clinical Laboratory Improvement Act (CLIA). CLIA established three categories for diagnostic tests. High-complexity tests — such as the EIA and Western Blot — demand elaborate laboratory equipment and adherence to rather complicated procedures. To perform high-complexity tests such as the standard HIV antibody test, labs must be certified under CLIA's requirements.

At the opposite end of the CLIA spectrum are low-complexity tests

that are waived from any certification requirement. To be waived, the test must use unprocessed specimens (e.g., pure blood or saliva), require no procedural step beyond adding the specimen to the testing device, and have a clear, well-defined end point (e.g., positive or negative). Home tests, urine dipstick tests, and the like are all simple tests that are waived from CLIA's requirements.

Between the opposite poles of high-complexity and waived tests are tests of moderate complexity. The SUDS test fits in this category. These tests are less difficult to administer than high-complexity

tests, but CLIA nonetheless requires institutions that use these diagnostic products to have a lab director and meet certain requirements regarding lab procedures. CLIA certification is required for anyone desiring to perform a test of moderate complexity.

The various newer rapid tests that are in clinical trials or awaiting federal approval include both moderate-complexity tests and those that could probably be eligible for a CLIA waiver. One group of unapproved rapid tests, for example, uses flow-through devices that require lab technicians to add reagents at various steps in the testing process. Because these tests have additional procedural steps beyond simply adding the specimen to the device, they would be classified as moderate-complexity tests and would require a laboratory.

Other rapid tests awaiting approval, by contrast, use a simple dipstick that requires neither addi-

tional procedural steps nor a certified lab technician. These tests would appear to meet the requirements for a waiver from CLIA.

Because many smaller community organizations may be unable to hire a lab director and satisfy CLIA laboratory requirements, approval of one or more moderate-complexity tests might not be sufficient to enable such organizations to provide rapid testing services. Waived tests, by definition, are simple to perform, and approval of these might well facilitate the development of many new venues for rapid community-based HIV testing services. However, although some rapid tests may be waived from CLIA certification, community-based organizations will still need to implement measures for quality assurance and proficiency testing. Local health departments can offer community-based organizations technical assistance to ensure sites are outfitted with well-trained personnel.

## Costs of Rapid Testing

The EIA costs approximately \$2 per test. However, the cost rises to about \$6 for a negative test result and \$51 (including confirmatory tests) for a positive result when accounting for laboratory expenses associated with processing. These costs are realized from the economy of running a large number of tests in a central laboratory. Unfortunately, much of the current cost of testing is wasted if the person tested never learns the results.

At approximately \$7.50 each, the currently available SUDS test costs more than the EIA. SUDS requires both a positive and negative control for each test, which brings the total cost of a negative result to \$22.50 per test. Testing sites in Columbus, Indianapolis, and Phoenix have found that client requests for the SUDS test have increased despite the cheaper EIA alternative. Moreover, clinics can reduce the per-test cost by running several tests as a batch with

the positive and negative controls. For most clinics, though, batching reduces the benefits of rapid testing because it requires the person being tested to wait until enough specimens are available.

The newer rapid tests may cost as little as \$2 each. Thus running two rapid tests will cost \$4 versus the \$6 per test cost of the EIA for a negative test result. The issue of batching should be minimized once federal approval is given for some of the newer rapid testing technologies. Some tests require that only a positive and negative control be run each day or for each technician's shift, rather than each time the test is administered. For people who come to the clinic for testing, this means that their test can be performed immediately, without waiting for enough tests to form a batch.

The cost effectiveness of rapid testing may enable AIDS service organizations with smaller budgets to offer HIV counseling and

testing services. Forty percent of AIDS service organizations surveyed by AIDS Action did not offer HIV testing and counseling. The organizations

most likely to offer on-site services are those with larger annual budgets (73% of those with budgets over \$2 million) and larger prevention budgets (77% of those with budgets over \$300,000).

## Counseling Considerations

Counseling is central to the HIV testing experience. Regardless of the mode of testing, every person who learns his or her HIV status needs accurate, sensitive, culturally appropriate counseling to understand the meaning and implications of the test result.

The person who presents for testing should receive extensive pre-

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test counseling in accordance with CDC guidelines (see Appendix D). The client can continue to receive counseling while waiting for the test results.

When the unconfirmed test results are disclosed, the counselor should make sure the person understands what the test results mean and provide additional information, assistance, linkages, or referrals based on the client's individual needs.

For the person who tests HIV positive, effective counseling includes, at the very least, the provision of accurate, comprehensible information on available medical and support services. Optimally, the testing center would take proactive steps to connect the person who tests positive with a primary care provider or case manager.

The rapid test presents at least two challenges for community-based testing sites. First, a reactive result on a single rapid test has a somewhat higher chance of being false than a confirmed positive result on the standard test. Thus, the counselor will need to clearly explain the meaning of a positive test result and the chances that it could be incorrect.

Clearly, it will be necessary during pre-test counseling to explain the nature and limitations of the rapid test about to be administered. During post-test counseling, particular care will need to be taken in helping the person with a reactive test understand the test result. Extra effort is likely to be required in helping reactive testers cope with the stress of waiting for the return of their confirmatory test, which may take two weeks. The

counselor can use the return of a reactive rapid test result to ease the news that this confirmatory test result may be positive.

It is often perceived that rapid testing will pose a logistical challenge to effective counseling. Use of the rapid HIV test might require some testing sites to alter or change at least some of their services and the way those services are delivered. As with the current test, the rapid test will require a follow-up appointment for the disclosure of confirmed test results. It would still be possible to make available on-site case management for people returning to receive the results of their confirmatory tests, so that the person testing positive can receive immediate practical assistance with benefits, health care, and the like.

