# HIV TESTING DURING PREGNANCY AND AT DELIVERY

## NEW YORK STATE PUBLIC HEALTH REGULATIONS

The following are mandated in New York State (NYS) and must be performed in accordance with State Law:

**All prenatal care settings regulated by the New York State Department of Health (NYSDOH), including hospitals, diagnostic and treatment centers, health maintenance organizations, and birthing centers, must provide HIV information and recommend HIV testing, preferably at the first prenatal visit for all women who present for care.**

**Diagnostic HIV tests must be performed in full compliance with the NYS Law.**

**If a woman presents for delivery without documentation of a negative HIV test during the current pregnancy and is not known to be HIV-infected, HIV expedited testing must be conducted on the mother with her consent:**

- **If the woman declines expedited testing, the newborn must be tested using the infant's blood specimen collected at birth. Maternal consent is not required.**
- **Results of expedited testing must be available as soon as possible, preferably within 1 hour, and no longer than 12 hours after the mother's consent or the infant's birth if the mother declines testing.**

**Preliminary positive expedited HIV test results obtained using HIV rapid testing or a laboratory-based screening test must be confirmed according to currently recommended procedures for diagnosing HIV infection.**

- **Confirmatory test results should be available as soon as possible and no later than 4 days after the preliminary positive HIV test result.**
- **Positive maternal confirmatory test results must be reported in accordance with NYS Law, which necessitates name reporting and partner notification.**

## I. HIV Testing During Third Trimester of Pregnancy

**RECOMMENDATIONS:**
**Clinicians should:**

- **Routinely recommend repeat testing in the third trimester, preferably between 34 and 36 weeks, for all women who test negative for HIV early in pregnancy. Repeat testing is strongly recommended for women who have continued high-risk behaviors during pregnancy or who acquire any other sexually transmitted infections during pregnancy**
- **Offer testing during labor and delivery for any woman who does not have documented third trimester HIV test results** (AIII)

**Clinicians should maintain a high level of suspicion for acute HIV infection in all pregnant women who present with a compatible clinical syndrome. Women who present with symptoms suggestive of acute HIV infection should be tested immediately, even if a previous HIV antibody test during current pregnancy was negative. Screening for acute infection can be performed by obtaining the following** (AIII)**:**

- **An HIV serologic screening test in conjunction with a plasma HIV RNA assay. The plasma RNA test should be performed even if the serologic screening test is negative. If available, a fourth-generation HIV antigen/antibody combination test is the preferred serologic screening test.**

**Detection of HIV RNA or antigen in the absence of HIV antibody should be considered a preliminary positive result; HIV RNA testing from a new specimen should be repeated immediately.** See *Acute HIV Infection in Pregnancy* for more information.

**NYS Law requires clinicians to discuss partner notification with patients who have been recently diagnosed with HIV infection. Assistance with partner notification can be provided through direct referral to the NYS and County Health Department Partner Services (PS) Programs, and the New York City Department of Health Contact Notification Assistance Program (CNAP). The partner notification discussion must be documented in the medical record and on the Medical Provider Reporting Form (DOH Form # 4189) as required by Public Health Law, Article 21, Title III, Section 213.** (More information on partner notification assistance and resources can be found at: Partner Services outside of NYC or Contact Notification Assistance Program (CNAP)**.**)

Identification and treatment of HIV-infected pregnant women during pregnancy can prevent mother-to-child HIV transmission (MTCT) during pregnancy and childbirth. Clinical care settings that are regulated by the NYSDOH, including hospitals, diagnostic and treatment centers, health maintenance organizations, outpatient clinics, and birthing centers, must provide HIV information and must recommend voluntary HIV testing to all women who present for prenatal care and delivery (if HIV testing was not already done during the current pregnancy). Other settings that are not regulated by NYSDOH, such as some private offices, should note that providing universal HIV information and recommended voluntary testing is the American College of Obstetrics and Gynecology (ACOG) and the NYSDOH standard of care for all pregnant women.[1,2]

In NYS, medical record reviews are conducted to assess care and outcomes for each HIV-exposed birth event. Because the overall number of HIV-infected newborns in NYS has been less than 20 per year for several years, each case of MTCT undergoes an expedited review to identify the factors that contributed to the transmission. Between 2002 and 2006, 9 of 65 HIV-infected infants in NYS were born to women who previously tested HIV-antibody negative during pregnancy.[3] Similar findings have been published from North Carolina.[4]

