



## In-Home HIV Collection Kits

### In-Home HIV Collection Kits

HIV testing through in-home collection provides additional options to individuals, and has a place in meeting the diverse needs of our communities.

In 1996, the Food and Drug Administration (FDA) approved the first in-home collection kit for HIV testing. The *only* FDA-approved kit is called the Home Access Express HIV-1 Test System and is manufactured by Home Access Health Corporation. Other kits, including a urine-based HIV test, may be reviewed at some point in the future.

Several other home test kits are being marketed in the U.S. and promoted on the Internet. These kits have not received FDA approval and at least one of their purveyors has been sentenced to jail time for selling a fraudulent product. So to start with, buyers beware! At the current time, only one product has been FDA-approved and operating under quality controlled standards.

While it may be true that receiving test results and counseling over the telephone with no face-to-face contact is not an appropriate approach for some people, it is equally true that others find any requirement for face-to-face encounters at a site associated with HIV testing to be a serious obstacle in getting tested. People must be empowered to choose which approach best suits their own needs and temperament.

Project Inform was the first organization in the country to urge people to get tested anonymously, learn about their HIV status, empower themselves with education, learn about HIV-disease and treatment options and make informed decisions about their health. Principally, it is the position of Project Inform that people have the right to have access to information and choices, and the right to self determination.

According to statistics compiled through the National Center for Health Statistics, at the Centers for Disease Control, less than 15% of adults in the U.S. have been tested for HIV. Based on findings from large population surveys of people who had not taken HIV tests, 8% indicated that they intended to test in the upcoming year. When given the option of in-home access to HIV tests, the willing-

ness of individuals to test for HIV tripled to 24%. Half of the people who comprise that 24% included people who perceive themselves to be at risk for HIV infection.

Clearly, statistics show that if HIV-testing through in-home access were available, there are people who may utilize this option who would not otherwise test through existing mechanisms. Furthermore, 31% of people surveyed who had been tested for HIV reported receiving test results either by mail or over the telephone. This statistic does not speak to the quality or appropriateness of how these test results were delivered based on individual's needs. It does speak to the need, however, of formalizing and developing options of anonymous and confidential telephone counseling in this regard, for people who choose to utilize this option and for people who feel phone-based notification and counseling best serves their needs.

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### HIV testing through in-home collection

The approved test is not an in-home HIV test, but rather an in-home collection kit. This means that people would call a phone number to register their test kit number and to seek pre-test counseling and then follow instructions in drawing a small amount of their own blood from the fingertip and rubbing it on a specimen card that is provided with the kit.

The specimen card, or dried blood spot, is mailed to a laboratory and tested for the presence of the HIV antibody through a standard process called ELISA, which will be run twice. If the ELISA test is positive for the HIV antibody, the results would then be confirmed by another test called a Western blot. The dried blood spot will be on a specimen card with an identification number, which the consumer would reference when calling a toll-free 800 number for their test results.





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Telephone counseling services will accompany positive test results and will be optional for people with negative test results. Callers will be permitted to recall the counseling line as often as they like, requiring only their ID number to gain access to the system. HIV testing through in-home collection differs from traditional in-home types of tests, such as pregnancy tests, in that the consumer does not have immediate and direct access to the results.

Approximately three to seven days after mailing the blood sample, the consumer may call the toll-free phone number to access test results. Entry into the telephone system would be done through a series of computerized prompts, whereby consumers enter their identification number and are routed either to a counselor or automated response.

If a person has a positive or indeterminate test result, they are automatically routed to speak with a counselor who can offer standardized counseling services and have access to information about other counseling and healthcare services available in the caller's local area. If a person has a negative test result they are delivered the information through an automated system with further options to speak with a counselor who can answer questions and respond to additional post-testing counseling needs.

Additional automated informational voicemail boxes are established for people seeking information on specific topics concerning HIV testing, transmission risk, etc. Live counselors would be available to people with negative test results if they choose to access them. People with positive test results would be able to access counseling services six times in the first year after their result, whereas people with negative test results would have limited access (three sessions) to continued use of the phone-based counseling services. Test results are available up to 30 days.

The in-home HIV collection kit is available through the internet and over-the-counter through some drugstores and pharmacies.

The in-home kits cost approximately \$45–\$55, retail. The less expensive kit offers results in seven days. The more expensive kits offer results in three days.

### Accuracy and reliability

Of major concern to Project Inform, regarding the marketing of HIV testing through in-home HIV collection kits, is the quality, accuracy and reliability of the product. The FDA will not approve a product that has not been demonstrated to be equivalent to the standard diagnostic assays, which is the cause to be concerned about unapproved and illegally marketed HIV test kits. The conditions under which accuracy and reliability are demonstrated must reflect a wide range of conditions under which blood spots will be collected in the home environment. For the currently approved test, data supports the accuracy and reliability of HIV testing through in-home collection, demonstrating 99.9% accuracy.

