

## HIV/AIDS Testing Services in Healthcare Settings

Effective Date:

### I. Purpose

To provide guidelines for Standard and Rapid HIV testing and counseling in the XXXX Service Unit patient/employee population.

To provide early detection, facilitating early intervention and treatment of HIV infection

To prevent infection of clients with behaviors putting them at risk for HIV, to prevent transmission of HIV by infected clients to other individuals and to meet exposure treatment guidelines.

To assist in determining and establishing local seroprevalence data.

### II. Background

Human immunodeficiency virus (HIV) infection and acquired immunodeficiency syndrome (AIDS) remain leading causes of illness and death in the United States. Treatment has improved survival rates dramatically, especially since the introduction of highly active antiretroviral therapy (HAART) in 1995. Early diagnosis and treatment are key factors affecting survival rates of HIV infected persons. Unfortunately, many people are still being diagnosed late in the course of their infection. A disproportionate number of those diagnosed later are members of minority populations. Perinatal transmission has decreased as a result of routine screening of pregnant women and the use of antiretroviral prophylaxis. As a result of this, the Centers of Disease Control and Prevention (CDC) released revised HIV Testing recommendations for adults, adolescents and pregnant women in health care settings in September 2006 (MMWR 2006 55(RR14);1-17). These new guidelines shift HIV testing away from risk-based testing with special consent to routine testing for HIV without the need for special consent. A summary of those recommendations is included below.

*For patients in all health-care settings*

- *HIV screening is recommended for patients in all health-care settings after the patient is notified that testing will be performed unless the patient declines (opt-out screening).*
- *Persons at high risk for HIV infection should be screened for HIV at least annually.*
- *Separate written consent for HIV testing should not be required; general consent for medical care should be considered sufficient to encompass consent for HIV testing.*

- Prevention counseling should not be required with HIV diagnostic testing or as part of HIV screening programs in health-care settings.

*For pregnant women*

- *HIV screening should be included in the routine panel of prenatal screening tests for all pregnant women.*
- *HIV screening is recommended after the patient is notified that testing will be performed unless the patient declines (opt-out screening).*
- *Separate written consent for HIV testing should not be required; general consent for medical care should be considered sufficient to encompass consent for HIV testing.*
- *Repeat screening in the third trimester is recommended in certain jurisdictions with elevated rates of HIV infection among pregnant women.*

CDC anticipates this will increase rates of HIV testing and decrease high risk behaviors in persons infected with HIV by providing them knowledge of their serostatus. CDC data support HIV screening as cost effective.

This policy and procedures was developed in consultation with a regional IHS attorney to ensure compliance with XXX state law regarding HIV testing, (which as of December 2006 is more stringent than the CDC recommendations – **check with your XXX state first on this statement**).

**Comment [SG1]:** You may or may not choose to pass by a regional lawyer, however, this template *is supported* from IHS HQ and supports CDC guidelines. You will have to check with your states to make sure it is appropriate to policy.

Certain CDC recommendations (e.g. universal screening), are based on the yield of screening (justified if the yield is at least 1 per 1,000 persons screened) of HIV in the local population, however, the seroprevalence of HIV in the AI/AN population of the XXX service unit has not yet been established and remains unknown.

This policy addresses screening and counseling for HIV. Diagnostic testing should be considered for patients presenting with symptoms compatible with acute or chronic HIV infection, AIDS and/or AIDS related co-morbidities.

### III. Definitions

HIV: Human Immunodeficiency Virus is a retrovirus that is the causative agent of HIV disease and AIDS.

AIDS: Acquired Immunodeficiency Syndrome is the advanced stage of HIV disease characterized by profound immunosuppression associated with opportunistic infections, secondary neoplasms, and neurological manifestations.

HIV Disease is a chronic and progressive condition that exists after infection with the virus that manifests with mild symptoms in early stages and eventually leads to more severe manifestations known as AIDS in late stages of the disease.

