

The Basics of HIV Screening and Testing

INTRODUCTION

It is estimated that 1 to 1.2 million people are living with HIV/AIDS in the United States. As many as 25% of these people, or approximately 300,000, are unaware they have HIV infection. It is important to identify these individuals because they may be unknowingly transmitting HIV. Studies have shown that once individuals learn about their HIV infection, they substantially reduce their high-risk sexual behaviors. The transmission rate among those who do not know they are infected is 3.5 times higher than for people who know about their HIV infection.

There are at least 56,300 new infections every year in the U.S., and this number has not changed for the last 10 years. Many of these individuals have advanced disease at the time of their first positive HIV test. It is estimated that 50% of patients develop AIDS within one year of first testing positive for HIV. Early recognition of HIV infection is important because antiretroviral therapy has been shown to improve morbidity and mortality.

Traditionally, screening for HIV has been targeted to high-risk individuals and required separate, written consent (“opt-in” testing), along with pre- and post-test counseling, by trained personnel. In the 1990’s, an “opt-out” approach was adopted for pregnant women, meaning HIV tests were performed as a routine component of prenatal care and did not require separate written consent or extensive pre-test counseling. Subsequently, rates of screening increased and neonatal infections declined substantially. Based on the success of opt-out HIV testing of pregnant women, and the need to decrease the number of new infections per year in the U.S., in September 2006 the Centers for Disease Control and Prevention (CDC) recommended **routine HIV screening for all individuals between the ages of 13-64 years, in all health care settings, on an opt-out basis.**

SUMMARY OF CDC RECOMMENDATIONS

CDC recommends that opt-out HIV screening be a part of routine clinical care in all health care settings, *while also preserving the patient's option to decline HIV testing* and ensuring a provider-patient relationship conducive to optimal care.

Initial Screening for HIV Infection

In all health care settings, screening for HIV infection should be performed routinely for:

- ☑ **All patients aged 13-64 years.** Health care providers should initiate screening for HIV unless prevalence of undiagnosed HIV infection in their patients has been documented to be <0.1% (<1 per 1,000 patients). In the absence of existing data for HIV prevalence, health care providers should initiate voluntary HIV screening until they establish that the diagnostic yield is <0.1%, at which point such screening is no longer warranted.
- ☑ **All patients initiating treatment for tuberculosis (TB).**
- ☑ **All patients seeking treatment for sexually transmitted diseases (STDs),** including all patients attending STD clinics. An HIV test should be done during each visit for a new complaint, regardless of whether the patient is known or suspected of having specific risk factors.
- ☑ **All pregnant women.**

Repeat Screening

Health care providers should perform repeat screening for:

- ☑ **All persons likely to be at high risk for HIV.** High risk individuals should be tested annually and include injection drug users and their sex partners, persons who exchange sex for money or drugs, sex partners of HIV-infected persons, and men having sex with men (MSM) or heterosexual persons who themselves or whose sex partners have had more than one sex partner since their most recent HIV test.
- ☑ Any patient and their prospective sex partner **before initiating a new relationship.**
- ☑ A **high risk pregnant patient who is in the third trimester.**
- ☑ Any person whose blood or potentially infectious body fluid is the source of an **occupational exposure to a health care provider.**

Consent and Pretest Information

Consent for HIV screening should be incorporated into the patient's general informed consent for medical care on the same basis as are other screening or diagnostic tests. A separate consent form for HIV testing is NOT recommended.

HIV screening should be voluntary and undertaken only with the patient's knowledge and understanding that an HIV test is planned. Before the test is performed, information explaining HIV infection and the meaning of a positive and negative test should be provided either orally or in writing in a language the patient can understand. Patients should be offered an opportunity to ask questions and decline testing. **If a patient declines an HIV test, this decision should be documented in the medical record.**

TYPES OF HIV DIAGNOSTIC TESTS

There are two types of testing required: a screening test and a confirmatory test.

Screening Tests: Conventional and Rapid

Conventional Tests

ELISA antibody test: looks for antibodies to HIV in the patient's blood. A patient's serum is placed in contact with particles of HIV in the presence of an indicating substance. If there are any HIV antibodies in the serum, they will bind to the HIV particles and cause the serum to change color. **If the ELISA test is positive, the laboratory automatically will perform a confirmatory test.** This test is considered the standard test for diagnosing infection with HIV.

