

# Testing and Counseling Section

The CDC believes that many people in the U.S. have HIV but have not been tested for it. These people do not know they are infected and that they need medical care. Also, they can unknowingly pass HIV infection on to others.

Some people do not find out that they are infected with HIV until they get sick or show symptoms and go to a clinic or hospital and get a test to find out their HIV status. Since most people don't have symptoms for years they do not find out their status until later in the disease progression. By the time they find out they are infected, they have missed opportunities to take care of their health and avoid passing the infection on to others.

It is important for anyone at risk of HIV infection to get tested. Those who are uninfected can learn to take steps to avoid infection and those who are infected can take steps to take care of their own health as well as to avoid passing the infection on to others.

## **HIV Testing: HIV Antibody Tests**

The first HIV antibody test was available in 1985. Since then, new HIV antibody tests have been developed and approved by the Food and Drug Administration (FDA). Currently, these antibody tests have a two step process of a **screening test** and, when the screening test is reactive, a **confirmatory test**.

### **Step 1: Screening Test**

The first test done on a specimen is a screening test called an Enzyme Linked Immunosorbent Assay ("EIA" or "ELISA"). This type of test screens for the presence of antibodies to HIV in blood, urine, or oral fluid. Screening tests are inexpensive tests that are highly accurate.

Most HIV antibody screening tests are "conventional" screening tests in that the specimen is collected from the client and sent to a laboratory for testing. If a screening test is negative (no antibodies detected), the results can be given to the client. If the screening test is reactive at the laboratory, the additional confirmatory Western Blot is conducted on the same sample.

Rapid tests are also screening tests. However; rapid screening test are conducted at the test site, often with the client present, and negative results are available in under an hour.

"Reactive" (antibodies detected) results from a rapid test must be confirmed by an additional test. This is because there is a small chance that an HIV screening test may detect proteins related to other autoimmune diseases and "react" to these proteins with a "positive" result.

## **Step 2: Confirmatory Testing**

If a rapid test is reactive, an additional specimen must be drawn from the client and sent to the lab for confirmatory Western Blot testing.

It is possible for someone who is *not* infected with HIV to test “reactive” on a screening test because the test detected something other than HIV. For this reason, it is critical that reactive screening tests are verified with a confirmatory test and that clients are *not* told they are infected with HIV *unless* the confirmatory test verifies that HIV antibodies are present.

## **Step 2: Confirmatory Testing, continued**

When a person has a reactive (positive) screening test, a confirmatory test called the Western Blot is done to verify the presence of HIV antibodies. The HIV Western Blot detects antibodies to individual proteins that make up HIV. This test is much more specific and more costly than the EIA screening test.

## **Different Antibody Testing Specimen Options**

HIV antibody tests are designed to detect HIV antibodies in blood, urine, or oral fluid (oral mucosa transudate) samples.

### **Blood**

The most frequently used HIV antibody test is a blood-based test. This test detects HIV antibodies in blood. Depending on test type, blood from a venipuncture or fingerstick will be used. This is the test that is used most often in public health clinics and doctor offices. Most rapid screening tests use fingerstick blood.

As with all screening tests, “reactive” blood fluid screening tests must be confirmed with a Western Blot test. For most HIV testing, this confirmatory testing is done on the same sample in the laboratory. For reactive rapid tests, an additional sample needs to be drawn and sent to the lab for the confirmatory Western Blot.

### **Oral Fluid**

This test detects HIV antibodies in the mucous membrane (oral mucosal transudate) of the mouth. The oral test kit uses a special collection device that looks like a toothbrush. No needles are used. There are some rapid tests that use oral fluids. Many public health clinics also offer oral fluid testing. Some provide rapid oral fluid testing. As with all screening tests, positive oral fluid screening tests must be confirmed with a Western Blot test.

It is important to note that although antibodies to HIV can be found in saliva and oral fluids, these fluids do not contain sufficient amount of the virus to be infectious and therefore, are not considered a risk for transmitting the virus.