### Counseling and linkage to local services

The heart of the community debate regarding HIV testing through in-home collection kits is the issue of counseling services. Clearly, no one can discount the value of the availability of in-person pre- and post-test counseling by well-trained staff. For this reason, it is imperative that HIV testing through in-home collection not replace anonymous HIV test sites and other counseling services. Rather, HIV testing through in-home collection kits should be an additional option for HIV testing, among a menu of available options, which enable the individual to choose, for themselves, what best serves their own needs. Currently there are no proposed plans to replace anonymous HIV test sites with HIV testing through in-home collection kits.

The counseling program which has been linked to the in-home collection kit provides standardized services, through 'live' telephone counselors, who will also have listings of HIV treatment and counseling services in a caller's local area.

The crux of the issue around opposing in-home collection kits is not an issue of in-person counseling or no counseling. Clearly counseling services are available. The question is around the appropriateness of telephone counseling and whose decision it is to determine the appropriateness and suitability of this type of counseling to meet individual needs. Project Inform believes that this decision rests with the individual.

There are a number of myths around in-person counseling that need to be acknowledged in the course of this discussion. While it may be true that in-person face-to-face pre- and post-test counseling, delivered by well-trained staff in a culturally sensitive and relevant way may prove to decrease anxiety around test results,

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may link individuals to services and/or reduce high risk-taking behaviors, it is also true that counseling services are not uniformly living up to these high standards.

The availability of quality in-person counseling services varies greatly from test-site to test-site, and from staff person to staff person. Some test sites provide little more than a video, a phlebotomist and a staff person to recite test results, with little or no knowledge of HIV and AIDS, local services or risk reduction counseling. Additionally, people who choose to receive HIV testing through their family practitioner are not necessarily, currently, being linked to HIV counseling services when they receive their test results. In other words, depending on the quality and types of services available, the type of counseling provided through an in-home HIV collection line may actually prove to be a vast improvement.

Furthermore, often the in-depth counseling required by some people who test positive in most (clearly not all) cases does not take place at an anonymous test site. In many cases, people who are seriously troubled must take the discussion elsewhere, to their physician, to a therapist, to telephone hotlines like those run through Project Inform, the San Francisco AIDS Foundation, the National AIDS Hotline, or to an AIDS service organization or another type of community-based organization. Often, the counseling provided at the test site is very limited, commonly scripted unless it is being delivered by a trained psychologist.

Through our own HIV treatment information hotline, we encounter numerous callers who in fact are soliciting our services as a form of post-test counseling. Our experience tells us that this form of post-test counseling sometimes is extended over multiple calls, and the typical profile of these callers are people who don't feel comfortable talking to someone in person and often the caller is someone who will not even discuss this issue with a family doctor or healthcare provider. Therefore, it is obvious that for some people, phone counseling is already a major factor in post-test counseling.

Moreover, the systems which require in-person face-to-face encounters are perceived as a major obstacle by many people who don't wish to be seen or in anyway identified at an HIV-related facility, or, in their own minds, a place that is perceived as 'gay identified'.

Finally, telephone counseling around HIV test results may prove more valuable, not less, for some people. For some people, culturally, the need to see a counselor implies that there is something 'wrong' with them. Telephone counseling services provide an option for these people to seek services and information and preserve their need for 'non-exposure', and allows them to 'save face'. Inherently, telephone counseling is not less effective than in-person face-to-face counseling.

Clearly, crisis intervention hotlines, battered women's hotlines, suicide prevention hotlines and youth crisis hotlines continue operating because they work and provide options for people in need. Telephone counseling in all of these crisis areas has demonstrated to be extremely effective in meeting the diverse needs of many communities. Criticism that telephone counseling associated with HIV test results will result in high suicide rates is speculation. It must be kept in mind, however, that currently the vast majority of suicide and crisis counseling which occurs in general is done over the phone, through suicide and crisis hotlines.

### Access, options and affordability

Through Project Inform's experience with our own HIV treatment hotline, national town meeting program and publications, we have learned that people have a variety of needs around information about HIV/AIDS. While the more intimate community setting of a town meeting may be a great way for some people to hear information, others prefer the toll-free hotline, where they can ask questions and get information while preserving their anonymity.

For some people, walking into a place that is associated with HIV/AIDS is in and of itself a large enough barrier to preclude accessing services. HIV testing through in-home collection provides an additional option to people who might not otherwise seek HIV testing through currently available mechanisms.

