

U.S. Centers for Disease Control Routine HIV Testing Recommendations compared to Current Illinois Laws and Regulations

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

Illinois AIDS Confidentiality Act:

<http://www.ilga.gov/legislation/ilcs/ilcs3.asp?ActID=1550&ChapAct=410%26nbsp%3BILCS%26nbsp%3B305%2F&ChapterID=35&ChapterName=PUBLIC+HEALTH&ActName=AIDS+Confidentiality+Act%2E>

Illinois HIV/AIDS Confidentiality and Testing Code: <http://ilga.gov/commission/jcar/admincode/077/07700697sections.html>

CDC definitions (from CDC guidelines)

Diagnostic testing. Performing an HIV test for persons with clinical signs or symptoms consistent with HIV infection.

Screening. Performing an HIV test for all persons in a defined population (12).

Targeted testing. Performing an HIV test for subpopulations of persons at higher risk, typically defined on the basis of behavior, clinical, or demographic characteristics (9).

Informed consent. A process of communication between patient and provider through which an informed patient can choose whether to undergo HIV testing or decline to do so. Elements of informed consent typically include providing oral or written information regarding 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.

Opt-out screening. Performing HIV screening after notifying the patient that 1) the test will be performed and 2) the patient may elect to decline or defer testing. Assent is inferred unless the patient declines testing.

HIV-prevention counseling. An interactive process of assessing risk, recognizing specific behaviors that increase the risk for acquiring or transmitting HIV, and developing a plan to take specific steps to reduce risks (13).

Illinois law (410 ILCS 305/):

"Written informed consent" means an agreement in writing executed by the subject of a test or the subject's legally authorized representative without undue inducement or any element of force, fraud, deceit, duress or other form of constraint or coercion, which entails at least the following:

- (1) a fair explanation of the test, including its purpose, potential uses, limitations and the meaning of its results; and
- (2) a fair explanation of the procedures to be followed, including the voluntary nature of the test, the right to withdraw consent to the testing process at any time, the right to anonymity to the extent provided by law with respect to participation in the test and disclosure of test results, and the right to confidential treatment of information identifying the subject of the test and the results of the test, to the extent provided by law.

Provision	CDC Recommendation	Illinois Law AIDS Confidentiality Act, (410 ILCS 305/)	Illinois Regulation (Chap. 77, Sec. 1, Subchapter K, Part 697)
Consent	Screening should be voluntary and undertaken only with patient's knowledge and understanding that HIV testing is planned. (7) Specific signed consent for HIV testing	Sec. 4. No person may order an HIV test without first receiving the written informed consent of the subject of the test or the subject's legally authorized representative.	Section 697.120 Written Informed Consent a) <i>No person may order an HIV test without first receiving the written, informed consent of the subject of the test or the subject's legally</i>

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	should not be required. General informed consent for medical care should be considered sufficient to encompass informed consent for HIV testing. (8)	(410 ILCS 305/4) (from Ch. 111 1/2, par. 7304) <i>Exceptions:</i> written informed consent not required for tissue or sperm donations, testing for exposure of a healthcare provider, EMT, firefighter or law enforcement officer; research; or if physician believes testing is medically indicated. (410 ILCS 305/7-8)	<i>authorized representative</i> , except as provided in subsection (b). (Section 4 of the AIDS Confidentiality Act) 1) This written informed consent and test results must be obtained by the physician ordering the test or by another physician involved in the patient's care. 2) The responsibility of obtaining written informed consent may not be delegated by the physician. However, the task of obtaining written informed consent from the patient may be delegated to another health care provider who is knowledgeable about HIV infection, including possible medical and psychosocial aspects of such infection.
Out-out screening	Patients should be informed orally or in writing that HIV testing will be performed unless they decline (opt-out screening).(7)	No provision since written consent required.	No provision since written consent is required.
Pre-test counseling	<ul style="list-style-type: none"> • Oral and written information should include an explanation of HIV infection and the meaning of positive and negative test results. The patient should be offered an opportunity to ask questions and to decline testing.(7) • Prevention counseling should not be required as a part of HIV screening programs in health-care settings. (8) Prevention counseling is strongly encouraged for persons at high risk for HIV in settings where risk behaviors are assessed 	<p>Sec. 5. No health care professional may order an HIV test without making available to the person tested information about the meaning of the test results, the availability of additional or confirmatory testing, if appropriate, and the availability of referrals for further information or counseling. (410 ILCS 305/5)</p> <p>Exceptions: research and if doctor believes testing is medically indicated.(410 ILCS 305/8)</p> <p>No requirement for prevention counseling</p>	<p>Section 697.110 HIV Pre-Test Information a) <i>No physician may order an HIV test without making available to the person tested pre-test information</i>, except as provided in subsection (b) below. The responsibility of providing pre-test information may not be delegated by the physician. However, the task of providing pre-test information to the patient may be delegated to another health care provider who is knowledgeable about HIV infection including possible medical and psychosocial aspects of such</p>

