

# Vital Facts About HIV Home Test Kits

Privacy and confidentiality are main factors that lead people to choose home testing kits to find out if they are infected with human immunodeficiency virus (HIV), which causes AIDS.

It is important that consumers know there is only one product currently approved by FDA and legally sold in the United States as a “home” testing system for HIV.

This product is a kit marketed as either “The Home Access HIV-1 Test System” or “The Home Access Express HIV-1 Test System.” The kit is a home

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The FDA-approved Home Access System kits allow people to collect their own blood sample and, using a personal identification (PIN) number, mail the sample anonymously to a laboratory for testing.

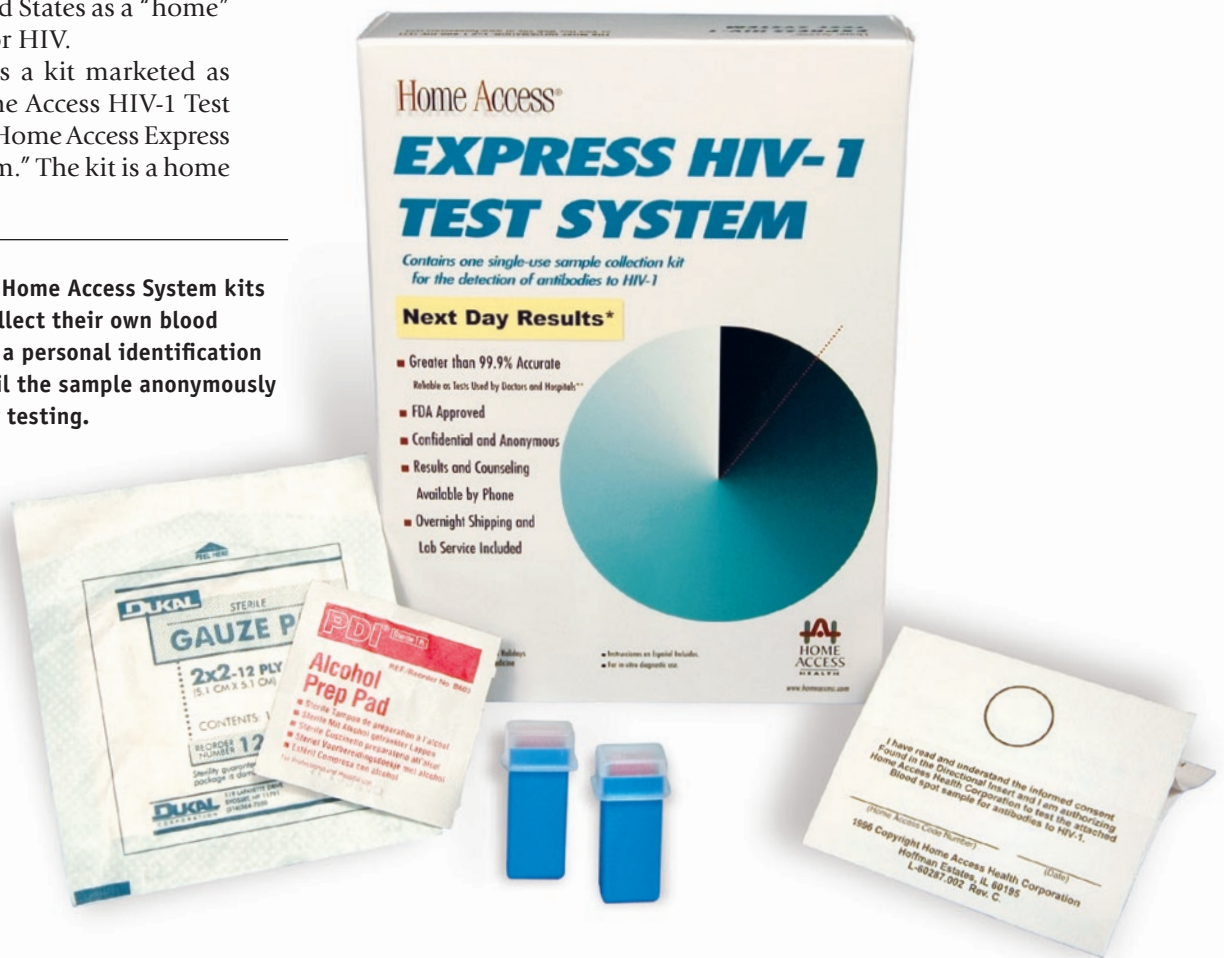


Photo courtesy of Home Access Health Corporation

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collection-test system that requires users to collect a blood specimen, and then mail it to a laboratory for professional testing. No test kits allow consumers to interpret the results at home.

### **Beware of False Claims**

Numerous HIV home test systems that have not been approved by FDA are currently being marketed online and in newspapers and magazines.

Manufacturers of unapproved systems have falsely claimed that their products can detect antibodies to HIV in blood or saliva samples, and that they can provide results in the home in 15 minutes or less. Some have even claimed that their systems are approved by FDA or are manufactured in a facility that is registered with FDA.

FDA takes appropriate action against people or firms that sell unapproved and ineffective tests.

### **About the Approved Product**

The FDA-approved Home Access System kits allow people to collect a blood sample. Using a personal identification number (PIN), they then mail the sample anonymously to a laboratory for testing. The PIN can then be used to obtain results.

The kits, manufactured by Illinois-based Home Access Health Corp., can be purchased at pharmacies, by mail order, or online. They only allow testing for the presence of antibodies of the virus known as HIV-1. They do not provide the ability to test for HIV-2, a less common cause of AIDS.

The Home Access System offers