In rural communities, anonymous HIV test sites are often nonexistent, as are skilled professionals with expertise in dealing with HIV/AIDS. HIV testing through in-home collection offers what may be the only availability of anonymous and confidential HIV testing to people in some rural areas. Moreover, in states that don't allow anonymous HIV testing and in states with 'contact tracing', access to HIV testing through in-home collection may prove a more accessible means to gain access to anonymous HIV testing than will leaving the state.

HIV testing through in-home collection is available through the Internet and over-the-counter through some drugstores and pharmacies. The cost ranges from \$45-\$55 depending on how quickly someone wants the results. Programs to provide access to the kit to low income people who wish to use in-home collection as a testing option have been developed via relationships with national organizations that distribute them to clinics serving indigent people.

### Use, abuse and ramifications

There is the potential for abuse of HIV testing through in-home collection, which is a serious concern. It is possible, for example, for someone to have a blood sample taken—against their will—



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and third parties, having access to the identification number in the kit, gaining access to HIV test results. This is of particular concern in institutional settings, such as correctional facilities.

Currently it is possible, in many of these settings, for blood to be drawn and tested against people's will as well. The in-home collection kit adds an element of ease to this process, however.

Misuse of HIV testing through in-home collection kits is also a possibility among employers and insurance companies, as a means to enable discrimination on the basis of HIV status. Some insurance companies currently screen for HIV through blood tests. In some states this is illegal. People should be aware of the laws in their area and use the law to protect themselves.

Some insurance companies routinely screen applicants for pre-existing health conditions prior to issuing insurance. Often individuals undergo a battery of tests which are not explained to them, and sometimes the test results are not even given to the individual. The root of the problem here, in many cases, is not that certain diagnostic tests exist, but rather that individuals are not being adequately informed of what is happening or they are not familiar with their rights. It is critical that all people become aware of their right to confidentiality and that mechanisms to ensure protection against misuse of this option be strengthened.

Mandatory testing for HIV has vast social, personal and political consequences. Currently, mandatory testing and routine screening for HIV is being conducted in a number of states, in various settings. Results of a study comparing AZT to placebo in pregnant women suggest that taking AZT during pregnancy reduces the risk of HIV-positive women transmitting the virus to their child. These study results sparked a handful of policy initiatives supporting mandatory or routine screening of pregnant women for HIV.

Because the decision to test for HIV has enormous personal consequences, mandatory or routine screening may prove harmful and takes decision-making control out of the hands of the individual. Informed consent, informed decision-making and securing confidentiality and anonymous test results is critical to preserving the rights of the individual. HIV testing through in-home collection does not effect mandatory testing laws, it may, however, enable ease of abuse in these regards.

If someone is forced, against their will to supply blood, the company has the ability to block test results if the person calls with the personal identification number associated with the blood sample. In a setting of coercion or force, however, the individual may not be able to memorize a 12-digit personal ID number, or even know what to look for. The possibility of misuse and abuse exists.

Currently there are laws which are designed to protect the individual from forced testing or coercion. Laws do not protect people from the trauma of this experience, however. If someone breaks the law, and forces someone to take an HIV-test, they are subject to the judicial system. Clearly laws do not prevent crime from occurring, cannot stop power imbalances and coercion in personal relationships, and simply because a law exists it does not protect against the emotional experience of being a victim of a crime. The possibility of abuse with in-home collection as well as other currently available options, exists and will continue to exist. HIV-testing through in-home collection brings this issue more intimately to the home.

### The Bottom Line

#### Pros:

- Provides an easily accessible, highly private and confidential form of counseling-based testing, which may reduce the number of people who receive test results without counseling.
- Provides a highly consistent form of counseling and referral to additional local resources.
- Provides additional options to people who may not otherwise seek HIV testing through existing mechanisms.
- Provides access to anonymous and confidential HIV testing to people who may not otherwise have access to it.
- Provide alternatives to HIV testing and counseling which may better meet individual's needs.
- May increase the number of people who seek HIV testing and empower more people with knowledge about their serostatus, the first step in taking control of one's health.

#### Cons:

- Phone-based counseling may not be able to provide intervention support or adequately address risk reduction issues for all people, in some cases this could be dangerous.
- In some (not all) cases, in-person counseling provides lasting networks of support and links individuals to services. These counseling programs would be available to people after receiving test results through in-home collection, but may not be sought out.
- In-person counseling may make it possible to recognize people who are being tested on a repeated basis and signal the need for increased safe-sex counseling.
- The cost of the kit is excessive and may be cost prohibitive.
- As with many diagnostic assays, in-home collection kits could be abused or misused and enable discrimination on the basis of HIV status.

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