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	routinely.	in any setting	infection. The required pre-test information consists of the following information: 1) <i>About the meaning of the test results</i> (such as the purpose, potential uses, limitations of the test and test results, and the statutory rights to anonymous testing and to confidentiality), 2) <i>The availability of additional or confirmatory testing, if appropriate</i> (See Section 697.100(b)), and 3) <i>The availability of referrals for further information or counseling.</i> (Section 5 of the AIDS Confidentiality Act).
Consent form	...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. (8)	Written informed consent required; nothing prohibits a combined consent.	Written informed consent required; nothing prohibits a combined consent
Communicating negative test results	<ul style="list-style-type: none"> • HIV test results should be provided in the same manner as results of other diagnostic or screening tests. (8) • HIV-negative results may be conveyed without direct personal contact between the patient and the health-care provider. (10) 	<p>No provision.</p> <p>No requirement that HIV test results be conveyed in person (except, per regs, in HIV testing and counseling centers).</p> <p>No requirement for post-test counseling, except in HIV counseling and testing centers.</p>	<p><i>HIV counseling and testing centers only:</i> It shall be the duty of every person providing results of an HIV antibody test to provide the subject of the test with an explanation of the test results, methods for prevention of HIV transmission, and referrals for medical and psychological follow-up appropriate to the needs of the test subject. Section 697.300 (f)</p> <p><i>HIV counseling and testing centers only:</i> It shall be the duty of every person conducting an HIV test in an HIV Counseling and Testing Center to provide results of the test only to the individual upon whom the test was</p>

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			performed. Such results are to be provided only in an individual face-to-face interview. The test subject may elect to have other persons present during the interview. It shall be the duty of the person providing the counseling to determine that the presence of a second party during the interview is not the result of undue inducement such as any element of force, fraud, deceit or other constraint or coercion. Section 697.300 (h)
Communicating positive test results & linkages to care	<p>HIV positive test results should be communicated confidentially through personal contact by a clinician, nurse, mid-level practitioner, counselor, or other skilled staff.... Active efforts are essential to ensure that HIV-infected patients receive their positive test results and linkage to clinical care, counseling, support, and prevention services (10)</p> <p>HIV-infected persons should receive or be referred for clinical care promptly, consistent with USPHS guidelines for management of HIV-infected persons. (11)</p>	No requirements specified, except in HIV counseling and testing centers.	<i>HIV counseling and testing centers only:</i> It shall be the duty of every person providing results of an HIV antibody test to provide the subject of the test with an explanation of the test results, methods for prevention of HIV transmission, and referrals for medical and psychological follow-up appropriate to the needs of the test subject. These referrals shall include appropriate referrals to physicians who will provide services to HIV positive individuals; tuberculosis and sexually transmissible disease services facilities for psychological counseling; and crisis intervention and substance abuse treatment facilities, as available. Section 697.300 (f)
Referral to prevention counseling	<ul style="list-style-type: none"> Prevention counseling should not be required as a part of HIV screening programs in health-care settings. Prevention counseling is strongly encouraged for persons at high risk for HIV in settings in which risk behaviors are assessed routinely (e.g., STD clinics) but 	Prevention counseling not required except in HIV counseling and testing centers.	<i>HIV counseling and testing centers only:</i> It shall be the duty of every person providing results of an HIV antibody test to provide the subject of the test with an explanation of the test results, methods for prevention of HIV transmission, and referrals for medical and psychological follow-up appropriate to the needs of

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	<p>should not have to be linked to HIV testing. (8)</p> <ul style="list-style-type: none"> Persons at high risk should be advised of the need for repeat testing and offered prevention counseling or referral for prevention counseling.(10) 		<p>the test subject. Section 697.300 (f)</p>
<p>Repeat screening</p>	<p>Health-care providers should subsequently test all persons likely to be at high risk for HIV at least annually. Persons likely to be at high risk include injection-drug users and their sex partners, persons who exchange sex for money or drugs, sex partners of HIV-infected persons, and MSM or heterosexual persons who themselves or whose sex partners have had more than one sex partner since their most recent HIV test.</p> <ul style="list-style-type: none"> Health-care providers should encourage patients and their prospective sex partners to be tested before initiating a new sexual relationship. Repeat screening of persons not likely to be at high risk for HIV should be performed on the basis of clinical judgment. Unless recent HIV test results are immediately available, any person whose blood or body fluid is the source of an occupational exposure for a health-care provider should be informed of the incident and tested for HIV infection at the time the exposure occurs. 	<p>No provision.</p> <p>No consent required to test an individual whose blood or body fluid is the source of an occupational exposure to a health care worker or public safety personnel.</p>	<p>No provision.</p>

