

June 2017 | Fact Sheet

# HIV Testing in the United States

## Key Facts

- 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.<sup>1,2</sup>
- 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.<sup>3</sup>
- U.S. Department of Health and Human Services guidelines recommend starting treatment as soon as one is diagnosed with HIV and new research (including the Strategic Timing of AntiRetroviral Treatment study or START) has underscored the importance of starting treatment early.<sup>4,5</sup>
- Recent policy decisions have expanded health insurance coverage of HIV testing, meaning that people with health insurance – both public and private – have greater access to testing, often at no cost.<sup>6,7,8</sup> And, for those without insurance or those wishing not to use their insurance, HIV testing can often be obtained at little or no cost.

### Key Dates in the History of HIV Testing<sup>9</sup>

1981: First AIDS case reported
1984: Human immunodeficiency Virus (HIV) identified
1985: First test for HIV licensed (ELISA)
1987: First Western Blot blood test kit
1992: First rapid test
1994: First oral fluid test
1996: First home and urine tests
2002: First rapid test using finger prick
2003: Rapid finger prick test granted CLIA (Clinical Laboratory Improvement Amendments) waiver
2004: First rapid oral fluid test (also granted CLIA waiver)
2006: CDC recommends routine HIV screening in U.S. health care settings <sup>10</sup>
2007: CDC launches Expanded HIV Testing Initiative in U.S.
2007: WHO/UNAIDS global guidelines recommend routine HIV screening in health care settings <sup>11</sup>
2010: First test approved that detects both antigen and antibodies <sup>12</sup>
2012: First rapid oral fluid home test <sup>13</sup>
2013: USPSTF gives routine HIV screening an "A" rating <sup>14</sup>
2013: First rapid test approved that detects both antigen and antibodies, and distinguishes between acute and established HIV-1 infection <sup>15</sup>
2015: Centers for Medicare and Medicaid Services announces Medicare coverage of annual HIV screening for all beneficiaries 15-65, and for those older and younger beneficiaries at "increased risk" for HIV <sup>16</sup>

# Testing Recommendations and Requirements

The U.S. Centers for Disease Control and Prevention (CDC) recommends **routine HIV screening in health-care settings** for all adults, aged 13-64, and repeat screening at least annually for those at high risk (e.g., CDC says that sexually active gay and bisexual men may benefit from more frequent testing, such as every 3 to 6 months).<sup>17</sup> According to the CDC, risk behaviors include:<sup>18</sup>

- injection drug or steroid use or sharing equipment (such as needles, syringes, works) with others;
- unprotected vaginal, anal, or oral sex with men who have sex with men, multiple partners, or anonymous partners;
- exchanging sex for drugs or money;
- diagnosis with or treatment for hepatitis, tuberculosis, or a sexually transmitted disease, like syphilis;
- unprotected sex with anyone who falls into an above category, or with someone whose history is unknown.

Additionally, HIV testing is recommended for all pregnant women and for any newborn whose mother's HIV status is unknown.<sup>19</sup> Treatment provided to pregnant HIV positive women can significantly lower the risk of transmission to her baby.<sup>20</sup> HIV testing is also recommended for anyone who has been sexually assaulted.

CDC recommends that all HIV screening be **voluntary**, and **opt-out** (patient is 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 explicitly consent to an HIV test, often in writing).<sup>21</sup>

HIV testing is **mandatory** in the U.S. in certain cases, including for: blood and organ donors;<sup>22</sup> military applicants and active duty personnel;<sup>23</sup> federal and state prison inmates under certain circumstances;<sup>24,25</sup> and newborns in some states.<sup>26</sup> As of January 2010, HIV testing is no longer mandatory for those wishing to emigrate to the United States or for refugees.<sup>27</sup>