Women who become infected with HIV *during* pregnancy benefit from subsequent aggressive treatment intervention which may further reduce the number of newborns infected with HIV.[5] To further decrease the number of children at risk for perinatal HIV infection, the NYSDOH recommends that all prenatal care providers routinely recommend repeat HIV testing, preferably at 34 to 36 weeks, for all women who test negative early in prenatal care. [5] The CDC recommends repeat HIV testing in the third trimester in areas of high prevalence of HIV; NYS is listed as an area of high HIV prevalence.[6]

Women who present with symptoms suggestive of acute HIV infection should receive a plasma HIV RNA assay in conjunction with an HIV serologic screening test to diagnose acute HIV infection. A fourth-generation HIV antigen/antibody combination assay is the preferred serology test, if available. See *Acute HIV Infection in Pregnancy* for more guidance on diagnosing and managing acute HIV infection during pregnancy.

## II. Evaluation and Management of Women Presenting in Labor Without Documentation of a Negative HIV Test During the Current Pregnancy and Who Are Not Known to Be HIV-Infected

**RECOMMENDATIONS:**

**All birth facilities should adopt point-of-care rapid HIV testing in labor and delivery settings for women who present in labor without documentation of a negative HIV test result during the current pregnancy and who are not already known to be HIV-infected. As per NYS Regulations, these women must receive expedited HIV testing or the infant must be tested at birth if the mother declines testing.**

**Facilities should perform expedited HIV testing using an FDA-approved HIV rapid test; however, a conventional, laboratory-based screening test, such as an enzyme immunoassay (EIA) or chemiluminescent immunoassay (CIA), may be used if results can be returned rapidly, preferably within 1 hour, and no longer than 12 hours. The most sensitive screening test available should be used to allow for detection of early or acute HIV infection.**

**Facilities should strive to have expedited HIV test results available prior to delivery to allow maximum benefits of intrapartum ARV prophylaxis for the fetus.**

**When maternal expedited HIV testing yields a preliminary positive result, the clinician should:**

- **Discuss the meaning of a preliminary positive HIV test result with the mother** (AIII)
- **Recommend immediate initiation of ARV prophylaxis during labor for the mother and for the infant in the immediate postnatal period, preferably within the first 6 to 12 hours, until HIV infection is definitively excluded.** (AIII) (In this instance, the benefits of HIV prophylaxis given for a short period of time outweigh the risks of the medications). **If a woman chooses to decline ARV prophylaxis for herself or her newborn, she should be educated about the benefits that ARV prophylaxis provides**
- **Inform the mother about the risk of postpartum MTCT via breast milk and that breastfeeding is contraindicated, even while receiving ARV prophylaxis, until there is definitive evidence that the mother is not infected with HIV.** [7] (AII) Safe formula alternatives are available in the US; however, for women who wish to breastfeed, pumping and discarding or saving breast milk can be recommended to prevent breast engorgement and to continue milk production if HIV infection is definitively excluded by diagnostic tests that are capable of detecting early infection
- **Discontinue maternal ARV prophylaxis after delivery.** If definitive test results indicate HIV infection, follow-up evaluation should occur by a provider who has experience with HIV management to discuss initiation of antiretroviral therapy

**NYS Regulations require that providers must obtain a confirmatory test for all preliminary positive HIV test results. Current recommendations require that a Western blot be obtained if the screening test produces a preliminary positive result, regardless of the type of screening test performed (rapid or EIA/CIA). If the Western blot is negative or indeterminate, a nucleic acid test (NAT) should be performed as soon as possible to distinguish between early HIV infection and a false-positive screening test result.***