Rapid Tests

Rapid tests are similar to the standard ELISA test in that they look for antibodies to HIV in the patient's blood. They are called "rapid" because the results are available within an hour or less. **If a rapid test is positive, it MUST be followed up with a confirmatory test.**

The six FDA-approved rapid HIV antibody screening tests currently on the market are listed below:

FDA-Approved Rapid HIV Tests

Test Name & Manufacturer	Specimen(s) to be tested	CLIA-waived specimens	Time to complete
OraQuick ADVANCE HIV 1/2 OraSure Technologies, Inc. www.orasure.com	Whole blood, saliva, serum/plasma	Whole blood and saliva	25-30 minutes
Reveal G-3 HIV-1 MedMira, Inc. www.medmira.com	Serum/plasma	None	30-60 minutes
Uni-Gold Recombigen Trinity Biotech www.unigoldhiv.com	Whole blood, serum/plasma	Whole blood	10-15 minutes
MultiSpot HIV1/HIV2 BioRad Laboratories www.biorad.com	Serum/plasma	None	10-15 minutes
Clearview 1/2 Stat-Pak and Clearview Complete HIV 1/2 Inverness Medical Professional Diagnostics www.invernessmedicalpd.com	Whole blood, serum/plasma	Whole blood, serum, plasma	20 minutes

All of the tests listed in the table detect HIV-1; all tests detect HIV-2 except Uni-Gold and Reveal G-3. The sensitivity and specificity for these tests is in the range of 98.4-100%.

Confirmatory Tests

Western blot (WB): This is the most widely used confirmatory test. It uses an electrophoretic technique that separates out specific HIV particles, or antigens. Rarely, the WB will be indeterminate if the patient was recently (i.e. within the last 3 months) exposed to HIV.

Immunofluorescence antibody (IFA): Infected HIV cells are fixed to a microscope slide. Serum with HIV antibodies is added and allowed to react with the HIV. A fluorescent label will light up the slide if positive for HIV.

Conventional Versus Rapid Testing

Conventional HIV tests utilize the ELISA and WB or IFA to confirm a diagnosis of HIV infection. These tests can take up to a week to complete, and many patients do not return to obtain the results. Studies have shown that from 12-31% do not return to receive their results.

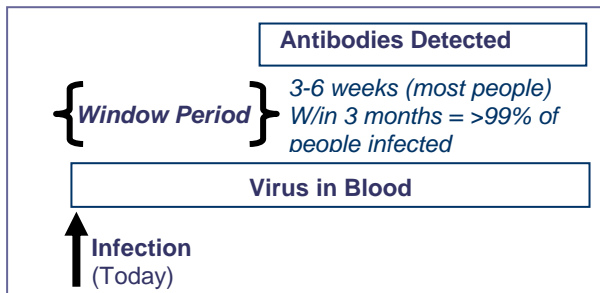
With rapid HIV testing, patients can receive their results during the same visit. Preliminary studies have shown a higher return for their confirmatory test results when they get an initial positive rapid test result.

How Should Rapid HIV Test Results Be Interpreted?

A positive HIV rapid test usually means the patient most likely is HIV positive. The *positive predictive value* of a single positive HIV rapid test, defined as the likelihood that a positive test means a person truly does have the disease, depends on the specificity of the test and the HIV prevalence in the community. *In other words, if the rapid HIV test result is positive, the likelihood that a patient is truly infected with HIV depends on how common HIV is in the community.* In a population with a high HIV prevalence, a positive rapid test result is likely to be a true positive, but in a population with a low HIV prevalence, that result may be a false positive. **Therefore any positive rapid test MUST be followed with a confirmatory test.**

The *negative predictive value* of a negative rapid test, defined as the likelihood that a negative test means a person truly does **not** have the disease, is close to 100%. This means that **a patient who receives a negative rapid HIV test result is almost assuredly not infected, barring recent exposures** (risky sexual contact or needle-sharing with an infected person within 3 months). A patient with a history of recent HIV risk behaviors or possible exposures should have a repeat

rapid HIV test because it may take up to 3-6 months for HIV antibodies to be detectable after infection with HIV. **Testing during this “window period”** (see diagram, below) **may result in a false negative test or indeterminate test result.**



DIAGNOSIS OF AN HIV POSITIVE INDIVIDUAL

A positive ELISA or a positive rapid HIV antibody test followed by a positive confirmatory test means the patient has HIV.

What Patients Should Be Told

For all tests:

- Knowing you have HIV infection can improve your prognosis with treatment.
- Knowing you have HIV infection can help you take precautions from passing HIV to others.
- Refusing an HIV test will not affect the care you receive.
- Test results are kept confidential. However, in certain states (including California), if a confirmatory test is positive, the law requires that the results be reported to the health department.
- A negative test means you do not have HIV infection; however the test may not show recent infection within the past 3 months.
- A negative test in patients recently exposed to HIV should prompt repeat screening in 3-6 months.
- If the test is positive, there are medications that help people live long, health lives.

For rapid tests:

- Results from rapid HIV tests are available at the same visit, usually in less than 1 hour.
- Results are very accurate – as accurate as the standard HIV test.
- If the rapid test is positive, a confirmatory test is always done to be sure the rapid test was accurate. It is important that you come back for the results of the confirmatory test. If the confirmatory test is negative, you do not have HIV infection unless you were recently exposed (i.e. within the past 3 months).