## Impact of Rapid Testing

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### *Field Evaluation*

**CDC undertook a field evaluation of the SUDS product in 1993** at two sites in Dallas County, Texas to learn more about the rapid test. The enzyme-linked immunosorbent assay (ELISA) was used at an anonymous test clinic and a sexually transmitted diseases (STD) clinic for approximately three months; the rapid test was then used for a similar period, and the results of both compared.

At the anonymous test clinic, 14% of all positive testers (three out of 22) who tested positive using the standard protocol never received their test results. By contrast, 100% (30) of those who tested positive using the rapid test actually received their positive test results. The percentage of individuals testing HIV negative who received their test results increased from 95% to 99% with use of the rapid test.

The results were even starker in the STD clinic. Whereas 21% (six out of 29) of those testing positive on the standard test never

received their results, the same could be said for only 3% (one out of 31) of positive rapid testers. A notable 97% of HIV-positive individuals who rapid tested actually learned their results — a marked improvement over the standard HIV test. In order to inform the 34% (10 out of 29) who tested positive on the standard test but did not return for their results, public health workers had to perform time-consuming, expensive outreach. Among individuals testing HIV negative in STD clinics, the percentage obtaining their test results rose from 30% on the standard test to 93% on the rapid test.

## **Making Testing More Accessible**

Whereas current tests normally require affiliation with a laboratory and adherence to often-complicated administrative regulations, rapid testing is easier to administer. With appropriate certification, community-based testing sites that use this new technology can evaluate HIV-tests “in-house.” FDA approval of low-complexity rapid tests means many community-based programs that may not currently perform HIV antibody testing — such as community centers, YMCAs, or meals-on-wheels programs — might now be able to integrate HIV testing into the range of services they offer their clients.

Thus, in addition to increasing the number of people who actually receive their HIV test results, rapid testing could also expand and diversify the range of venues in which testing takes place. It invites greater use of testing by

neighborhood-centered programs, bars, or street fairs as well as needle exchange, street, and mobile outreach programs. Springfield, Illinois began a pilot mobile testing program that provides rapid HIV testing for people who do not have transportation and for those who feel uncomfortable in a clinic setting (D.Hunt, personal communication, March 2000). Rapid HIV testing can be made available in non-medical settings with which people are familiar and comfortable and therefore more likely to consent to voluntary testing.

Rapid testing technology deployed in emergency rooms could also play an important role in detecting HIV early through voluntary screening. In 1994 and 1995, hospital and surgical patients accounted for the highest percentage of patients not receiving their test results.

## **Implications for Anonymous Testing**

The CDC strongly encourages states and localities to provide the option of anonymous testing for people who wish to learn their HIV status. Recent CDC-sponsored research found that HIV-positive individuals who are tested anonymously tend to learn of their infection at a much earlier stage of disease than those tested confidentially.

There is no reason to believe that rapid testing will make anonymous testing less accessible. It merely reflects a technological change in the way testing is performed. Like the current test, rapid testing can be performed anonymously or confidentially.

Unfortunately, some states do not currently permit anonymous testing, and even in states that allow

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such testing, the anonymous option is not always accessible. Whether a community-based organization can perform anonymous testing is normally governed by state regula-

tions. Many states restrict the anonymous option solely to public testing sites. The clear evidence of the public health benefits of anonymous testing, when combined with the obvious advantages of enabling more people at risk of infection to learn their serostatus, provides local programs with a powerful argument for expansion of anonymous testing to community-based settings. Rapid tests make this possible.

## **Discrimination**

Unfortunately, experience has shown HIV testing can be used as a vehicle for discrimination.

Surreptitious use of rapid testing conceivably could invite discrimination in a variety of settings. Rapid HIV tests also could increase the likelihood of testing without consent, for example mandatory testing of pregnant women and/or newborns. Rapid tests could make it easier to force incarcerated individuals, alleged criminals, and patients to be tested when security personnel, crime victims, or providers are exposed to bodily fluids. Finally, rapid tests could aggravate concerns about confidentiality and consent that may arise with private or public screening for benefits or services.

In virtually all situations, such discrimination would be illegal under current statutes such as the Americans With Disabilities Act. Preventing such transgressions, however, will require vigilance by community advocates and by all levels of government to ensure that the clear benefits of rapid testing are not diluted by illegal acts of discrimination.

### **Potential National Impact of Rapid Testing**

The impact on the national epidemic could be enormous were rapid tests routinely utilized. The convenience of rapid testing technologies may be key to reaching the nearly 300,000 Americans who do not know they are HIV positive. Whereas only two out of three people testing HIV positive in STD clinics currently return for their results, rapid testing provides 97% of all positive testers with their test results. In STD clinics, the number of HIV-positive individuals who would receive their test results without costly outreach would be 43% greater with the rapid test than with the current standard test.

With rapid testing, the number of HIV-positive people receiving results could be 32% greater in drug treatment settings, 18% greater in HIV counseling and testing sites, 26% greater in family planning clinics, and 33% greater in other publicly funded testing sites.

According to the CDC, if rapid testing had been available, it would have resulted in the receipt of test results by nearly 30,000 HIV-positive people between 1995 and 1997.

### **On the Horizon**

Rapid testing technology fills the critical information gap that hinders the decision-making capacity of clients who are HIV positive and negative as well as those who need to make urgent treatment decisions perinatally, post-partum, or after occupational exposure. The CDC is developing an expanded access program to help meet these needs while ensuring that rapid testing technology is thoroughly “road-tested.” An expanded access program would enable community-based organizations to offer rapid tests awaiting approval from the FDA while simultaneously gathering data to expedite the approval process.

