

CHAPTER 1

HIV TESTING AND DIAGNOSIS IN INFANTS AND CHILDREN

I. INTRODUCTION

Although there have been tremendous advances in the care of HIV-infected adults and children in the last several years, HIV remains a chronic infection with serious potential long-term impairments. Identification and treatment of HIV-infected pregnant women can prevent HIV infection in their children. **Clinical care settings that are 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 counseling and must recommend voluntary testing to all women in prenatal care.** Other settings that are not regulated by NYSDOH, such as some private offices, should be aware that universal HIV counseling and recommended voluntary testing is the standard of care for all pregnant women. The goal is to diagnose HIV infection in all pregnant women as early as possible in order to provide optimal treatment for the woman and ARV prophylaxis for the child.

The New York State Comprehensive Newborn Testing Program for HIV began in February 1997 when HIV was added to the list of conditions tested for under New York State's Newborn Screening Program. Through this program, essentially all HIV-exposed newborns were identified. However, the test results were not available until approximately 10 days after delivery, which is too late to initiate ARV prophylaxis to reduce the risk of perinatal HIV transmission. Observational data from New York State demonstrate that zidovudine administered in the intrapartum or newborn periods soon after birth can reduce the risk of perinatal HIV transmission.¹ Nevertheless, in 1997, approximately 50% of women who gave birth in New York State did not know their HIV status prior to delivery. Therefore, New York State regulations were amended in August 1999 to require expedited HIV counseling and testing in the labor and delivery and newborn settings. This mandated rapid intrapartum HIV antibody testing of the mother (with consent) or of her newborn (without consent) for all women with unknown HIV status or without documentation of an HIV test during their current pregnancy. As of November 2003, preliminary results of such testing must be available as soon as possible and always within 12 hours of the mother's consent for maternal tests or within 12 hours of birth for infant tests. Laboratories are allowed to return preliminary positive HIV test results (before Western blot confirmation) if the ordering clinician requests it and are expected to do so in the Labor and Delivery or nursery setting. Clinicians may use the preliminary test result, along with other clinical factors, to determine the need for prophylactic treatment, recognizing that false-positive preliminary test results may occur (see Appendix A). When a positive preliminary HIV test result occurs in the maternity setting, a confirmatory Western blot test result must be available within 4 days.

Rapid testing of women and/or their infants in the peripartum period should be viewed as a "safety net" designed to screen a small number of women not tested earlier in pregnancy and not as a convenient, universal testing methodology. The peripartum period is not the ideal time or setting for HIV counseling and testing, but it is the final opportunity to provide ARV prophylaxis to HIV-exposed infants. Prophylaxis is most likely to be beneficial if given as soon as possible after delivery, and the benefit decreases with time, such that there is unlikely to be any benefit when initiated after 48 hours of delivery. A more complete discussion of perinatal transmission, including guidelines for prevention, is available (see the New York State Department of Health AIDS Institute's *Management of the HIV-Infected Pregnant Woman Including the Prevention of Perinatal HIV Transmission*²).

II. RESPONSIBILITIES OF CHILD HEALTHCARE PROVIDERS

RECOMMENDATIONS:

As part of the initial newborn evaluation, the pediatric clinician should determine whether HIV testing of the mother has been completed properly and should follow up on any outstanding laboratory values. (III)

Pediatric clinicians should obtain testing for HIV beyond the neonatal period if the child presents with signs and symptoms of HIV disease. Testing should be performed in children who have not yet been tested when risk factors for HIV infection exist in the child or one of his/her parents. (III)

Even with ongoing public health efforts, it is necessary for pediatric clinicians to know how to diagnose HIV and how to perform tests to definitively diagnose HIV infection in an HIV-exposed infant. As part of newborn care, the provider should check that the HIV status of the mother has been properly determined before the infant is discharged. Such documentation should be included in the baby's chart.

Children who were born outside New York State and children born in New York State prior to 1997 may not have been screened. If a mother was infected with HIV shortly before delivery, she may not have had antibodies at the time of delivery and the child would have tested negative. Theoretically, extremely pre-term infants could also have false-negative antibody test results as maternal IgG is transferred across the placenta primarily in the third trimester of pregnancy. A test for antibody in infant blood in this circumstance would have decreased sensitivity compared with the same test in full-term infants. Signs and symptoms of HIV disease in a child requires testing for HIV outside the neonatal period, even if the child was already tested as an infant.