HIV Antibody Test is the laboratory procedure that detects antibodies to HIV, the virus that causes AIDS. Antibodies appear about 6 weeks after initial infection. A positive antibody test indicates infection with the HIV virus. Other laboratory procedures or symptoms determine the stage of HIV infection. Some EIA tests confirm both HIV-1 and HIV-2 and Western blot test procedures confirms HIV-1 variant of the virus. The FDA has recently approved two EIAs that screen for a rare third variant known as type O. The EIA antibody test is the conventional procedure performed in the laboratory, and the Western blot, indirect immunofluorescence assay, or qualitative RNA tests are confirmatory procedures, which are performed when a reactive result is shown from the EIA test. A negative test means that no antibodies were detected at the time of testing. A negative test does not guarantee the absence of HIV if a person was exposed very recently (within a month or two of being tested) and has not yet developed antibodies.

Rapid HIV Test is a screening test that produces near immediate results, most in 20 minutes or less. Rapid tests use blood from a vein, finger stick or oral fluid to look for the presence of antibodies to HIV. As is true for all screening tests, a reactive rapid HIV test result must be confirmed with a follow-up confirmatory test before a final diagnosis of infection can be made. These rapid tests have similar accuracy (sensitivity and specificity) as conventional EIA screening tests.

**Comment [SG2]:** The terms 'non-reactive' and 'reactive' will be used for screening test results. Avoid inadvertently using the terms 'negative' or 'positive' to describe a rapid or standard screening test result.

Confidential Testing means that test results are charted in the patient's record and kept confidential according to law, rules and regulations. Positive HIV results are reported to the State Health Department in the manner required by the state, with strict confidentiality requirements enforced by law. HIV testing at XXX Service Unit is confidential. Breaches in confidentiality are not tolerated and will be dealt with according to privacy laws.

Anonymous Testing is testing with no name identified. The client is identified by code and only he/she receives the results. Anonymous testing is available at XXX test sites.

**Comment [SG3]:** (For ex. County Health Department)

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

Screening involves HIV testing for all persons in a defined population.

Targeted testing is HIV testing for population groups at higher risk of HIV infection based on behaviors or demographics. In many settings, targeted testing has not proven to be as effective as a more universal screening approach.

Informed consent involves communication between a provider and patient regarding HIV, the risks and benefits of testing, how and when test results will be provided. Information may be communicated orally or in writing. The patient should be given the opportunity to have any questions answered. The informed patient can then choose whether to undergo HIV testing or decline to do so.

**Comment [SG4]:** Informed consent is required, although there are options for accomplishing this. It can be written and separate from general consent, written within general consent or verbally documented by provider if consent is granted. Informed consent procedures for HIV CTR should be in accordance with local and state requirements, CDC guidelines and IHS recommendations (which support CDC guidelines) if possible. CDC and state sometimes don't match exactly and state law should be checked. Informed consent procedures and forms should be reviewed and approved by the appropriate health department prior to use. Protocols should clearly describe procedures for obtaining informed consent for HIV CTR.

Opt-out screening involves 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 is 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

#### **IV. Policy**

- A. Any I/T/U medical staff provider can order the HIV test.
- B. HIV testing should be viewed as a routine public health screening. HIV testing should be offered to all patients 13-64 years of age regardless of risk in the clinic or inpatient setting,
- C. Patients need to be informed that they are being tested for HIV, and given the opportunity to ask questions or decline. Declination of testing should be documented in the medical record
- D. A written consent form is not needed.
- E. Prevention counseling is encouraged, but not required, in conjunction with HIV screening in health-care settings. Individual and community based counseling is separate from testing
- F. Persons at high risk for infection should be screened at least annually.
- G. Pregnant women should be tested as soon as possible in pregnancy, ideally immediately after Hcg+ test as part of a bundled screening panel.
- H. The confidentiality of individuals tested for HIV shall be maintained at all times.
- I. All HIV testing will be voluntary.
- J. Consent may be obtained verbally and documented as “Consent for HIV Test”.  
**OR** Consent will be given by patient in accordance with general medical consent.
- K. HIV testing will be included as a routine component of prenatal care and will be part of the standard battery of prenatal laboratory tests given to all prenatal clients. Providers will provide information about HIV and the meanings of a positive or negative HIV test results. Patients should also be informed that testing is planned unless the patient declines the test. Testing will be performed routinely unless the client specifically requests not to be tested. (Opt-out format)