Like any new technology, rapid testing poses challenges. But the potential it offers to revolutionize testing and prevention campaigns — to ensure that millions of Americans receive their HIV test results — is truly promising. Rapid testing technology revitalizes the critical message of early, consistent testing. The opportunity to make HIV testing available in community venues facilitates outreach to individuals who might otherwise be apprehensive of AIDS service organizations or health clinics. Community-based organizations can promptly assuage the anxiety of clients who test negative and offer immediate support and services for those who test positive. With FDA approval of additional invasive and non-invasive rapid HIV tests, there is tremendous potential to reduce the number of new infections and to draw hundreds of thousands of HIV-positive Americans into a system of care and support.

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## Appendix A: The Standard HIV Test vs. the Rapid Test

	Standard Test	Rapid Test
<b>Type of Test</b>	EIA (Enzyme Immunoassay)	SUDS (Single Use Diagnostic System)
<b>Detects</b>	HIV Antibodies	HIV Antibodies
<b>Confirmatory Test</b>	If reactive, Western Blot or IFA	If reactive, Western Blot or IFA
<b>Waiting Period for Test Results</b>	1-2 weeks	5-30 minutes
<b>Number of Visits</b>	2	1 or 2*
<b>Cost**</b>	\$6.00	\$22.50
<b>Testing Site</b>	Centralized laboratories	Potential for any site to provide HIV testing services
<b>Counseling Issues</b>	<p>Possibility that HIV+ individual will not return for test results</p> <p>Outreach costs</p> <p>Ability for case-manager to prearrange for post-test + counseling</p>	<p>More likely to link those who test + w/services &amp; counseling regarding risk reduction</p> <p>Greater chance for false positives</p> <p>Need for available on-site case management</p>

\*One visit for a negative result and a second visit for a positive result.

\*\*Total cost of a negative result. The cost of a negative rapid test result could drop to \$4 with FDA approval of the newer rapid tests.

## Appendix B: Positive Predictive Value of Rapid HIV Test Combinations

Positive Predictive Value of HIV Tests for Screening and Confirmation of HIV Infection in Populations with Low HIV Prevalence (1.5%)\*

Combination**	Predictive Value
Abbott EIA + Gen Svs EIA	100%
Abbott EIA + HIVCHEK	100%
Abbott EIA + Genie	100%
Abbott EIA + Retrocell	100%
Retrocell + HIVCHEK	100%
Retrocell + Genie	100%
HIVCHEK + Genie	100%

\* Calculated for test with sensitivity 77-100%, specificity 99.6-100%

\*\* Stetler et al., *AIDS* 1997 (cited in Branson, 2000)

The above table demonstrates that the use of two screening tests — either rapid tests or EIAs — is comparable to the presently approved protocol of an EIA and Western Blot to confirm positive results. For example, if 1,000 people were tested with any of the last three combinations of rapid HIV tests, an STD clinic with an HIV prevalence of 1.5% would expect to see 100 true positives and 0 false positives, for a positive predictive value of 100% for the HIV rapid test results (i.e. 100% of those with a positive test result would be truly positive).

Abbott EIA and Gen Sys EIA are both standard HIV screening tests. Retrocell, HIVCHEK, and Genie are all rapid screening tests that are not authorized for use in the U.S. Abbott, which produced Retrocell, is now developing a different rapid test called Determine. Ortho-McNeil produced HIVChek. Genie is now known as Multispot and is produced by BioRad.

## Appendix C: Positive Predictive Value of a Single Rapid HIV Test Result

Positive Predictive Value of HIV Tests in Populations with Differing HIV Prevalence\*

HIV Prevalence	Predictive Value
10%	96%
5%	91%
2%	80%
1%	67%
0.5%	50%
0.3%	38%
0.1%	18%

\* Calculated for test with sensitivity 99.9%, specificity 99.6%

The one currently available FDA-licensed rapid HIV antibody test has a sensitivity of 99.9% and a specificity of 99.6%. This means, for example, if 1,000 people were tested with this rapid HIV test, an STD clinic with an HIV prevalence of 10% would expect to see 100 true positives and four false positives, for a positive predictive value of 96% for the HIV rapid test result (i.e. 96% of the persons with a positive test result would be truly positive). Use of the same test on 1,000 clients in a family planning clinic with an HIV prevalence of 0.4% would yield four true positives and four false positive results, for a positive predictive value of 50% for the HIV rapid test result (four of the eight individuals with reactive test results would be truly positive).

## Appendix D: CDC Guidelines Regarding Rapid HIV Tests — Issues for Counselors Providing HIV Prevention Counseling

### Why Provide Rapid HIV Testing?

Rapid HIV tests provide opportunities for persons to learn their HIV antibody test results on the day they are tested. Use of rapid HIV tests can substantially increase the number of uninfected persons who learn their HIV status. Furthermore, HIV-infected persons may learn their status sooner.

Approximately 2.0 to 2.5 million tests are conducted annually in publicly funded counseling and testing (CT) programs. In 1996, only 41% of these were performed for persons who said they had not been tested before. However, many persons do not return for their test results: 26% of persons who tested HIV-positive during 1996 and 33% of persons who tested HIV-negative did not return. (HIV CT Client Record Report, 1996 U.S. Total; CDC, unpublished data.) The use of rapid HIV testing can help resolve this problem, because it enables persons to learn their HIV status on the day they are tested.

### What Are Considerations for HIV Prevention Counseling with Rapid HIV Tests?

Rapid HIV testing will change how and when HIV prevention counseling is delivered. Counseling might increase from one session per client (HIV risk assessment) to two sessions (HIV risk assessment and test results) per client in a single day.

Experience to date in counseling clients tested with the rapid HIV test comes from several public health clinics in the United States that have instituted their routine use. Techniques developed for counseling clients receiving rapid test results have been published.<sup>21</sup> Additional counseling guidance is being developed in collaboration with CDC's prevention partners as we acquire more experience with rapid HIV tests. In the interim, the information here can help staff as they begin to provide prevention counseling to clients who are receiving same-day results from rapid HIV tests.