III. LABORATORY TESTS FOR HIV IN NEWBORNS, CHILDREN, AND ADOLESCENTS

RECOMMENDATIONS:

Because positive antibody results alone do not establish infection in children younger than 18 months of age, assays to detect virus (HIV DNA PCR or viral culture) should be used for diagnosis (see Figure 1). (II)

In children older than 18 months of age, HIV infection may be diagnosed on the basis of a positive HIV antibody test (ELISA) and a confirmatory test, such as Western blot. (I)

Because of the time period between infection and the development of detectable antibodies, children/adolescents exposed via sexual activity, sexual abuse/assault, or infected blood who have an initial negative test result should be retested at 1 month, 3 months, and 6 months after exposure. (III)

Because a child with end-stage HIV disease may become HIV-antibody seronegative as a result of severe humoral immunodeficiency, children who are clinically suspected to be HIV-infected yet test HIV antibody negative should be tested by DNA PCR (or HIV culture). (III)

Children older than 18 months of age with an indeterminate Western blot result should be retested as soon as possible. If the Western blot result remains indeterminate, the patient should be tested for HIV-2 or specific viral tests (e.g., DNA PCR) for HIV-1 should be performed. (III)

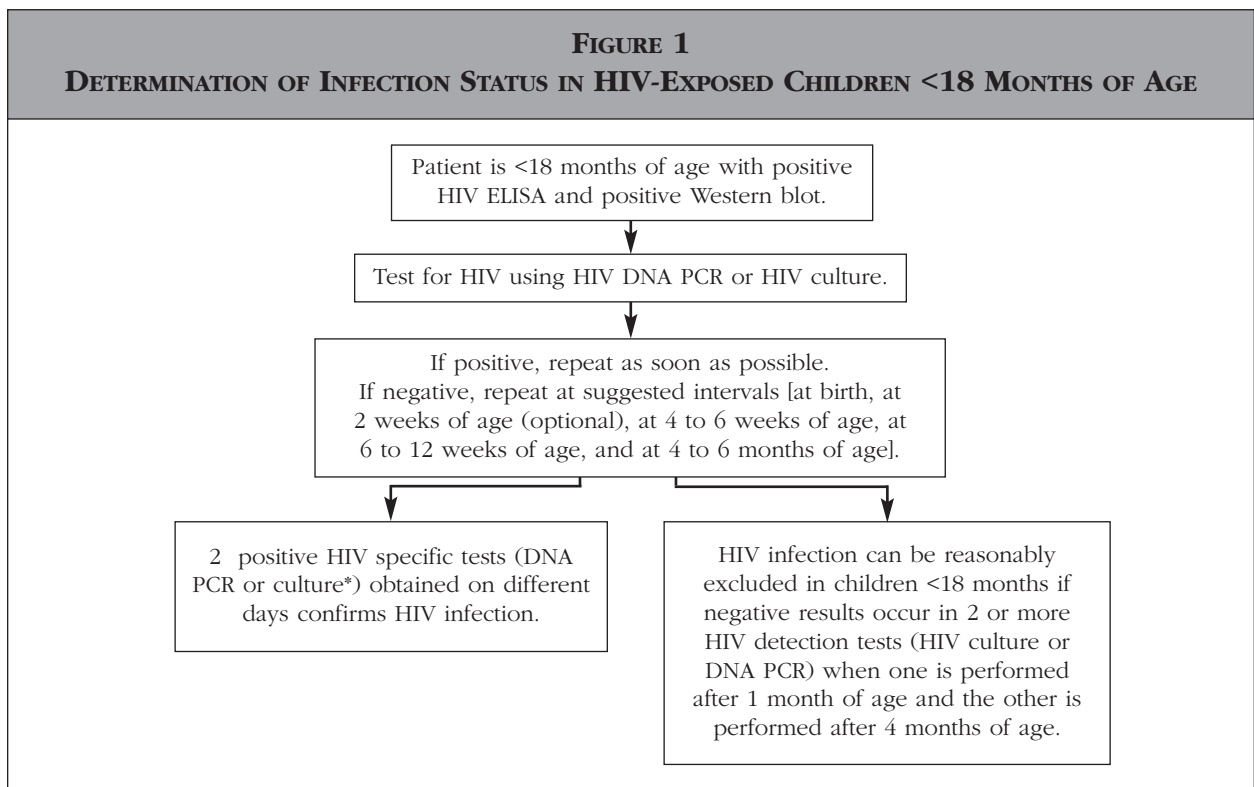
Rapid testing and expedited preliminary test results prior to Western blot confirmation should generally be used only when immediate information is needed to determine the need for post-exposure prophylaxis in the labor/delivery, newborn, or other acute exposure settings, or when the person who is being tested is unlikely to return for a follow-up visit. (III)

