May 2014 | Fact Sheet

HIV Testing in the United States

HIV testing is integral to HIV prevention, treatment, and care. Knowledge of one’s HIV status is important for preventing the spread of disease. Studies show that those who learn they are HIV positive modify their behavior to reduce the risk of HIV transmission. Early knowledge of HIV status is also important for linking those with HIV to medical care and services that can reduce morbidity and mortality and improve quality of life.

<table>
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<th>Key Dates in the History of HIV Testing³</th>
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<td>1981: First AIDS case reported</td>
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<td>1984: Human immunodeficiency Virus (HIV) identified</td>
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<td>1985: First test for HIV licensed (ELISA)</td>
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<td>1987: First Western Blot blood test kit</td>
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<td>1992: First rapid test</td>
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<td>1994: First oral fluid test</td>
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<td>1996: First home and urine tests</td>
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<td>2002: First rapid test using finger prick</td>
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<td>2003: Rapid finger prick test granted CLIA (Clinical Laboratory Improvement Amendments) waiver</td>
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<td>2004: First rapid oral fluid test (also granted CLIA waiver)</td>
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<td>2006: CDC recommends routine HIV screening in U.S. health care settings⁴</td>
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<td>2007: CDC launches Expanded HIV Testing Initiative in U.S.</td>
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<td>2007: WHO/UNAIDS global guidelines recommend routine HIV screening in health care settings⁴</td>
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<td>2010: First test approved that detects both antigen and antibodies⁵</td>
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<td>2012: First rapid oral fluid home test⁶</td>
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<td>2013: USPSTF gives routine HIV screening an “A” rating⁷</td>
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<tr>
<td>2013: First rapid test approved that detects both antigen and antibodies, and distinguishes between acute and established HIV-1 infection⁸</td>
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Testing Recommendations and Requirements

The U.S. Centers for Disease Control and Prevention (CDC) recommends routine HIV screening in healthcare settings for all adults, aged 13-64, and repeat screening at least annually for those at high risk. HIV testing is recommended for all pregnant women and for any newborn whose mother’s HIV status is unknown. CDC recommends screening be voluntary, and opt-out (patient will be notified that the test will be performed and consent is inferred unless the patient declines) vs. opt-in (test is offered to the patient who must then explicitly consent to an HIV test, often in writing).
Currently, CDC recommends that all those at high risk for HIV, regardless of setting, be tested routinely for HIV infection. Risk behaviors include having:

- injected drugs or steroids or shared equipment (such as needles, syringes, works) with others
- had unprotected vaginal, anal, or oral sex with men who have sex with men, multiple partners, or anonymous partners
- exchanged sex for drugs or money
- been diagnosed with or treated for hepatitis, tuberculosis, or a sexually transmitted disease, like syphilis
- had unprotected sex with anyone who falls into an above category, or with someone whose history is unknown.

A key decision that impacts the implementation of the CDC guidelines came in April 2013, when the U.S. Preventive Services Task Force (USPSTF) gave routine HIV screening of all adolescents and adults, ages 15 to 65, an “A” rating – generally aligning the rating with the CDC’s HIV screening guidelines. This rating expands the already existing “A” rating for people at increased risk for HIV (such as injection drug users and men who have sex with men), and for all pregnant women. The USPSTF ratings are developed by an independent panel of clinicians and scientists, and are important because many private and public insurers link their coverage of preventive services to ones rated “A” or “B” by the USPSTF. The “A” rating has further implications given the Affordable Care Act (ACA), which requires or incentivizes new private health plans, Medicare, and Medicaid to provide preventive services rated “A” or “B” at no cost to patients.

HIV testing is mandatory in the U.S. in certain cases, including for: blood and organ donors; military applicants and active duty personnel; federal and state prison inmates under certain circumstances; and newborns in some states. As of January 2010, HIV testing is no longer mandatory for those wishing to emigrate to the United States or for refugees.

**Testing Statistics**

More than half (54%) of U.S. adults, aged 18-64, report ever having been tested for HIV, including 22% who report being tested in the last year. The share of the public saying they have been tested for HIV at some point increased between 1997 and 2004, but has remained fairly steady since then.

- Of those U.S. adults, aged 18-64, who say they have never been tested for HIV, nearly 6 in 10 (57%) say it is because they do not see themselves as at risk.
- HIV testing rates vary by state, age, and race/ethnicity. For example, Blacks and Latinos are significantly more likely to report having been tested for HIV than whites.
Among the more than 1.1 million people living with HIV/AIDS in the U.S., an estimated 16% do not know they are infected (down from 25% in 2003) and knowledge of HIV status is even lower among some populations.\textsuperscript{1,23,24}

Many people with HIV are diagnosed late in their illness; in 2010, 32% received an AIDS diagnosis within one year of testing HIV positive.\textsuperscript{25}

## Testing Sites and Policies

HIV testing is offered at CDC funded testing sites (accounting for more than 3 million tests) and in other public and private settings, including free-standing HIV counseling and testing centers, health departments, hospitals, private doctor offices, and STD clinics.\textsuperscript{26} Those testing positive for HIV are most likely to have been tested in health care facilities (e.g., inpatient and outpatient facilities, emergency rooms).\textsuperscript{26}

All states/territories have moved to **HIV name reporting** (in addition to reporting AIDS cases) where a person’s name is reported to the state if they test HIV positive. The state then reports the number of unique positive HIV tests to CDC (no names or other personally identifying information are reported to CDC; only clinical and basic demographic information are forwarded). This is considered **confidential** HIV testing. There is also **anonymous** HIV testing offered at some testing sites.