Counseling should still include a personalized client risk assessment and should be interactive. Special attention should be given to the ongoing behaviors and circumstances that place the client at risk of acquiring or transmitting HIV infection.

Clinical studies have demonstrated that the sensitivity and the specificity of rapid HIV tests are comparable to those of the enzyme immunoassays (EIAs) currently used for screening. The negative predictive value of screening tests is high at the HIV prevalence observed in most U.S. testing settings. Thus, a negative rapid HIV test result means that the client is negative for HIV antibody and need not return for a second visit.

The content of the prevention counseling session before providing a reactive<sup>22</sup> test result will have to be tailored to each person, because it involves both an understanding of the technical aspects of screening tests and an assessment of each client's behavioral risk for HIV infection. Because the positive predictive value of a test is low in populations with low prevalence,

every reactive rapid test must be confirmed by a supplemental test (either Western blot or an immunofluorescence assay [IFA]), as is done currently for EIA-positive results.<sup>23</sup> However, studies have shown that an assessment of behavioral risk factors can substantially improve the predictive value of an HIV screening test. That is, a reactive test for an individual with risk behavior(s) is more likely to represent a true positive than is a reactive test for an individual with no identifiable risks for HIV. (See Appendix: Positive Predictive Value for Rapid HIV Tests.)

Each clinic will need to establish its own policy to guide counselors in the correct interpretation of reactive rapid HIV test results. These policies will need to take into consideration the proportion of reactive rapid-test results that may be false-positive. This proportion will differ, as it depends on the prevalence of HIV infection among the clients tested. Staff of each clinic should develop suggested language for counselors to use when explaining the results of reactive rapid HIV tests.

## Should We Provide Client-Centered Prevention Counseling with Rapid Testing?

**Yes.** CDC is currently revising its guidance for HIV counseling, testing, and referral to incorporate new information about counseling as well as new developments in testing technology. HIV prevention counseling should follow the concepts of client-centered counseling currently recommended by CDC.<sup>44</sup>

- The focus of the counseling session is on developing prevention goals and strategies with the client, rather than simply providing information.
- All prevention counseling should be “client-centered.” Counseling should be interactive, allowing the counselor to recognize and respond to each client’s needs.
- HIV counseling should result in a realistic and incremental personalized plan for the client to reduce his or her risk of acquiring or transmitting HIV.
- Quality assurance must be in place to ensure that appropriate, competent, and sensitive methods are used for risk assessments, counseling, and referral of clients.

## Providing Prevention Counseling with Rapid Testing

### General Considerations

After learning the test results, many HIV-negative clients may not receive counseling beyond that provided with their test results, and clients who receive reactive screening test results may be too worried to focus on developing a personalized risk reduction plan. Therefore, the counseling received by the client before testing takes place at a crucial intervention point.

Counseling **before** rapid HIV testing should

- ensure that the client is aware that rapid testing is being used and that he or she can receive test results during this visit.
- include an explanation of a reactive screening test result, and a statement about the necessity for a waiting period of 1 to 2 weeks for the confirmatory test result.
- help the client specify behaviors that place him or her at risk for HIV. It is useful to explain that understanding the risk behaviors of clients is important in

explaining rapid test results, especially if the rapid test should be reactive.

- be used as an opportunity to help the client develop a realistic and incremental plan for reducing risk, regardless of the client’s HIV test result.

### Communicating Negative Rapid HIV Test Results

Counselors communicating **negative** rapid HIV test results should do the following:

- review the protective behaviors that have helped the client avoid infection with HIV and reinforce the client’s plan to remain uninfected.
- ensure that the client is aware that, as is true of any antibody test, the negative HIV test result may be unreliable when risk exposure has been very recent. Specifically, the client needs to be informed that after a person is infected with HIV, it takes time (average, 25 days) before antibodies develop that can be detected by the test.
- Although most persons who are tested can rely on their negative

rapid test results, some clients with recent risk exposures will need to be retested after sufficient time has elapsed since their most recent risk exposure in order to verify that they are HIV negative.

### Communicating Reactive Rapid HIV Test Results

One of the more challenging counseling issues posed by the introduction of rapid HIV tests is providing reactive rapid HIV test results to clients without the benefit of a same-day confirmatory test. Currently, confirmatory tests results are usually not available for 1 to 2 weeks.

Counselors providing **reactive** rapid HIV test results should do the following:

- Explain the meaning of the reactive screening test result and communicate the likelihood of HIV infection.

The phrase the counselor chooses when providing the test result should be simple. For example, a counselor may say,

*Your first screening test came back reactive.*

Counselors may use the following language to emphasize the importance of a confirmatory test, especially in settings that have low HIV prevalence and thus a high proportion of false-positive screening test results (true of many family planning clinics):

- *There is a possibility you are HIV infected, but we won't know for sure until we get the results from your confirmatory test.*

or

- *We need to verify this result with a follow-up test.*

Or counselors may use phrases that convey a higher likelihood of infection. These phrases require skill and good judgment. The counselor will need to explain the test result on the basis of the prevalence of HIV infection in their clinic, and from the assessment of the client's risks that was made during the prevention counseling session.<sup>15</sup>

Several phrases can be used when the counselor is less certain whether the reactive rapid HIV test result means the client is truly infected:

*... likely to be infected*

*...a good chance of being infected*

Other phrases can be used when the counselor wishes to convey that the reactive rapid HIV test result probably means the client is truly infected:

*... probably infected*

*...very likely (or highly likely) infected.*

*...a very good chance of being infected.*

- Do not initiate partner notification or provide medical referrals, but advise the client to adopt behaviors to prevent HIV transmission (i.e., to act as if he or she is HIV infected) until the reactive rapid test result has been confirmed.
- Schedule a return visit for confirmatory test results, explaining that the confirmatory test is important but that it cannot be done in one day.
- Discuss whether and how to disclose the results of the reactive rapid test to partners and other persons important to the client (before the test result is con-

firmed), give options for support, and make psychosocial referrals.