**Comment [SG5]:** Depending upon state law

L. Perinatal HIV transmission is considered a sentinel event. The CDC recommends the following:

- Opt-out, rapid testing during labor for all women whose HIV status is unknown and initiation of antiretroviral therapy if a rapid result is reactive, without waiting for confirmatory testing.
- Opt-out, rapid postpartum screening for all women whose HIV status is unknown at the time of delivery to allow for initiation of antiretroviral therapy in the newborn as soon as possible after birth if the rapid test result is reactive, without waiting for confirmatory testing.
- Rapid testing of the newborn as soon as possible after delivery if the mother's HIV status is unknown. Antiretroviral therapy should be initiated as soon possible after a reactive rapid HIV test result in the newborn because antiretroviral therapy is most effective for preventing infection in the infant when initiated within 12 hours of delivery.

M. Criteria for use of the Rapid HIV Test

1. For determining serologic status of the source in healthcare worker exposures.
2. For pregnant women who present in labor and have not been tested. When the mother's HIV status is unknown prior to the onset of labor and rapid HIV testing is not done during labor, CDC recommends rapid testing of the mother or infant immediately post-partum, so that antiretroviral prophylaxis can be offered to HIV-exposed infants.
3. Patients ill enough to require hospitalization (in-house or transferred out) and whose HIV status is unknown and where rapid results are needed for urgent medical decisions. For hospitalized patients not needing such urgent results the conventional HIV test may be preferred as it may be more sensitive in this setting.
4. Survivors of sexual assault when significant exposure has occurred, such as direct contact of the vagina, anus, or mouth with the semen or blood of the perpetrator, with or without physical injury, tissue damage or the presence of blood at the site of the assault. Recommendation is to perform an HIV test with regard to appropriate timing given the lack of relevance of immediate testing – unless it is to establish prior HIV infection of victim.

## **V. Procedures**

A. Informed Consent:

- a. Separate written consent is for HIV testing should not be required, unless mandated by state law or regulation. Consent for general medical care is sufficient to cover consent for HIV testing. **OR**
- b. If consent is required by the state, verbal consent may be obtained from the patient prior to testing and documented in the medical record as “consent for HIV test”. The requirement for documentation of verbal consent is included to comply with XXX State law. If and when state law changes are consistent with CDC recommendations, this requirement will be adjusted accordingly.
- c. A patient should be given the opportunity to “opt-out” or decline HIV testing.
- d. Consent of the parent or guardian is not required for testing minors under 18, but over 12 (ARS #36-661). Unless permission is given by the patient to disclose test results to parents or guardians, results will be communicated to the patient only.

**Comment [SG6]:** Check with state directly by phone as regulations often change regularly. Or check with HIV state law compendium at [www.ucsf.edu/hivcntr](http://www.ucsf.edu/hivcntr)

**Comment [SG7]:** Can use either a. or b. for ‘consent’. Check with state law.

**Comment [BMB8]:** Opt-out suggests documentation when patient declines. This provision is also contingent on state law or regulation

**Comment [SG9]:** Check with state to see if verbal consent is appropriate. Often, this will not be stated in the policy, however allowed if you call the state.

B. Partner notification and referral services should not be initiated until the reactive rapid HIV test result has been confirmed.

C. Confidentiality:

1. An array of state and federal laws exist providing protection of confidentiality and HIV testing. As well, CDC recommendations for HIV surveillance also address confidentiality.
2. The laboratory specimen (usually blood) will be collected, labeled and processed in a manner to minimize the number of personnel who have access to this information. Laboratory policy will outline procedures to provide this protection and confidentiality.
3. If the confirmatory test results are positive, the medical staff provider will contact the patient and arrange for follow-up medical care.

The laboratory application specialist or designee will enter all confirmatory HIV test results, positive or negative, into the RPMS Laboratory Package.

4. The only required and routine disclosure of positive results will be to the State Health Department as mandated for surveillance purposes only. Other disclosures may be made per the signed release of information form (by patient) to third parties consistent with IHS policy and state law. Usually, insurance companies are not entitled to receive test results.