When preliminary diagnostic tests are used for expedited HIV testing, a preliminary positive test result must be confirmed with a Western blot as soon as possible. (I)

The most common method for diagnosing HIV-1 infection in adults is antibody detection. HIV-1, group M, subtype B is the most common type of HIV infection in North America, and testing methods used in this country are designed for optimal detection of these isolates. HIV-2 infection has been reported in the United States and Europe. In addition, HIV-1 subtypes more common in other parts of the world are occasionally seen in the United States.^{3,4} These epidemiologic changes have implications for some testing procedures, which will be discussed in this section.

Children born to HIV antibody-positive women are born with passively acquired maternal anti-HIV immunoglobulin (IgG). If the child is not HIV infected, the maternal IgG gradually decreases, and antibody is usually immeasurable by 7 to 10 months of age but can sometimes persist as long as 18 months, making test results uninterpretable. Therefore, in children younger than 18 months of age, use of assays for virus or viral components is necessary (see Figure 1).

As with adolescents and adults, HIV antibody tests are highly reliable as diagnostic tests for children older than 18 months of age.



* Plasma HIV RNA detection (HIV RNA PCR) also may indicate HIV infection. However, at this time, experience in using this test for diagnosis of HIV infection in infants has limitations (see text, subsection B3: Plasma HIV RNA). If it is used as a screening method, positive results should be confirmed with at least one of the other two test methods. A negative RNA PCR does not exclude HIV infection.

A. Testing for HIV Antibody

The most widely used test for detecting antibodies to HIV is ELISA with confirmation using Western blot (immunoblot). An antibody test is considered positive only if a screening test, such as ELISA, is repeatedly reactive and a confirmatory test, such as Western blot, confirms the presence of specific anti-HIV antibodies. Although antibody testing is reliable for most subtypes of HIV-1, group M, some of the test kits have some limitations in detecting non-B subtypes.⁵ Commercially available ELISA test kits should identify antibody in individuals infected with HIV-2. Individuals infected with HIV-2 may test positive according to ELISA but indeterminate or negative according to a Western blot. Patients with reactive ELISAs but indeterminate HIV-1 Western blot should have an HIV-2 Western blot performed. Because antibody tests do not test for virus, they will not detect infection in an individual with acute retroviral syndrome in whom an antibody response has not yet developed.

1. Screening Tests

The ELISA method in a microplate format is the most common screening test for IgG HIV antibodies. The technique uses HIV antigens derived from HIV grown in human T lymphocytes or recombinant proteins immobilized on beads or microplate wells. A patient's serum is incubated with the immobilized antigens. Subsequently, an enzyme-labeled antibody specific for human immunoglobulin is added. Detection of the enzyme-labeled antibody occurs by the addition of a substrate that yields a colored reaction product. Competitive ELISAs and "double-antigen" assays are two modifications also in use, but both rely on the same general principle of antibody detection.

2. Confirmatory Testing of Positive Results

Western blot is the primary method used to confirm repeatedly reactive antibody screening tests. In the analysis, HIV antigens from purified viruses are electrophoretically separated and transferred to nitrocellulose sheets. The sheets are then cut into strips and incubated with the patient's serum. Binding of the patient's antibody to HIV antigens on the strip is detected with labeled anti-human immunoglobulin antibody.