- Verify the client's locating information, so that it will be possible to contact the client if he or she does not return for the

result of the confirmatory test.

- If the confirmatory test result is positive, help with partner notification and make medical referrals, after discussing these with the client and obtaining the client's cooperation.

## References for Appendix D

1. Kassler WJ, Dillon BA, Haley C, et al. On-site rapid HIV testing with same day results and counseling. *AIDS* 1997;11:1045-51.
2. "Reactive rapid test" as used in this paper means a repeatedly reactive rapid test, i.e., the same test was performed twice and was reactive both times.
3. Centers for Disease Control. Interpretation and use of the Western blot assay for serodiagnosis of human immunodeficiency virus type 1 infections. *MMWR* 1989; 38(suppl 7): S4-S6.
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5. Centers for Disease Control and Prevention. Technical guidance on HIV counseling. *MMWR* 1993; 42: (RR-2).

## Appendix E:

### **Resources for More Information**

- **Centers for Disease Control and Prevention**

*For more information on rapid HIV testing and HIV prevention counseling, agencies or jurisdictions receiving HIV prevention funds should contact their CDC project officer. Others should contact:*

Kay E. Lawton, RN, MN  
Deputy Chief, Prevention Services Research Branch  
Division of HIV/AIDS Prevention — Surveillance and Epidemiology  
NCHSTP, CDC  
1600 Clifton Road, E-46  
Atlanta, GA 30333  
(404) 639-6131 phone  
(404) 639-2029 fax  
kel1@cdc.gov

*For information on referrals to counseling and testing sites, contact:*

CDC National AIDS Hotline  
(English) 800-342-2437  
(Spanish) 800-344-7432  
(TTY) 800-243-7889

*For information on CDC-sponsored training for performing HIV testing, contact:*

National Laboratory Training Network  
(telephone) 770-488-7811

*CDC Division of HIV/AIDS Prevention Website:*  
<http://www.cdc.gov/hiv/dhap.htm>

*CDC Division of HIV/AIDS Rapid Testing Website:*  
<http://www.cdc.gov/hiv/pubs/rt.htm>

- **U.S. Food and Drug Administration**

FDA Center for Biologics Evaluation and Research (CBER)  
Licensed / Approved HIV Tests Website:  
<http://www.fda.gov/cber/products/testkits.htm>

- **World Health Organization**

*For information on HIV test kits commercially available for use in other nations:* [http://www.who.int/pht/blood\\_safety/hivkits.html](http://www.who.int/pht/blood_safety/hivkits.html)

## AIDS Action's Contributing Organizations

(AIDS Action board members in bold)

Action for a Better Community - Action Front Center, Rochester, NY  
 ADAP Working Group, Washington, DC  
 Advocates For Youth, Washington, DC  
 African Services Committee, Inc., New York, NY  
 African-American AIDS Support Services and Survival Institute, Inglewood, CA  
**AID Atlanta**, Atlanta, GA  
**AIDS Action Committee of Massachusetts**, Boston, MA  
 AIDS Administration - Maryland Department of Health and Mental Hygiene, Baltimore, MD  
 AIDS Alliance for Children, Youth & Families, Washington, DC  
 AIDS ARMS, Inc., Dallas, TX  
 AIDS Care Ocean State, Providence, RI  
 AIDS Community Alliance, Lancaster, PA  
 AIDS Community Services of Western New York, Inc., Buffalo, NY  
 AIDS Consortium of Southeast Michigan, Detroit, MI  
 AIDS Council of Northeastern New York, Inc., Albany, NY  
 AIDS Council of Western Virginia, Roanoke, VA  
 AIDS Delaware, Wilmington, DE  
**AIDS Education Training Centers**  
 AIDS Foundation Miami Valley, Dayton, OH  
**AIDS Foundation of Chicago**, Chicago, IL  
 AIDS Healthcare Foundation, Los Angeles, CA  
 AIDS Help, Inc., Key West, FL  
 AIDS Housing Corporation, Boston, MA  
 AIDS Legal Referral Panel, San Francisco, CA  
 AIDS Network, Madison, WI  
 AIDS Network of Western New York, Buffalo, NY  
**AIDS Nutrition Services Alliance**, Washington, DC  
**AIDS Outreach Center**, Fort Worth, TX  
 AIDS Partnership Michigan, Detroit, MI  
 AIDS Project Arizona, Phoenix, AZ  
**AIDS Project Los Angeles**, Los Angeles, CA  
 AIDS Project Rhode Island, Providence, RI  
 AIDS Project Worcester, Worcester, MA  
 AIDS Project, Inc., Portland, ME  
**AIDS Research Alliance**, West Hollywood, CA  
 AIDS Resource Alliance, Inc., Orlando, FL  
**AIDS Resource Center of Wisconsin**, Milwaukee, WI  
 AIDS Resources Information & Services, San Jose, CA  
 AIDS Response Seacoast, Portsmouth, NH  
 AIDS Rochester, Inc., Rochester, NY  
 AIDS Service Agency of North Carolina, Raleigh, NC