The **virus** is the **disease**. The virus causes infection. **Antibodies** are the immune system's **response to the disease**. Antibodies do not cause disease, they fight the infection.

### **Different Antibody Testing Specimen Options, continued**

#### **Urine**

A urine-based test for HIV antibodies is available for use only in physician's offices or medical clinics. It tests for HIV antibodies in the urine. It is important to note that, even though antibodies to HIV can be found in urine, urine is not considered a risk for transmitting the virus.

As with all screening tests, positive urine HIV screening test must be confirmed with a Western Blot test, which can be done on the same specimen.

### **Rapid HIV test**

The rapid HIV test is a screening test that can provide results in less than an hour. Rapid testing can be conducted on either blood and/or oral mucosal transudate, depending on the type of rapid test.

As with all screening tests, any "reactive" positive rapid test must be confirmed with a conventional Western Blot test.

### **Home HIV test kits**

Currently, the only licensed and FDA-approved test kit for home HIV antibody testing is the "Home Access HIV-1 Test System" manufactured by Home Access Health Corporation. If you are unsure if an HIV test is FDA approved, you can always look for the test on the list of FDA approved HIV tests (<http://www.fda.gov/cber/products/testkits.htm>).

The test requires a few drops of blood, which is mailed to the company in a safe mailer. If the screening test is reactive, a confirmatory Western Blot test is done by the same laboratory so that final results are available to clients. The client calls the company to learn their results over the phone.

### **Internet test kits**

Although other "home test" kits may be ordered over the internet, they may not be approved by the FDA. They are not guaranteed to be accurate. It is not recommended to use any test which has not been approved by the FDA.

### **Other HIV Tests**

#### **p24 antigen test**

This blood test measures a core protein of HIV. This protein occurs during primary infection (the first few weeks of infection) but may disappear as soon as antibodies to the virus are present. Because of this, and because of the expense of the test, p24 antigen tests are currently only available in specific circumstances.

#### **Plasma HIV RNA or proviral DNA tests**

These blood tests may be run on people with suspected new HIV infection. They are expensive and not used as screening tests for the general public. However, anyone who has had a potential exposure to HIV through unprotected sex or sharing needles, and who presents with symptoms of primary infection (usually seen within the first two weeks of infection with HIV) should ask their medical practitioner if this test is advisable. Primary infection is discussed later in this manual on page 49.

#### **HIV viral load test**

This test measures the amount of HIV in an infected person's bloodstream. It is rarely used to diagnose HIV infection. It is most often used in individuals who are HIV-positive to measure the effectiveness of antiretroviral medications used to treat HIV infection.

## **How and where to get tested for HIV**

### **Who should be tested?**

Anyone who has put themselves at risk through anal, vaginal or oral sex, or shared needles, and anyone who has had an occupational exposure may benefit from HIV testing. Many people may have partners who have risk factors, and these people (along with their partners) should consider testing. For occupational exposure, refer to your employer protocol or to the Infection Control section of this manual starting on page 6 for more information.

### **Where to test for HIV?**

People may get an HIV test at public health departments,

through their medical provider, family planning or sexually transmitted disease clinics, and in some cases at community clinics. Call the Washington State HIV/AIDS hotline at 1-800-272-2437 for a referral to a public health, family planning or community clinic in your county.

### **Confidential testing**

With confidential HIV testing, the client gives their real name, and the information about their testing is maintained in medical records. Their results are confidential. Results and testing information are not released to others except when medically necessary or under special circumstances including when they sign a release for the results to be given to another person or agency.

### **Confidential testing, continued**

HIV is a reportable condition. Confidential HIV results are reported to local public health officials. See page 72 in the legal section of this manual for more information.

### **Anonymous testing**

An anonymous HIV antibody test means that the client doesn't give their name and the person who orders or performs the test does not maintain a record of the name of the person they are testing.