## Insurance Coverage of HIV Testing

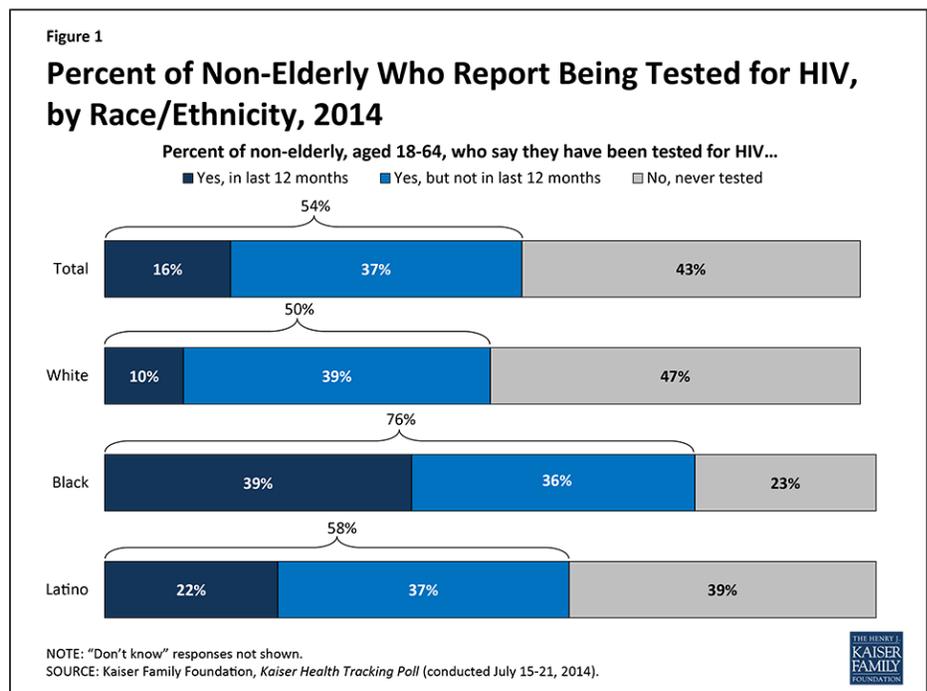
HIV testing that is “medically necessary” – recommended by a physician due to risk – is generally covered by insurance. Coverage of routine HIV screening (screening provided to all patients/clients regardless of risk), however, was historically not always covered by payers. This changed significantly 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.<sup>28</sup> 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, developed by an independent panel of clinicians and scientists, are important because many private and public insurers link their coverage of preventive services to those rated “A” or “B” by the USPSTF. Moreover, the Affordable Care Act (ACA), passed in 2010, requires or incentivizes insurers to cover preventive services rated “A” or “B” and do so without cost-sharing, as follows:

- **Private Insurance:** The ACA requires that all private plans (except those that are grandfathered, meaning they were in place before the ACA was passed and have made no significant changes to coverage) must cover routine HIV testing without cost-sharing.<sup>29</sup>
- **Medicaid:** While all traditional state Medicaid programs must cover “medically necessary” HIV testing,<sup>30</sup> state coverage of “routine” HIV screening varies because it is an optional benefit under Medicaid. A recent analysis found that more than two thirds of state Medicaid programs do cover routine HIV screening.<sup>31</sup> Medicaid programs expanded under the ACA are required to cover preventive services rated "A" or "B" by the USPSTF, including HIV testing, without cost-sharing.
- **Medicare:** In April 2015, CMS expanded Medicare coverage to include annual HIV testing for beneficiaries ages 15-65 regardless of risk, and those outside this age range at increased risk.<sup>32</sup> Additionally, Medicare will cover up to three tests for pregnant beneficiaries.<sup>33</sup>

For those without insurance coverage (or wishing not to use their insurance), HIV testing can be obtained at little or no cost in some settings (e.g., stand-alone HIV testing sites, mobile testing clinics).

## Testing Statistics

- As of 2014, more than half (54%) of U.S. adults, aged 18-64, reported ever having been tested for HIV, including 16% who reported 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.<sup>34</sup>
- HIV testing varies by state, age, and race/ethnicity.<sup>35,36,37,38</sup> For example, Blacks and Latinos are more likely to report having been tested for HIV than whites.
- According to a recent survey of gay and bisexual men in the U.S., relatively few report being tested as regularly as is often advised. Seven in 10 say they have been tested at some point in their lives, 1 in 5 say they were tested within past six months, and 3 in 10 say they’ve never been tested for HIV, a share that rises to 44 percent among those under age 35.<sup>39</sup>
- Among the more than 1.1 million people living with HIV in the U.S., an estimated 15% do not know they are infected and knowledge of HIV status is even lower among some populations.<sup>40</sup>



## 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.<sup>41</sup> While testing also occurs in community settings and in mobile testing units, those testing positive for HIV are most likely to have been tested in health care facilities (e.g., inpatient and outpatient facilities, emergency rooms).<sup>42</sup>

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 where identifying information is not collected.