**AIDS Service Center**, Pasadena, CA  
 AIDS Service for the Monadnock Region, Keene, NH  
 AIDS Services Center Coalition, Inc., Louisville, KY  
**AIDS Services Foundation Orange County**, Irvine, CA  
 AIDS Services of Dallas, Dallas, TX  
 AIDS Services of North Texas, Inc., Denton, TX  
 AIDS Survival Project, Atlanta, GA  
 AIDS Task Force of Alabama, Birmingham, AL  
 AIDS Task Force Ft. Wayne, Fort Wayne, IN  
**AIDS Taskforce of Greater Cleveland**, Cleveland, OH  
 AIDS Vaccine Advocacy Coalition, Washington, DC  
**AIDS Volunteers of Cincinnati**, Cincinnati, OH  
 AIDS Walk Kansas City, Kansas City, MO  
 AIDSCARE, Inc., Chicago, IL  
 AIDServe Indiana, Inc., Indianapolis, IN  
 Albany Medical Center AIDS Program, Albany, NY  
 All Souls AIDS Task Force, New York, NY  
 Allan Guttmacher Institute, New York, NY  
 American Academy of Family Physicians, Washington, DC  
 American Academy of Pediatrics, Washington, DC  
 American Association for World Health, Washington, DC  
 American Civil Liberties Union, Inc., Washington, DC  
 American Dental Education Association, Washington, DC  
 American Federation of State, County and Municipal Employees, Washington, DC  
 American Foundation for AIDS Research, Washington, DC  
 American Friends Service Committee, Washington, DC  
 American Lung Association, Washington, DC  
 American Nurses Association, Washington, DC  
 American Psychiatric Association, Washington, DC  
 American Psychological Association, Washington, DC  
 American Public Health Association, Washington, DC  
 American Red Cross, Washington, DC  
 American Social Health Association, Washington, DC  
**Amigos Volunteers in Education and Services, Inc.**, Houston, TX  
 Asian & Pacific Islander Coalition on HIV/AIDS, Inc., New York, NY  
 Association of Maternal and Child Health Programs, Washington, DC  
 Association of Nurses in AIDS Care, Reston, VA

Association of Schools of Public Health, Washington, DC  
 Association of State and Territorial Health Officials, Washington, DC  
 Aunt Bee's Laundry, Los Angeles, CA  
 Bailey House, Inc., New York, NY  
**Bering Omega Community Services, Houston, TX**  
 Berks AIDS Network, Reading, PA  
 Better Existence With HIV, Evanston, IL  
**Bienestar Health Services, Inc., Los Angeles, CA**  
 Billy De Frank Lesbian and Gay Community Center, San Jose, CA  
 Boulder County AIDS Project, Boulder, CO  
 Broward House, Inc., Fort Lauderdale, FL  
 CAEAR Coalition, Washington, DC  
 Cambridge Cares About AIDS, Inc., Cambridge, MA  
 Caracole, Inc., Cincinnati, OH  
 CARES, Kalamazoo, MI  
 Catholic Charities of The Archdiocese of San Francisco, San Francisco, CA  
 Catholic Charities USA, Alexandria, VA  
 CBAF, Inc., Corpus Christi, TX  
 Center for AIDS Research Education and Services, Sacramento, CA  
 Center for Community Alternatives, New York, NY  
 Center for Health Policy Development, Inc., San Antonio, TX  
 Center For Women Policy Studies, Washington, DC  
 Central Florida AIDS Unified Resources, Inc., Orlando, FL  
 Central Ohio HIV Consortium, Columbus, OH  
 Central Ohio Ryan White Consortium, Columbus, OH  
 Chase-Brexton Health Services, Inc., Baltimore, MD  
 Chicken Soup Brigade, Seattle, WA  
**City of Chicago Department of Public Health**, Chicago, IL  
 City of Chicago Office of City Comptroller, Chicago, IL  
 City of Los Angeles - AIDS Coordinator's Office, Los Angeles, CA  
 Clark and Associates Advocacy, Detroit, MI  
 Coastal Bend AIDS Foundation, Inc., Corpus Christi, TX  
 Colorado AIDS Project, Denver, CO  
 Columbia University School of Public Health - New York/Virgin Islands AIDS ETC, New York, NY  
**Columbus AIDS Task Force**, Columbus, OH  
 Community Action Against Addiction, Cleveland, OH  
 Community AIDS Network - Ohio, Akron, OH  
 Community Care HIV/AIDS Program, Ukiah, CA  
 Community Health Awareness Group, Detroit, MI  
 Community Health Law Project, Bloomfield, NJ  
 Community Healthcare Network Inc., New York, NY  
 Community Prescription Services, Inc., New York, NY  
 Community Research Initiative, Brookline, MA  
 Comprehensive AIDS Program of Palm Beach County, Inc., Belle Glade, FL  
 Comprehensive AIDS Resource Education, Long Beach, CA  
 Comprehensive Substance Abuse Program, Virginia Beach, VA  
 Connecticut AIDS Residence Coalition, Hartford, CT  
 Connecticut Positive Action Coalition, Hartford, CT  
 County of Los Angeles, Los Angeles, CA  
 CRI-Help, Inc., North Hollywood, CA  
 D.C. Comprehensive AIDS Resource and Education Consortium, Washington, DC  
 Damien Ministries, Inc., Washington, DC  
 David's House of Compassion, Toledo, OH  
 Delaware HIV Consortium, Wilmington, DE  
 Department of Health and Mental Hygiene, Baltimore, MD  
**Desert AIDS Project, Inc.**, Palm Springs, CA  
 Doorways, Interfaith Residence, St. Louis, MO  
 Douglas County AIDS Project, Lawrence, KS  
 Drug Policy Foundation, Washington, DC  
 Economic Opportunity Family Health Center, Inc., Miami Springs, FL  
 Elizabeth Glaser Pediatric AIDS Foundation, Washington, DC  
 Emory University School of Medicine - Southeast AIDS ETC, Atlanta, GA  
 Episcopal Church, Washington, DC  
 Escambia AIDS Services and Education, Pensacola, FL  
 Exponents, Inc. - Arrive Project, New York, NY  
 Family Care Agency, Inc., Reseda, CA  
 Fenway Community Health Center, Boston, MA  
 Florida AIDS Action Council, Inc., North Miami, FL  
**Florida AIDS Consortium**  
 Food & Friends, Inc., Washington, DC  
 Food for Thought / Sonoma County AIDS Food Bank, Forestville, CA  
 Fraternity House, Inc., Escondido, CA  
 Funders Concerned About AIDS, New York, NY  
**Gay Men's Health Crisis**, New York, NY