## Testing Techniques

Most HIV tests used to screen for HIV infection detect the presence of antibodies produced by the body to fight HIV. Detectable antibodies usually develop within 2-8 weeks after infection, but may take longer; the period after initial infection with HIV before detectable antibodies develop is the “window period”.\textsuperscript{9} In 2010, the FDA approved the first HIV diagnostic test that detects both antibodies and antigen, a component of the virus that triggers the production of antibodies.\textsuperscript{5} In 2013, the FDA approved the first rapid antigen-antibody test, the first test also to distinguish between acute and established HIV-1 infection.\textsuperscript{8} Tests for antigen allow for earlier detection of HIV, although there will still be a window period after initial infection during which no test can detect the virus.

The currently available tests used to diagnose HIV infection in the U.S. are below. They differ based on type of specimen tested (whole blood, serum, or plasma; oral fluid; urine); how the specimen is collected (blood draw/venipuncture; finger prick; oral swab); where the test is done (laboratory; point-of-care site; at home); and how quickly results are available (conventional or rapid).\textsuperscript{27,28} The main types of tests are:

### Conventional Blood Test:
Blood sample drawn by health care provider; tested at lab. Results: less than an hour to several days, depending on location.

### Conventional Oral Fluid Test:
Oral fluid sample collected by health care provider, who swabs inside of mouth; tested at lab. Results: a few days to two weeks. Avioq is the only FDA-approved conventional oral fluid test for HIV, which is used with OraSure, the only FDA-approved collection device for oral fluid.

### Rapid Tests:
Sample collected by health care provider at lab or care site, depending on complexity of rapid test. Results: in as little as 10 minutes. If test is negative, no further testing is needed. If positive, test must be confirmed with a more specific test through conventional method. There are eight FDA-approved rapid tests: OraQuick Advance Rapid HIV-1/2 Antibody Test (whole blood finger prick or venipuncture; plasma; oral fluid); Reveal Rapid HIV-1 Antibody Test (serum; plasma); Uni-Gold Recombigen HIV Test (whole blood finger prick or venipuncture; serum; plasma); Multispot HIV-1/HIV-2 Rapid Test (serum;
plasma); INSTI HIV-1 Antibody Test (whole blood finger prick or venipuncture; plasma); Alere Determine HIV-1/2 Ag/Ab Combo Test (serum; plasma; whole blood finger prick or venipuncture); and two Clearview tests – Clearview HIV 1/2 Stat Pak, Clearview Complete HIV 1/2 (whole blood; serum; plasma). Some rapid tests have been granted CLIA waivers which allow them to be used outside traditional laboratories.

**HOME TESTS:** There are two approved home tests. For the HomeAccess HIV-1 Test System, an individual performs the test by pricking finger with a lancet, placing drops of blood on treated card, and mailing to lab for testing. Identification number on card is used when phoning for results; counseling and referral available by phone. Results: in as little as three days. In July 2012, the FDA approved the first rapid oral fluid test for home use – OraQuick In-Home HIV Test. Results: in as little as 20 minutes. Both home tests may be purchased from drug stores and online.6

**URINE TEST:** Urine sample collected by health care provider; tested at lab. Calypte is the only FDA-approved HIV urine test. Results: a few days to two weeks.

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1 CDC, MMWR 55(RR14); September 2006.
2 CDC, MMWR 52(15); April 2003.
3 KFF, Global HIV/AIDS Timeline.
5 FDA Consumer Information, Fourth Generation HIV Diagnostic Test Approved, permitting earlier detection of infection; June 2010.
7 U. S. Preventive Services Task Force, Current Recommendations.
8 FDA Consumer Information, First rapid diagnostic test to detect both HIV-1 antigen and HIV-1/2 antibodies approved.
9 CDC, Testing Q&A.
11 KFF, State Medicaid Coverage of Routine HIV Screening.
13 U.S. Department of Defense, Instruction Number 6485.01; October 2006.
17 CDC, Final Rule Removing HIV Infection from U.S. Immigration Screening.
20 CDC, Behavioral Risk Factor Surveillance System.
21 CDC, Early Release of Selected Estimates from the January – September 2013 National Health Interview Survey; March 2014.
22 CDC, National Health Interview Surveys.
23 CDC, HIV Surveillance Supplemental Report, Vol. 18, No. 5; October 2013.
28 FDA, Complete List of Donor Screening Assays for Infectious Agents and HIV Diagnostic Assays.