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Diagnostic Testing	<p>All patients with signs or symptoms consistent with HIV infection or an opportunistic illness characteristic of AIDS should be tested for HIV.</p> <ul style="list-style-type: none"> • Clinicians should maintain a high level of suspicion for acute HIV infection in all patients who have a compatible clinical syndrome and who report recent high-risk behavior. When acute retroviral syndrome is a possibility, a plasma RNA test should be used in conjunction with an HIV antibody test to diagnose acute HIV infection (96). • Patients or persons responsible for the patient's care should be notified orally that testing is planned, advised of the indication for testing and the implications of positive and negative test results, and offered an opportunity to ask questions and to decline testing. With such notification, the patient's general consent for medical care is considered sufficient for diagnostic HIV testing. (8) 	<p>Sec. 8. Notwithstanding the provisions of Sections 4 and 5 of this Act, written informed consent, information and counseling are not required for the performance of an HIV test...when in the judgment of the physician, such testing is medically indicated to provide appropriate diagnosis and treatment to the subject of the test, provided that the subject of the test has otherwise provided his or her consent to such physician for medical treatment. (410 ILCS 305/8)</p> <p>No requirement that "persons responsible for the patient's care" be advised of the indication for testing, or be permitted to decline testing. (Although if the person "responsible for the patient's care" is a legal surrogate then surrogate laws would authorize the communication and delegation of responsibility.)</p>	<p>When in the judgment of the physician, such testing is medically indicated to provide appropriate diagnosis and treatment to the subject of the test, provided that the subject of the test has otherwise provided his or her consent to such physician for medical treatment. (Section 697.120 (b) (7))</p>
Partner Counseling and Referral	<p>When HIV infection is diagnosed, health-care providers should strongly encourage patients to disclose their HIV status to their spouses, current sex partners, and previous sex partners and recommend that these partners be tested for HIV infection. Health departments can assist patients by notifying, counseling, and providing HIV testing for partners without disclosing the patient's identity (114). Providers should inform patients who receive a new diagnosis of HIV infection that they</p>	<p>No provision. Related provisions in STD Control Act (410 ILSC 325/)</p>	<p>Required for HIV Counseling and Testing Centers.</p>

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	might be contacted by health department staff for a voluntary interview to discuss notification of their partners. (11)		
Availability of informational materials	Easily understood informational materials should be made available in the languages of the commonly encountered populations within the service area. The competence of interpreters and bilingual staff to provide language assistance to patients with limited English proficiency must be ensured.(8)	Informational materials required in some settings, such as prisons and jails. No requirement for translators, but health care providers who receive federal funds, including any who participate in Medicaid, are required to offer language-appropriate services to limited English speaking individuals by the 1964 Civil Rights Act and subsequent Executive Orders.	No provision.
Availability of anonymous testing	No provision.	Sec. 6. A subject of a test who wishes to remain anonymous shall have the right to do so, and to provide written informed consent by using a coded system that does not link individual identity with the request or result, except when written informed consent is not required by law. (410 ILCS 305/6)	Section 697.130 Anonymous Testing <i>Any person upon whom an HIV test is performed shall have the right to request anonymity and to provide written informed consent by using a coded system that does not link individual identity with the request or the result except when written informed consent is not required by law as specified in Section 697.120. (Section 6 of the AIDS Confidentiality Act.) Any anonymous testing system adopted by the health care provider ordering the test must ensure that the correct test results are transmitted by the persons conducting the laboratory tests to the proper physician, and that the correct test results are given to the correct patient. When a test subject does not have the right to request anonymity, the test subject may request that the blood sample be labeled in such a manner as to prevent persons from learning the</i>

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			<p>identity of the test subject unless such persons are authorized to receive such information pursuant to Section 697.140 of this Part. a) If anonymous testing is requested, the physician shall assign to such person a unique number or notation, which shall be used by the person to sign the written informed consent in lieu of the person's name. The blood sample for testing shall be labeled with the physician's name and the unique number or notation assigned to the patient for the purpose of receiving the test results. Unless otherwise authorized by the patient, any record of the test result shall be maintained in a manner identifying the record only by its unique number or notation. b) Anonymous testing shall not be permitted under the following circumstances: 1) When identification of the test subject is permitted or required in order to comply with the provisions of Section 697.140(a)(3) or (6) of this Part, or 2) If the test is performed in order to determine eligibility as a donor or acceptability of a donation of blood, plasma, semen, oocytes or other human tissue.</p>