If you want to know where to get tested anonymously, call the Washington State HIV/AIDS hotline at 1-800-272-2437 for information about anonymous testing in your area.

### **Informed consent required**

HIV testing can only be done with the person's consent. Consent may be contained within a comprehensive consent for medical treatment. It can be verbal or written, but must be specific to HIV and must be documented.

There are some rare exceptions where a person can be tested without their consent (including source testing relating to occupation exposures and legally-mandated situations specified in Washington State law). See the legal section of this curriculum, starting on page 72, for more information on mandatory testing.

### **Testing Information And Risk Assessment Required**

Except for the exceptions listed above, all people tested for HIV should be assessed for their risk of infection and, unless previously tested and declining information, they should be provided with appropriate information about the test including, but not limited to:

- The benefits of learning their HIV status and the potential

- dangers of the disease;
- How HIV is transmitted and way in which it can be prevented;
- Meaning of HIV test results and the importance of obtaining the results; and
- As appropriate, the availability of anonymous testing and the differences between anonymous and confidential testing.

## HIV Antibody Test Results

### The "window period"

It is important to remember that HIV antibody testing has a "window period". The window period is the time between infection with the virus and when the HIV-infected person develops enough antibodies to be detected by the antibody test. Until the infected person's immune system makes enough antibodies to be detected, the test will be negative even though the person is infected with HIV.

Some infected people are able to produce antibodies as early as two weeks after infection. Almost everyone will develop enough antibodies to be detected by 12 weeks after infection.

Unfortunately, there is no way to know how long each infected person will take to develop antibodies. However, virtually everyone who is infected will produce enough antibodies for detection by 12 weeks (three months). Therefore, to be sure people should test three months after the last potential HIV exposure.

Because people who are newly infected have so few antibodies to fight HIV, the virus can grow and multiply unchecked. During this time, they can have a large amount of virus in their blood making them highly infectious for HIV. Therefore, during the window period it is possible for an infected person to test negative (before they develop antibodies) but still be able to infect another person.

### Negative Results

If the test result is negative, it means one of two things:

- Either the person is *not infected* with the virus, or
- The person *became infected recently* and has not produced enough antibodies to be detected by the test.

If a person is concerned about a recent incident, they should test three months from the date of their last possible exposure. A negative test result does **not** mean a person is immune to HIV. If risky behavior continues, infection may occur.

## **Positive Results**

A positive confirmatory test indicates the presence of HIV antibodies:

- This person is infected with HIV;
- They can spread the virus to others through unsafe sexual practices, sharing contaminated injection equipment and/or breastfeeding; and
- The person is infected for life.

## **Indeterminate Results**

Occasionally, a Western Blot test result will come back with an "indeterminate" or "inconclusive" test result. If a person has recently engaged in behaviors that put them at risk for getting HIV, it could mean that they are newly- infected with HIV and are developing antibodies. This is called "sero-converting."

If sero-conversion is suspected, RNA testing can determine if the HIV virus is present. If RNA testing is not available, a second specimen should be gathered and tested with an antibody test. If sero-converting, this second test could show additional bands or give a positive result.

Indeterminate results are not always indicative of sero-conversion. These results can also be caused by cross reaction with other proteins from several sources including pregnancy, other autoimmune diseases, and recent influenza vaccinations.

For low risk people when sero-conversion is not suspected, re-testing should be conducted at one month and at three months from the last possible exposure to verify that they are not infected. Non-infection is indicated if the subsequent tests continue to be indeterminate (without additional HIV antibody protein bands) or are negative.

Indeterminate results for low risk clients are rare. It is possible for some uninfected people to always test indeterminate (due to the cross reaction from protein bands from something other than HIV). Other uninfected people who first test indeterminate may clear their bodies of those other proteins that are causing the cross-reaction and in subsequent tests, test negative. Still others go back and forth between indeterminate and negative.