D. Occupational Exposure In the case of potential parenteral or mucosal exposure of an employee to possible HIV infected body fluids, the Blood borne Pathogen

Exposure policy will be followed.

E. Indeterminate Results

If a confirmatory test is indeterminate, an HIV viral load or qualitative RNA test should be performed. If the patient is pregnant and in the second or third trimester, and has an indeterminate result, contact the Perinatal Hotline at 1-888-448-8765 for further guidance. Questions regarding non-pregnant patients with indeterminate results should be referred to the Positive Care Team or to the HIV Warmline at 1-800-933-3413.

E. Communicating Non-Reactive (Negative) Rapid HIV Test Results

Providers communicating negative HIV test results should do the following:

- a. If HIV negative, the results go into the computer after testing.
- b. If prevention counseling is warranted or scheduled, review the protective behaviors that have helped the patient avoid infection with HIV and reinforce the client's plan to remain uninfected. CDC does not require counseling for implementation of more universal screening. Also, if test is non-reactive, CDC recommends post-test information for those at higher risk.
- c. Ensure that the client/employee is aware that, as is true of any antibody test, the negative HIV test result may be unreliable when risk exposure has been very recent. Specifically, the client/employee needs to be informed that after a person is infected with HIV, it takes time before antibodies develop that can be detected by the test.
- d. A negative antibody test result, whether it is from a rapid HIV test or an EIA, does not require a confirmatory test. However, a person may have been tested too soon, called the "window period", before antibodies developed. The average time between infection and the development of detectable antibodies is 25 days.

F. Communicating Reactive Rapid HIV Test Results

One of the more challenging issues posed by the introduction of rapid HIV tests is providing "reactive" (preliminary positive) rapid HIV test results to patients without the benefit of a same-day confirmatory positive test. Currently, confirmatory positive test results are usually not available for 1 to 2 weeks.

- a. If the rapid HIV test is reactive, the test result is entered into the computer as "preliminary positive Rapid HIV test result". The laboratory will also initiate

confirmatory testing procedure as part of a reflex protocol. The test result is then called to the attending provider/counselor as a critical value. The provider/counselor will explain to the patient, privately and confidentially, the meaning of the reactive screening test result and communicate the possibility of HIV infection and need to take precautions regarding transmission until confirmatory results are available.

- b. If a lab is sent out, make sure the remote lab is aware the initial reactive test was done via a rapid testing technology. This is to ensure it is confirmed via Western Blot, IFA or RNA and not done as a second EIA.
- c. The phrase the provider/counselor chooses when providing the test results should be simple. For example:
  - o Your first screening test came back reactive.
  - o There is a possibility you are HIV infected, but we won't know for sure until we get the results from your confirmatory test.
  - o We need to verify this result with a follow-up test.
- d. Do not initiate partner notification or provide medical referrals, but advise the patient/employee to adopt behaviors to prevent HIV transmission until the reactive rapid test result has been confirmed by an approved confirmatory test.
- e. Discuss whether and how to disclose the results of the reactive rapid test to partners and other persons important to the patient (before the test result is confirmed), give options for support, and make psychological referrals.
- f. Verify the locating information, so that it will be possible to contact the patient if he or she does not return for the result of the confirmatory test.
- g. If the confirmatory test result is positive, help with partner notification and make medical referrals, after discussing these with the patient and obtaining the patient's cooperation.
- h. When rapid test results are reactive, antiretroviral interventions can be offered to the mother intra-partum and to her infant based on the preliminary positive results. Confirmatory testing will be done if the initial rapid test is reactive.

F. Partner notification and referral services - Refer to F.c. above

\_\_\_\_\_  
Name: \_\_\_\_\_ Date \_\_\_\_\_  
Title: Chief Executive Officer, XXX Service Unit

References:

Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings. MMWR 2006; 55 (RR14);1-17.

HIV Prophylaxis following Sexual Assault: Guidelines for Adolescents and Adolescents. NYS  
DOH AIDS Institute, #9315, 6/98  
<http://www.cdc.gov/hiv/>  
<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5019a1.htm>  
Policy and Procedures Review Date(s): 8/2006, 7/2008, xx/xxxx