users pre- and post-test, anonymous and confidential counseling through both printed material and telephone interaction. It also provides the user with an interpretation of the test result.

### **Checking for Antibodies to HIV**

Like most HIV tests, the approved Home Access testing system checks for the presence of antibodies to HIV that are produced once the virus enters the body. The rate at which individuals infected with HIV produce these antibodies differs.

There's a "window period" between the time someone is infected with HIV and the time the body produces enough antibodies to be detected through testing. During this time, an HIV-infected person will still get a negative test result.

According to FDA's Center for Biologics and Research (CBER), which regulates all HIV tests, detectable antibodies usually develop within two to eight weeks. The average is about 22 days.

Still, some people take longer to develop detectable antibodies. Most will develop antibodies within three months following infection. In very rare cases, it can take up to six months to develop detectable antibodies to HIV.


### **Rapid Tests: A Clinical Option**

Consumers do have the option of taking a rapid test, some of which test for both HIV-1 and HIV-2. These tests are run where the sample is collected, and produce results within 20 minutes.

Because HIV testing requires inter-

pretation and confirmation, rapid antibody tests are only approved and available in a professional health care setting, such as doctors' offices, clinics and outreach testing sites.

According to the Centers for Disease Control and Prevention (CDC), there are tests that look for HIV's genetic material directly, but these are not in widespread use. Tests using saliva or urine are also available, although not for "at-home" use.

If you are unsure whether a certain type of HIV test is FDA-approved, look for the test on the agency's list of at [www.fda.gov/cber/products/testkits.htm](http://www.fda.gov/cber/products/testkits.htm). You can also contact CBER by phone at (800) 835-4709, or e-mail at [OCTMA@CBER.FDA.GOV](mailto:OCTMA@CBER.FDA.GOV). 

### **For More Information**

Deciding If and When to Be Tested (CDC):

[www.cdc.gov/hiv/topics/testing/resources/qa/be\\_tested.htm](http://www.cdc.gov/hiv/topics/testing/resources/qa/be_tested.htm)

HIV and AIDS (FDA Office of Special Health Issues)

[www.fda.gov/oashi/aids/hiv.html](http://www.fda.gov/oashi/aids/hiv.html)