Counseling messages should explain that only HIV positive tests indicate infection with HIV; and, that some people test indeterminate because of other (non-HIV) proteins in their bodies that register on the test. No further testing for other diseases is indicated.

### **Advantages of early testing for HIV infection**

New drug therapies for HIV infection can sustain an infected person's health for long periods of time. Early detection allows people with HIV the option to receive medical treatment sooner, take better care of their immune system, and stay healthier longer. Additionally, early detection of HIV allows people to take precautions not to infect others.

## **HIV Counseling with HIV Testing**

Washington State law (WAC 246-100-207 and -209) requires that HIV test counseling be offered to all clients who are at risk for HIV or who request counseling. At the same time, the law states that persons who refuse counseling should not be denied an HIV test (clients can refuse counseling); and, that the person conducting the HIV test does not have to provide the counseling themselves. They can refer the client to another person or agency for counseling (the person testing the client does not have to provide the counseling themselves).

The person who provides HIV test counseling to clients should direct the counseling towards increasing the client's understanding of their own risk of acquiring or transmitting HIV; motivating the client to reduce their risk; and assisting the client to build skills to reduce their risk.

### **Pre-test counseling**

Pre-test counseling should be based on the Federal Centers for Disease Control and Prevention's (CDC) Revised Guidelines for HIV Counseling, Testing and Referral recommendations (<http://www.cdc.gov/hiv/topics/testing/index.htm#guidelines>) ; and should:

- Assist the individual to set realistic behavior-change goals and establish strategies for reducing their risk of acquiring or transmitting HIV;
- Provide appropriate risk reduction skills-building opportunities to support their behavior change goals
- Provide or refer for other appropriate prevention, support or medical services.

### **Post-test counseling**

Everyone who tests negative should be offered an individual counseling session at the time they receive their test results. This counseling can be provided by the person providing the results or can be a referral for the client to receive these services at another

agency. This post-test counseling should accomplish the same goals as pre-test counseling: assist the client to set behavior change goals, establish strategies to achieve these goals, provide skills-building to support achieving these goals and provide appropriate referrals.

For those clients who test positive, counseling can't just be offered, it must be provided or referred and (in addition to what is provided to negative clients) must also include:

### **Post-test counseling, continued**

- If confidentially tested, the information that HIV is a reportable condition;
- Either the provision of partner notification support or referral to public health for these services;
- Appropriate referrals for alcohol and drug and mental health counseling, medical evaluation, TB screening, and HIV prevention and other support services.

### **Testing Confidentiality**

Information about a person's HIV test and results is confidential information and must not be shared with others. People who perform HIV counseling and testing in public health departments or health districts must sign strict confidentiality agreements. These agreements regulate the personal information that may be revealed in counseling and testing sessions, and test results.

HIV test results are kept in locked files, with only a few appropriate staff members having access to them. More information on confidentiality requirements can be found in the Legal section of this curriculum starting on page 72.

### **HIV Testing: Pregnancy**

Health care providers caring for pregnant clients are required by Washington State law to ensure HIV counseling and testing for each pregnant woman who is seeking prenatal care (RCW 70.24.095 and WAC 246-100-208).

All pregnant women are to be offered an HIV test and should be tested unless they refuse the HIV test. Those who refuse HIV testing must sign a form saying that they "opt-out" of the HIV test.

HIV-infected women can reduce the chance of transmitting the virus to their children if they take AZT during pregnancy and delivery. See the Transmission and Infection Control section of

this manual starting on page 6 for more information.

## **HIV Testing: Sexual Assault**

Sexual assault is prevalent in the U.S. More than 300,000 women and almost 93,000 men are raped annually, according to the National Violence Against Women Survey (NVAWS). Based on existing crime report data, an estimated 40% of female rape victims are under age 18; and most sexual assault victims know their assailant. Men are also victims of sexual assault; however they are much less likely to report being assaulted so data and reporting are not accurate. Apart from the emotional and physical trauma that accompanies sexual assault, many victims are concerned about HIV.