## 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 3-8 weeks after infection, but may take longer; the period after initial infection with HIV before detectable antibodies develop is the “window period.”<sup>43</sup> 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.<sup>44</sup> In 2013, the FDA approved the first rapid antigen-antibody test, the first test also to distinguish between acute and established HIV-1 infection.<sup>45</sup> Tests for antigen allow for earlier detection of HIV because they can detect the virus before the body has mounted a response, although there will still be a window period of approximately two weeks after initial infection during which no test can detect the virus. RNA, or nucleic acid tests, which detect the virus itself in the blood, are also available, but not routinely used for screening. The test may be used in cases where there has been a high-risk exposure to HIV and as a follow-up test to a positive antibody test.<sup>46</sup>

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; via urination); where the test is done (laboratory; point-of-care site; at home); and how quickly results are available (conventional or rapid).<sup>47,48</sup> 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:**<sup>49</sup> 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.<sup>50</sup>
- **Urine Test:** Urine sample collected by health care provider; tested at lab. *Calypste* is the only FDA-approved HIV urine test. Results: a few days to two weeks.

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<sup>1</sup> CDC, *MMWR* 55(RR14); September 2006.

<sup>2</sup> CDC, *MMWR* 52(15); April 2003.

<sup>3</sup> CDC, *MMWR* 55(RR14); September 2006; CDC, *MMWR* 52(15); April 2003.

<sup>4</sup> U.S. Department of Health and Human Services, *Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents*; updated July 2016.

<sup>5</sup> AIDSinfo, *Statement by the HHS Panel on Antiretroviral Guidelines for Adults and Adolescents Regarding Results from the START and TEMPRANO Trials*.

<sup>6</sup> AIDS.gov, “[The Affordable Care Act and HIV/AIDS](#).”

<sup>7</sup> U.S. Preventive Services Task Force, “[Human Immunodeficiency Virus \(HIV\): Screening](#),” April 2013.

<sup>8</sup> Centers for Medicare & Medicaid Services, “[Decision Memo for Screening for the Human Immunodeficiency Virus \(HIV\) Infection \(CAG-00409R\)](#),” April 2015.

<sup>9</sup> KFF, [Global HIV/AIDS Timeline](#).

<sup>10</sup> CDC, *MMWR* 55(RR14); September 2006.

<sup>11</sup> WHO/UNAIDS Press Release, “[WHO and UNAIDS issue new guidance on HIV testing and counselling in health facilities](#),” May 2007.

<sup>12</sup> FDA Consumer Information, “[Fourth Generation HIV Diagnostic Test Approved, permitting earlier detection of infection](#),” June 2010.

<sup>13</sup> FDA Approval Letter, [July 3, 2012 Approval Letter, OraQuick In-Home HIV Test](#).

<sup>14</sup> U.S. Preventive Services Task Force, “[Human Immunodeficiency Virus \(HIV\): Screening](#),” April 2013.

<sup>15</sup> FDA Consumer Information, “[First rapid diagnostic test to detect both HIV-1 antigen and HIV-1/2 antibodies approved](#).”

<sup>16</sup> Centers for Medicare & Medicaid Services, “[Decision Memo for Screening for the Human Immunodeficiency Virus \(HIV\) Infection \(CAG-00409R\)](#),” April 2015.

<sup>17</sup> CDC, *MMWR* 55(RR14); September 2006.

<sup>18</sup> CDC, [HIV Basics: Testing](#).

<sup>19</sup> CDC, *MMWR* 55(RR14); September 2006.

<sup>20</sup> CDC, *MMWR* 55(RR14); September 2006.

<sup>21</sup> CDC, *MMWR* 55(RR14); September 2006.