Genesis House, Chicago, IL  
 Georgia AIDS Coalition, Snellville, GA  
 God's Love We Deliver, New York, NY  
 Good Samaritan Project, Kansas City, MO  
 Government of the District of Columbia, Washington, DC  
 Gregory House Programs, Honolulu, HI  
 Gulf Coast Jewish Family Services, Inc., Clearwater, FL  
 H.C.C., Washington, DC  
 Harlem Congregations for Community Improvement, New York, NY  
**Harlem Directors Group**, New York, NY  
 Health Education Resource Organization, Baltimore, MD  
 Health Horizons of East Texas, Inc., Nacogdoches, TX  
 Hemophilia Association of New Jersey, East Brunswick, NJ  
 Hetrick-Martin Institute, New York, NY  
 HIV Law Project, Inc., New York, NY  
 HIV/AIDS Center of Virginia Commonwealth University, Richmond, VA  
 HIV/AIDS Resource Center, Ypsilanti, MI  
 HIV/AIDS Services, Inc., Grand Rapids, MI  
 Home Nursing Agency Community Services - AIDS Intervention Project, Altoona, PA  
 Howard University - National Minority AIDS ETC, Washington, DC  
 Human Rights Campaign, Washington, DC  
 Hyacinth AIDS Foundation, New Brunswick, NJ  
 Institute for Health Policy Studies, San Francisco, CA  
 International AIDS Vaccine Initiative, New York, NY  
 Inter-Tribal Council of Arizona, Inc., Phoenix, AZ  
 John XXIII AIDS Ministry, Monterey, CA  
 Johns Hopkins School of Medicine - National AIDS ETC Resource Center, Baltimore, MD  
 Justice Resource Institute, Boston, MA  
 Kentuckiana People With AIDS Coalition, Inc., Kevil, KY  
**L.A. Gay & Lesbian Center**, Los Angeles, CA  
 Lansing Area AIDS Network, East Lansing, MI  
 Latino Family Services, Inc., Detroit, MI  
 Legal Action Center, New York, NY  
 Life Force: Women Fighting AIDS, Inc., Brooklyn, NY  
**Los Angeles County Health Department**, Los Angeles, CA

Louisiana State University Health Sciences Center - Delta Region AIDS ETC, New Orleans, LA  
 Low Country AIDS Services, Charleston, SC  
 Maricopa Integrated Health System, Phoenix, AZ  
 Marin Treatment Center, Inc., San Rafael, CA  
 Maui AIDS Foundation, Wailuku, HI  
 Medical and Health Research Association of New York City, New York, NY  
 Metrolina AIDS Project, Inc., Charlotte, NC  
 Metropolitan AIDS Neighborhood Nutrition Alliance (MANNA), Philadelphia, PA  
 Metropolitan Charities, Inc., St. Petersburg, FL  
 Metropolitan Housing and CDC, Inc., Washington, NC  
 Metropolitan Residential Services, Columbus, OH  
**Minnesota AIDS Project**, Minneapolis, MN  
 Mobile AIDS Support Services, Mobile, AL  
**Montrose Clinic**, Houston, TX  
 Mothers' Voices Inc., New York, NY  
 Mountain States Regional Hemophilia & Thrombosis Center - University of Colorado Health Sciences Center  
 Multi-County Community Development Corporation, Saugerties, NY  
**Nashville CARES**, Nashville, TN  
 National AIDS Fund, Washington, DC  
 National Alliance of State and Territorial AIDS Directors, Washington, DC  
 National Association of Alcoholism & Drug Abuse Counselors, Arlington, VA  
 National Association of Children's Hospitals, Inc., Alexandria, VA  
 National Association of Community Health Centers, Inc., Washington, DC  
 National Association of People with AIDS, Washington, DC  
 National Association of Protection & Advocacy Systems, Washington, DC  
 National Association of Public Hospitals & Health Systems, Washington, DC  
 National Association of Social Workers - NY State Chapter, Albany, NY  
 National Catholic AIDS Network, San Francisco, CA  
 National Council of Negro Women Empowerment Program, New Orleans, LA  
 National Episcopal AIDS Coalition, Washington, DC  
 National Gay And Lesbian Task Force Policy Institute, Washington, DC

National Health Care for the Homeless Council, Nashville, TN  
 National Health Law Program - DC, Washington, DC  
 National Hospice and Palliative Care Organization, Inc., Alexandria, VA  
 National Mental Health Association, Alexandria, VA  
 National Minority AIDS Council, Washington, DC  
 National Native American AIDS Prevention Center, Oakland, CA  
 National Rural Health Association, Kansas City, MO  
**Nebraska AIDS Project**, Omaha, NE  
**New Mexico AIDS Services, Inc.**, Albuquerque, NM  
 New York AIDS Coalition, New York, NY  
 New York City AIDS Housing Network, New York, NY  
 New York City Department of Health, New York, NY  
**New York Planning Council**, New York, NY  
 New York State Department of Health - AIDS Institute, Albany, NY  
 NO/AIDS Task Force, New Orleans, LA  
 North Central District AIDS Coalition, Lock Haven, PA  
 North Coast HIV/AIDS Coalition, Cleveland Heights, OH  
 North Jersey Community Research Initiative, Newark, NJ  
 Northeast Valley Health Corp., Panorama City, CA  
**Northwest AIDS Foundation**, Seattle, WA  
 Ohio AIDS Coalition, Columbus, OH  
 Ohio Department of Health, Columbus, OH  
 Outer Cape Health Services, Inc., Truro, MA  
 Parkland Health & Hospital System - Texas and Oklahoma AIDS ETC  
 Peabody House, Inc., Portland, ME  
 Pediatric and Family HIV/AIDS Project - Catholic Charities Diocese of Fort Worth, Inc., Fort Worth, TX  
 People With AIDS Coalition of Houston, Houston, TX  
 Persad Center, Inc., Pittsburgh, PA  
 Philadelphia Health Management Corporation, Philadelphia, PA  
 Phoenix Body Positive, Inc., Phoenix, AZ  
 Piedmont Consortium, Durham, NC  
 Pierce County AIDS Foundation, Tacoma, WA  
 Pima County AIDS Program, Tucson, AZ  
 Plan International, Arlington, VA  
 Planned Parenthood Federation of America, Inc., Washington, DC