## **HIV Testing: Sexual Assault, continued**

### **Sexual Assault HIV Risks**

According to CDC, the odds of HIV infection from a sexual assault in the U.S. are 2 in 1,000. This is a low risk.

Unfortunately, the fear of HIV, even though it is a low risk, adds an additional emotional burden to many people who have been a victim of sexual assault.

### **HIV Testing**

HIV is a low risk from sexual assault. However; because so many assault victims are concerned about HIV, it can help the healing process to have an HIV test. Almost all HIV tests will be negative and be a relief to the victim. For those very few that are positive, the individual will need that information both for health reasons and for criminal court cases.

### **Assault and the Window Period**

Bear in mind that the window period for HIV antibody testing must be taken in to account when testing after an assault. Any test shortly after the assault will only show the baseline status of the victim. If the victim is negative, this first early test will provide proof that the victim was negative at the time of the assault. This can be helpful in the rare cases that a victim is infected with HIV through an assault as it can be used as evidence in criminal cases.

In order to verify that the victim was not infected by the assault it will be necessary to test again after the window period. If this test is negative it will indicate that the individual was uninfected at the time of the assault. If positive, this test will indicate that the victim was infected by the assault (if no other behaviors the victim engaged in could have infected the victim).

### **Other Testing**

When counseling victims about the risk of HIV from assault, remember that the risk is low and that there other higher risks victims should consider: contracting other STDs and, if the victim is female, becoming pregnant.

### **HIV Testing: Sexual Assault, continued**

The risk of STDs and pregnancy are much higher than HIV. Victims of sexual assault should get testing for STDs, and if female, she should take emergency contraception. The emergency contraception hotline number (1-888-668-2528) should be provided by “telephone” rape counselors or other counselors. Most experts recommend that a sexual assault victim go directly to the nearest hospital emergency room, without changing their clothing, bathing or showering first. Trained staff in the emergency room will counsel the victim, and may also offer testing or referral for HIV, STDs, and pregnancy. It is common practice for the emergency room physician to take DNA samples of blood or semen from the vagina, rectum, etc. which can be used as evidence against the attacker. Some emergency departments may refer sexual assault survivors to the local health jurisdiction for HIV testing.

Many people feel that the emergency room setting is a profoundly unpleasant time to question a sexual assault victim regarding her/his sexual risks, etc. However, testing shortly after a sexual assault will provide baseline information on her/his status for the various infections. This information can be useful for the victim and health care provider, especially for follow-up care and treatment. Additionally, baseline information can be used for legal and criminal action against the assailant. All testing to be used for baseline information and legal action should be done confidentially.

### **Assailant Testing**

In Washington State, only the victims of convicted sexual offenders may learn the attacker's HIV status. The victim needs to consider whether to start post-exposure prophylaxis (PEP) independently of the source's test result, because the time between the attack and the conviction will likely be longer than the 24-48 hours recommended to start PEP. More information about PEP is available on page 28.

### **Partner notification**

Partner notification is a voluntary service provided to HIV-positive people and their sex and/or injection equipment-sharing partners. This service is provided using a variety of strategies to

maintain the confidentiality of both the HIV-infected client and the partners.

HIV-infected people are counseled about the importance of their partners being notified of exposure to HIV and offered an HIV test. Clients can notify their partners themselves or have public health staff notify their partners. When public health staff notify partners, they notify them of their exposure, provide counseling and information, and offer HIV testing without informing the partner who tested positive.

**Partner notification,  
continued**

Partner notification is a critical tool to inform partners who of their exposure so that they can test for HIV. If uninfected, they can take steps to ensure that they do not become infected. If infected, they can take steps to take care of their health and ensure that they do not pass the virus on to others.

**Reporting  
requirements**

HIV and AIDS are both reportable conditions in Washington State. See the Legal section of this curriculum starting on page 72 for more information on this topic.