<sup>22</sup> FDA, “[Keeping Blood Transfusions Safe: FDA's Multi-layered Protections for Donated Blood](#),” Publication No. FS 02-1; February 2002.

<sup>23</sup> U.S. Department of Defense, Instruction Number 6485.01; October 2006.

<sup>24</sup> U.S. Federal Bureau of Prisons, *Legal Resource Guide to the Federal Bureau of Prisons*; November 2008.

<sup>25</sup> U.S. Department of Justice, Bureau of Justice Statistics, *HIV in Prisons, 2007-2008*; December 2009.

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- <sup>26</sup> KFF/NASTAD, *The National HIV Prevention Inventory*; July 2009.
- <sup>27</sup> CDC, “[Final Rule Removing HIV Infection from U.S. Immigration Screening](#).”
- <sup>28</sup> U.S. Preventive Services Task Force, “[Human Immunodeficiency Virus \(HIV\): Screening](#),” April 2013.
- <sup>29</sup> KFF, [Preventive Services Covered by Private Health Plans under the Affordable Care Act](#); June 2015.
- <sup>30</sup> Each state Medicaid program determines its own definition of medical necessity, although it generally refers to procedures recommended by a physician. In the case of HIV, for example, HIV testing is clinically indicated based on a patient’s risk factors and/or signs of HIV infection.
- <sup>31</sup> KFF, [State Medicaid Coverage of Routine HIV Screening](#); February 2014.
- <sup>32</sup> Centers for Medicare & Medicaid Services, “[Decision Memo for Screening for the Human Immunodeficiency Virus \(HIV\) Infection \(CAG-00409R\)](#),” April 2015.
- <sup>33</sup> Centers for Medicare & Medicaid Services, “[Decision Memo for Screening for the Human Immunodeficiency Virus \(HIV\) Infection \(CAG-00409R\)](#),” April 2015.
- <sup>34</sup> KFF, [Kaiser Health Tracking Poll: July 2014](#); August 2014. “Don’t know” responses not shown; totals may not equal 100% due to rounding.
- <sup>35</sup> KFF, [Kaiser Health Tracking Poll: July 2014](#); August 2014. “Don’t know” responses not shown; totals may not equal 100% due to rounding.
- <sup>36</sup> CDC, [Behavior Risk Factor Surveillance System](#).
- <sup>37</sup> CDC, [National Health Interview Surveys](#).
- <sup>38</sup> CDC, [MMWR 65\(6\)](#); June 2016.
- <sup>39</sup> KFF, [HIV/AIDS In The Lives Of Gay And Bisexual Men In The United States](#); September 2014.
- <sup>40</sup> CDC, [HIV in the United States: At a Glance](#); updated June 2017.
- <sup>41</sup> CDC, [CDC-Funded HIV Testing, United States, Puerto Rico, and the U.S. Virgin Islands, 2014](#).
- <sup>42</sup> CDC, [CDC-Funded HIV Testing, United States, Puerto Rico, and the U.S. Virgin Islands, 2014](#).
- <sup>43</sup> CDC, [HIV Basics: Testing](#).
- <sup>44</sup> FDA Consumer Information, “[Fourth Generation HIV Diagnostic Test Approved, permitting earlier detection of infection](#),” June 2010.
- <sup>45</sup> FDA Consumer Information, “[First rapid diagnostic test to detect both HIV-1 antigen and HIV-1/2 antibodies approved](#).”
- <sup>46</sup> CDC, [HIV Basics: Testing](#).
- <sup>47</sup> Jeffrey L. Greenwald et al., “A Rapid Review of Rapid HIV Antibody Tests,” *Clinical Infectious Diseases* 8(2); March 2006.
- <sup>48</sup> FDA, [Complete List of Donor Screening Assays for Infectious Agents and HIV Diagnostic Assays](#).
- <sup>49</sup> Jeffrey L. Greenwald et al., “A Rapid Review of Rapid HIV Antibody Tests,” *Clinical Infectious Diseases* 8(2); March 2006. FDA, [Complete List of Donor Screening Assays for Infectious Agents and HIV Diagnostic Assays](#).
- <sup>50</sup> FDA Approval Letter, [July 3, 2012 Approval Letter, OraQuick In-Home HIV Test](#).