

Additional Resources:

- Clinicians are encouraged to review the complete recommendations at www.cdc.gov/hiv/topics/testing/healthcare
- Mountain Plains AIDS Education and Training Center: www.mpaetc.org
- AIDS InfoNet: www.aidsinfonet.org/
- AETC National Resource Center: www.aidsetc.org/
- National HIV/AIDS Clinicians' Consultation Center: www.ucsf.edu/hivcntr/
- CDC HIV Website with many information links: <http://www.cdc.gov/hiv/>
- HIV InSite: <http://hivinsite.ucsf.edu/InSite>
- National HIV Testing Resources: <http://www.hivtest.org/>



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HIV Testing Recommendations



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Recommendations are based on best practices and meant to comply with ethical principles of informed consent. Recommendations do not take into account state, local, or institutional regulations.

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CDC Recommendation for HIV Testing: Opt-out HIV screening and HIV diagnostic testing should be a part of routine clinical care in all healthcare settings.¹

- “Screening” means that all patients in a certain population are tested for a disease regardless of the presence of signs, symptoms, or risk factors. The CDC recommends that HIV screening be a routine part of healthcare for all individuals in any of the following circumstances:
 - › between the ages of 13 and 64 years of age²
 - › in care for tuberculosis (TB)
 - › in care for other sexually transmitted diseases (STDs)³
 - › women considering conception and pregnancy
 - › pregnant women⁴
 - › women in delivery with undocumented HIV status at the onset of labor⁵
 - › infants born to mothers with undocumented HIV status.⁶

- “Opt-out testing” means that a test will be performed unless the patient specifically declines to have the test. The CDC recommends that:
 - › Oral or written information should be provided at the time of the test. Information should be at an appropriate health literacy level for the patient and in the patient’s primary language. Information should include:
 - An explanation of HIV infection
 - A description of ways to prevent HIV transmission
 - The meaning of positive and negative test results
 - › HIV testing should be voluntary and free from coercion. No patient should be tested without prior knowledge that the test will be done. The patient should then be given the opportunity to ask questions and to decline testing.
 - If a patient – especially one who is pregnant – refuses testing, providers should elicit reasons for that decision (i.e., fear

¹Healthcare settings include emergency and urgent care sites, primary care settings, corrections health care, substance use treatment services, outpatient clinics, and inpatient services in all public and private sectors.
²Unless the prevalence of undiagnosed HIV in clinic patients has been documented at < 1/1000 (0.1 %); if prevalence rates are not known, voluntary HIV screening should be implemented.
³Should be screened at each visit for a new STD complaint.
⁴Should be screened as soon as possible during pregnancy. Repeat testing during the third trimester (preferably at < 36 weeks) may be considered for all pregnant women but is recommended for women who live in jurisdictions with elevated rates of HIV in women between the ages of 15 and 45, in women who receive care in facilities with 0.1 % HIV infection prevalence in pregnant women, in women with known high risk factors, or in women who have signs and symptoms of HIV.
⁵Rapid testing is recommended in these cases.
⁶The recommendations are not specific about parental consent, which in many cases is dictated by specific state law.

- of stigma, lack of perceived risk, concerns about partner/family reactions, fear of a positive test, etc.) and discuss those concerns with the patient.
 - The decision to opt out of testing should be documented in the patient record.
 - Patients who decline testing – especially those who are pregnant – should be offered the test at subsequent clinic visits.
- › General consent for medical care is sufficient for HIV testing; separate, written consent for an HIV test should not be required.
- “Diagnostic testing” is performed when a patient presents with the signs and symptoms of a specific disease. The CDC recommends that:
 - › Patients with signs and symptoms of HIV be tested as part of the diagnostic workup⁷
 - › Patients at high risk for HIV, based on risk assessment, be screened every year⁸

CDC Recommendations for Communicating HIV Test Results:

- A negative HIV test result can be conveyed without direct personal contact. Patients known to have recent or continuing high-risk behaviors should be encouraged to have periodic testing, and provided with (or referred to) prevention counseling services.
- A positive HIV test result should be communicated in a private setting with direct contact between the patient and clinician.
 - › Assure confidentiality. Family members should not be used as translators.
 - › Help the patient find appropriate resources for healthcare, counseling, prevention services, and mental health/substance use care.
 - › Discuss partner notification and offer services to help in that process.⁹

⁷Clinicians should be familiar with the many manifestations of acute and chronic HIV infection, which include not only opportunistic infections but nonspecific abnormalities such as weight loss, lymphadenopathy, hypoalbuminemia, anemia, increased rate of community acquired pneumonia, etc. See also, Orenstein, R. (2002). Presenting syndromes of human immunodeficiency virus. *Mayo Clinic Proceedings*, 77, 1097. Available at: <http://www.mayoclinicproceedings.com/inside.asp?AID=196&UID=>
⁸People considered to be at high risk for HIV include injection drug users (IDUs) and their sex partners, those who have sex with more than one person or whose sex partner has sex with more than one partner, people who exchange sex for drugs or money, and sex partners of individuals known to have HIV infection.
⁹Funding for HIV care is available for infected patients. Local health departments can help with patient referrals to care services. Remember: The privacy rule under HIPAA prohibits disclosure of a patient’s health information, including HIV status, without the patient’s permission, except as required by local public health law.