Project Response, Inc., Melbourne, FL  
 PWA Coalition of Broward County, Fort Lauderdale, FL  
 Regional HIV/AIDS Consortium, Charlotte, NC  
 Religious Action Center of Reform Judaism, Washington, DC  
 Research & Policy Reform Center, Inc., Washington, DC  
 River Region Human Services, Inc., Jacksonville, FL  
 Saint Joseph's Mercy Care Services, Atlanta, GA  
 San Diego County Department of Health - Office of AIDS Coordination, San Diego, CA  
 San Francisco Department of Public Health, San Francisco, CA  
 SAVE, Inc., Kansas City, MO  
 Service Employees International Union, Washington, DC  
 Service To AIDS Victims Endowment Foundation, Kansas City, MO  
 Simon House, Detroit, MI  
 South Jersey AIDS Alliance, Atlantic City, NJ  
 Southern Arizona AIDS Foundation, Tucson, AZ  
 Southern Colorado AIDS Project, Colorado Springs, CO  
 Southern Tier AIDS Program, Johnson City, NY  
 Spokane AIDS Network, Spokane, WA  
 Springfield AIDS Resource Association, Springfield, IL  
 St. Louis Effort For AIDS, Saint Louis, MO  
 State of Alaska Department of Health and Social Services, Anchorage, AK  
 Staten Island AIDS Task Force, Staten Island, NY  
 Tapestry Health Systems, Northampton, MA  
 Tarrant County AIDS Interfaith Network, Inc., Fort Worth, TX  
 Tarzana Treatment Center, Inc., Tarzana, CA  
 The AIDS Council of Greater Kansas City, Kansas City, MO  
 The American Dietetic Association, Chicago, IL  
**The Assistance Fund**, Houston, TX  
 The Cascade AIDS Project, Inc., Portland, OR  
 The Center for AIDS, Houston, TX  
 The City of New York - Mayor's Office, City Hall, New York, NY  
 The CORE Center, Chicago, IL  
 The Damien Center, Indianapolis, IN  
 The Free Medical Clinic of Greater Cleveland, Cleveland, OH

The Hektoen Institute for Medical Research, L.L.C.,  
Chicago, IL  
The Henry J. Kaiser Family Foundation, Menlo Park, CA  
The Irene Diamond Fund, Inc., New York, NY  
The Jewish Healthcare Foundation, Pittsburgh, PA  
The Momentum AIDS Project, Inc., New York, NY  
The Names Project Foundation, San Francisco, CA  
The Pittsburgh AIDS Task Force, Inc., Pittsburgh, PA  
The Salvation Army - Social Services/AIDS  
Ministries, Hartford, CT  
The San Francisco AIDS Foundation, San Francisco, CA  
The Serra Project, Los Angeles, CA  
The Sharing Community, Inc., Yonkers, NY  
The Society for the Advancement of Women's  
Health Research, Washington, DC  
The Stewart B. McKinney Foundation, Inc.,  
Fairfield, CT  
Therapeutic Communities of America, Washington, DC  
Tidewater AIDS Crisis Task Force, Norfolk, VA  
Title II Community AIDS National Network,  
Washington, DC  
Treatment Action Group, New York, NY  
Triangle AIDS Network, Beaumont, TX  
United Communities AIDS Network, Olympia, WA  
United Jewish Appeal - Federation of Jewish  
Philanthropies of New York, Inc., New York, NY  
Universidad de Puerto Rico - Puerto Rico AIDS ETC,  
San Juan, PR  
University of California San Francisco AIDS Health  
Project, San Francisco, CA  
University of California San Francisco - Pacific  
AIDS ETC, San Francisco, CA  
University of Colorado Health Sciences Center -  
Mountain Plains AIDS ETC, Aurora, CO  
University of Illinois at Chicago - Midwest AIDS  
ETC, Chicago, IL  
University of Kansas School of Medicine AIDS ETC,  
Wichita, KS  
University of Massachusetts - New England AIDS  
ETC, Brookline, MA  
University of Medicine and Dentistry of New Jersey  
- New Jersey AIDS ETC, Newark, NJ  
University of Pittsburgh - Pennsylvania/Mid  
Atlantic AIDS ETC, Pittsburgh, PA  
University of Washington - Northwest AIDS ETC,  
Seattle, WA  
University of Wyoming, Laramie, WY  
**Urban Coalition for HIV/AIDS Prevention Services**  
Us Helping Us...People Into Living, Inc.,  
Washington, DC  
Victory House, Boston, MA  
WAM Foundation, Inc., Houston, TX  
Wayne State University - Great Lakes to Tennessee  
Valley AIDS ETC, Detroit, MI  
We The People living with AIDS/HIV, Philadelphia, PA  
Wellness House of Michigan, Detroit, MI  
**Western Colorado AIDS Project, Grand Junction, CO**  
Western North Carolina Community Health Services  
Inc., Asheville, NC  
Westside Community Mental Health Center, Inc.,  
San Francisco, CA  
**Whitman-Walker Clinic, Inc., Washington, DC**  
William F. Ryan Community Health Center, New  
York, NY