LEGAL ISSUES

While the CDC has recommended universal testing for all persons aged 13-64, laws regarding HIV testing continue to vary from state to state. Therefore, health care providers need to familiarize themselves with the current laws of their state and stay abreast of any changes which are likely to come about because of the new recommendations. Areas where state laws may differ include verbal versus written consent, opt-out testing, and pre-test and post-test counseling. The National HIV/AIDS Clinicians' Consultation Center (NCCC) provides a national **State HIV Testing Laws Compendium**, describing key HIV testing laws and policies for each state, online at:

<http://www.ucsf.edu/hivcntr/StateLaws/Index.html>

HIV Testing In California

In California, the laws around written consent for HIV testing have changed to support routine testing. The HIV/AIDS Testing Bill, Assembly Bill 682, took effect January 2008. This legislation essentially supports the CDC recommendations in making HIV screening a routine part of medical care. Specifically, it repeals the need for written informed consent to perform HIV testing. It also states that a patient has the right to decline the test and if he/she does so, it should be noted in the medical chart. There are still provisions in the law for maintaining and safeguarding patient confidentiality. **Anonymous testing is also still available in California.**

DEFINITIONS

CLIA-waived: simple laboratory examinations and procedures that are cleared by the Food and Drug Administration (FDA) for use outside of an approved laboratory.

Diagnostic testing: performing an HIV diagnostic test based on the presence of clinical signs or symptoms.

Health care settings: hospital emergency departments (EDs), urgent-care clinics, inpatient services, STD clinics or other venues offering clinical STD services, tuberculosis (TB) clinics, substance abuse treatment clinics, other public health clinics, community clinics, correctional health-care facilities, and primary care settings.

HIV prevention counseling: an interactive process to assess risk, recognize risky behaviors, and develop a plan to take steps that will reduce risks for acquiring (or transmitting) HIV infection.

Indeterminate test results: the Western Blot test is unclear and requires repeat testing with a new blood sample, usually several weeks later. This may occur if

the person is tested during the window period; has an auto-immune disorder; or has had multiple pregnancies.

Informed consent: a process of communication between patient and provider, through which the patient participates in choosing whether or not to undergo HIV testing. Typically, it includes providing oral or written information about HIV, the risks and benefits of testing, the implications of HIV test results, how test results will be communicated, and the opportunity to ask questions.

Negative predictive value: the likelihood that a negative test means a person truly does not have the disease being tested

Opt-in screening: performing an HIV diagnostic test on patients only after risk is assessed, patient provides explicit consent (usually written), and pre- and post-test counseling is administered

Opt-out screening: performing an HIV diagnostic test after notifying the patient that the test will be done. An additional process for written consent or pre-test counseling is not required beyond what is usually performed for routine medical tests.

Positive predictive value: the likelihood that a positive test means a person truly does have the disease being tested

Prevalence: the proportion of individuals in a population having a disease.

Routine screening: performing an HIV diagnostic test for all persons in a defined population

Sensitivity: the proportion of persons with the disease who are correctly identified by a screening test.

Specificity: the proportion of persons without a disease who are correctly identified by a test.

Targeted testing: performing an HIV diagnostic test on persons at higher risk, defined on the basis of behavioral, clinical, or demographic characteristics. Targeting testing has been the main strategy for HIV testing until now.

Window period: the time it takes for a person to be HIV antibody positive after having been exposed to the virus. This usually occurs within 3 months of exposure.

**Contact your local Pacific AIDS
Education and Training Center:**
[http://familymedicine.medschool.
ucsf.edu/paetc/](http://familymedicine.medschool.ucsf.edu/paetc/)

References and Resources

Reference:

Centers for Disease Control and Prevention. Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings. MMWR 2006;55 (No. RR-14):1-17. Available online at:

<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm>

HIV Testing Information and Resources:

AETC National Resource Center

<http://www.aids-etc.org/>

Clinician training and reference materials developed by the AETC network

AIDSinfo

<http://aidsinfo.nih.gov>

Current, federally approved guidelines; health information for patients; resources for clinicians

AIDS InfoNet

<http://www.aidsinfonet.org/>

HIV/AIDS testing and treatment information provided in the form of single-topic fact sheets

CDC HIV Testing Topics

<http://www.cdc.gov/hiv/topics/testing/index.htm>

HIV testing information, fact sheets, tools and resources for health care providers

CDC National HIV Testing Resources

<http://www.hivtest.org/>

Where to find testing sites, frequently asked questions, and basic HIV/AIDS information

HIV Rapid Testing in Labor & Delivery Resources & References Manual

<http://www.sfaetc.ucsf.edu/RTLDR/RTLDRManual/index.html>

Sample policies, procedures and protocols

HIV Testing in Emergency Departments: A Practical Guide

<http://edhivtestguide.org/>

Practical guide developed by Health Research and Educational Trust (HRET)

State HIV Testing Laws Compendium

<http://www.ucsf.edu/hivcntr/StateLaws/Index.html>

Key HIV testing laws and policies listed by state

National HIV Telephone Consultation Service
(Warmline): 1-800-933-3413

National Clinicians' Post-Exposure Prophylaxis Hotline
(PEPLINE): 1-888-HIV-4911

Perinatal HIV Hotline:
1-888-448-8765

<http://www.nccc.ucsf.edu>