- HIV test results should be documented in the patient’s confidential medical record.
- CDC Recommendation about Counseling:** Prevention counseling should not be required as a part of the HIV testing or screening process. Testing may, however, create an ideal opportunity to discuss risk and to provide (or arrange for) prevention counseling.

Why provide routine screening for HIV infection?

- 25% of people living in the U.S. with HIV do not know they are infected.
- HIV is a serious health problem that can be reliably diagnosed prior to symptom development and patients are more likely to be tested if it is suggested by a clinician.
- Routine testing helps to de-stigmatize the disease.
- Early entry into care increases the likelihood of a longer, healthier life. Unfortunately, an estimated 39% of people with HIV in the U.S. are not diagnosed until they are in the late stages of the disease.
- Transmission rates are higher in people who do not know they have HIV. Individuals who know their positive HIV status are more likely to engage in risk reduction efforts.
- Appropriate treatment during pregnancy can reduce the perinatal transmission rate to < 2%. Pregnant women who know they are infected are better able to make critical decisions about care for themselves and their infants.

Practical Considerations

- CDC recommendations do not supersede local laws about HIV testing and reporting. Providers should be aware of current local laws and should also be aware that these laws may need to be changed in order to implement these recommendations.¹⁰
- CDC recommendations do not consider facility/institution rules about HIV testing. Providers should be aware of these regulations as well.
- Rapid Testing can substantially decrease the large number of individuals who do not learn their HIV test results.
 - › Rapid test analysis can be completed in 20-30 minutes and reported to patients before they leave the testing site.
 - › Although positive rapid test results can be immediately reported to the patient, they must be confirmed with a more specific laboratory test before a diagnosis of HIV is made. A blood sample should be drawn for the confirming test at the time of the initial

¹⁰See a compendium of state HIV testing laws at: www.ucsf.edu/hivcntr

- test and arrangements made for the patient to return for those results.
 - › A preliminary positive test can be frightening and care must be taken to provide support or counseling services to those who need it.¹¹
 - › The following table discusses FDA-approved rapid tests.

FDA-Approved Rapid HIV Antibody Screening Tests

Test (manufacturer, approval date)	Specimen Type	CLIA* Category	Sensitivity+ (95% CI)	Specificity+ (95% CI)
OraQuick Advance Rapid HIV-1/2 Antibody Test (OraSure Technologies, 2004)	Whole blood**	Waived	99.6% (98.5-99.9)	100% (99.7-100)
	Oral fluid	Waived	99.3% (98.4-99.7)	99.8% (99.6-99.9)
	Plasma	Moderate complexity	99.6% (98.9-99.8)	99.9% (99.6-99.9)
Uni-Gold Recombigen HIV (Trinity Biotech, 2003)	Whole blood**	Waived	100% (99.5-100)	99.7% (99.0-100)
	Serum/plasma	Moderate complexity	100% (99.5-100)	99.8% (99.3-100)
Reveal G-2 (MedMira, 2003)	Serum	Moderate complexity	99.8% (99.2-100)	99.1% (98.8-99.4)
	Plasma		99.8% (99.0-100)	98.6% (98.4-98.8)
MultiSpot HIV-1/HIV-2 (BioRad Laboratories, 2004)	Serum/plasma	Moderate complexity	100% (99.9-100)	99.9% (99.8-100)
	HIV-2		100% (99.7-100)	

Adapted from Health Research and Education Trust (HRET). FDA-Approved Rapid HIV Antibody Screening Tests, January 10, 2005. Accessed September 27, 2006, from: www.hret.org/hret/programs/hivtransmrpd.html
 * The Clinical Laboratory Improvement Amendments (CLIA) program categorizes tests as waived, moderate complexity, or high complexity. Tests approved as CLIA-waived tests may be done at the point of care after appropriate staff training and with procedures in place to insure quality control; results can be available in about 20 minutes. Other rapid tests are "non-waived" and must be performed in laboratories; results can be available in about an hour with available lab support.
 **finger stick or venipuncture
 + Sensitivity is the probability that the test will be reactive if the specimen is a true positive
 ± Specificity is the probability that the test result will be non-reactive test if the a true negative

¹¹See also, Greenwald, J.L., Burstein, G. R., Pincus, J., & Branson, B. (2006). A rapid review of rapid HIV antibody testing. *Current Infectious Diseases Report*, 8, 125-131. Available at: www.cdc.gov/hiv/topics/testing/resources/journal_article/pdf/rapid_review.pdf