**When the definitive test results indicate HIV infection is present:**

- **ARV prophylaxis with at least zidovudine for the infant should be continued for 6 weeks.** (AI) **The infant should be discharged from the birth facility with the full 6-week supply of ARV prophylaxis**
- **The importance of not breastfeeding should be emphasized. The infant should be discharged with a supply of formula**
- **Arrangements should be made prior to discharge for the infant to receive HIV-related follow-up care from, or in consultation with, a pediatric provider who has experience with HIV management. This includes making arrangements for diagnostic testing to determine the infant's HIV status. The first diagnostic specimen should be sent within 48 hours of birth to the Pediatric HIV Testing Service at the Wadsworth Center, NYSDOH** (see *Diagnosis of Pediatric HIV Infection in HIV-Exposed Infants*)
- **Arrangements should be made prior to discharge , if possible, for the mother to receive follow-up evaluation by a provider who has experience with HIV management to discuss maternal health and future ART; referral should be made for subsequent HIV primary care** (AIII)

- **Referral should be made for HIV-specific case management and supportive services**
- **It should be explained to the mother that a confirmed positive antibody test result obtained from the infant is not reported unless the infant's HIV virologic assay (i.e., NAT, a general term which includes DNA PCR and RNA virologic assays) is positive** (see *Diagnosis of Pediatric HIV Infection in HIV-Exposed Infants*)

**After HIV infection has been definitively excluded in the mother:**

- **Infant ARV prophylaxis should be discontinued** (AI)
- **Maternal ARV prophylaxis should be discontinued after delivery** (AI)
- **Mothers may initiate breastfeeding if desired** (AII)

* *An alternative diagnostic strategy that uses a combination of FDA-approved immunoassays and NAT to determine HIV infection status without Western blot testing has been proposed[8] and may provide a more definitive result in less time; however, formal recommendations are required before laboratories can implement this alternative strategy for expedited maternal testing.*

Use of point-of-care rapid HIV testing in labor and delivery units is recommended. Rapid tests for HIV are single-use test devices that use simple, one-step procedures and require no instrumentation. They detect antibodies to HIV and provide rapid results within 60 seconds to 40 minutes, depending on the type of rapid test used. All of the rapid tests currently approved by the FDA detect antibodies to HIV and thus will not detect very recent infection. All have sensitivity and specificity similar to laboratory-based HIV antibody screening tests and similar positive and negative predictive values. If standard ELISA HIV testing is performed for expedited testing, results should be available within an hour. Laboratory-based screening tests that can detect HIV antigens and antibodies, referred to as fourth-generation or combination screening tests, can also be used for expedited testing. See Table 2 in *Diagnostic, Monitoring, and Resistance Laboratory Tests for HIV* for a list of the characteristics of each of the current FDA-approved rapid tests.

Rapid testing of women and/or their infants in the peripartum period should not be viewed as a convenient, universal testing methodology but rather as a "safety net" designed to screen the small number of women who were not tested earlier in pregnancy or who seroconverted during pregnancy after the initial negative HIV test.

**Key Point:**
The ideal time for providing HIV information and testing in pregnancy is as early as possible. The peripartum period is the final opportunity to provide ARV prophylaxis and decrease the risk for MTCT to HIV-exposed infants in mothers who have not been previously identified as HIV-infected.

*Preliminary Positive Test Results*

Most preliminary positive HIV test results are true-positive results; the precise ratio of true-positive to false-positive test results will depend on the test used and the local prevalence of HIV infection. When a preliminary positive result from a rapid test occurs in the labor and delivery setting, a second rapid test may be performed using a different, FDA-approved rapid test device to obtain quick verification of the initial result. If both rapid tests are reactive, the likelihood of infection is great. Regardless of whether one or two rapid tests are performed, a preliminary positive result must be followed up with additional testing to confirm infection.

Prophylaxis in women identified as HIV-infected during labor is more likely to be beneficial when started during labor. One NYS study showed that when zidovudine was given prenatally, the infant HIV transmission rate was 5%; when given within the first 48 hours of life, the transmission rate was 9.5%; and when given on day 3 of life or later, the transmission rate was 25%.[9] The benefit of infant prophylaxis decreases with the length of time to initiation, such that there is unlikely to be any benefit when initiated in the infant after 48 hours of delivery. For specific prophylaxis regimens, see *Labor and Newborn Management in the Absence of Antenatal Antiretroviral Treatment*.

## REFERENCES


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**Further Reading**


Gray AD, Carlson R, Morgan MA, et al. Obstetrician gynecologists' knowledge and practice regarding HIV screening. *Obstet Gynecol* 2007;110;1019-1026. [PubMed]