Most Western blot tests approved by the FDA use Centers for Disease Control and Prevention (CDC) criteria for the interpretation of band patterns.⁶ Under these criteria, a Western blot is interpreted as positive if bands are present at the site of two or more of the following HIV antigens: p24, gp41, or gp120/160. The test is considered indeterminate if fewer than two of these bands are present. It is interpreted as negative only if no viral bands are present. Infection with HIV-2 may result in negative or indeterminate results and requires referral for further testing. Individuals with an indeterminate result should be retested as soon as possible. Western blot, like other antibody tests, does not test for virus and will not detect infection in someone with acute retroviral syndrome in whom an antibody response has not yet developed.

3. Rapid Test Assays

Rapid tests for HIV are assays that detect antibodies to HIV within minutes. Some require little training to perform and read; a positive result is indicated by the presence of a pink line or circle in the appropriate area. The specific tests that have been approved, the indications for use, and the manner in which they are used have evolved over the past year and will continue to evolve. The most up-to-date information is available on the Food and Drug Administration (FDA) website at <http://www.fda.gov/>

As of September 1, 2004, three rapid tests have been approved for use as screening tests for HIV infection (see Table 1). These are the OraQuick ADVANCE from OraSure Technologies, Reveal Rapid HIV-1 Antibody Test from MedMira Laboratories, and the Uni-Gold Recombigen HIV Test from Trinity Biotech. All detect antibody to HIV, and thus will not detect very recent infection with any more accuracy than the standard HIV-antibody tests. All have sensitivity and specificity similar to standard HIV antibody tests and similar positive and negative predictive values.

When rapid testing is performed, preliminary positive test results should be given to the patient before confirmatory test results are available. Confirmatory Western blot testing of preliminary positive test results should be completed as soon as possible. Specific protocols and test methods are outlined in Section B: *Testing for HIV or Viral Components*. Rapid testing is used preferentially when immediate information is necessary to determine the need for prophylaxis, such as in the labor/delivery, newborn, or post-exposure settings, or when the person who is being tested is unlikely to return for a follow-up visit.⁷

OraQuick is approved for the detection of HIV-1 and HIV-2, while Reveal and Uni-Gold are approved for HIV-1 detection only. All three rapid tests performed as well as standard antibody tests on serum specimens with low titers of antibody and on seroconversion

panels, identifying HIV infection as early as the standard ELISA tests. They were tested with specimens from patients with potentially interfering substances, including antibodies to HCV, EBV, CMV, HSV, rubella, RA, varicella, HAV, HBV, HCV, syphilis, and mycoplasma, CRP, ASLO, ANA positivity, infectious mononucleosis, anticoagulants, and chemical derangements of the blood. Uni-Gold and Reveal were not affected by any of these, and OraQuick was minimally affected, with very rare false-positive results.

OraQuick can be used on whole blood, plasma, or oral fluid; Uni-Gold on whole blood, plasma, or serum; and Reveal on plasma or serum. Both OraQuick (including the updated ADVANCE) and Uni-Gold are approved as “waived” tests, meaning that they can be performed by persons with limited training under the auspices of a clinical laboratory, whereas Reveal is of moderate complexity and must be performed only by certified personnel. At the present time, the package insert instructing providers in the use of the Oraquick ADVANCE (for oral fluid) and Uni-Gold tests have not been approved by the FDA; thus although these tests are approved for use as waived tests, they are not yet available as such. It is unknown when they will be available for use as waived tests.

TABLE 1 CHARACTERISTICS OF AVAILABLE RAPID TESTS			
	OraQuick	Reveal	Uni-Gold Recombigen
Manufacturer	OraSure Technologies	MedMira Laboratories	Trinity Biotech
Date approved	11/13/02	4/16/03	12/23/03
Detection	HIV-1 and HIV-2	HIV-1 only	HIV-1 only
For use on	Whole blood, plasma, oral fluid	Serum, plasma	Whole blood, serum, plasma
Complexity*	Waived	Moderate	Waived
Time to complete	20-40 min	3 min (+/-) + preparation	10 min
Acceptable preservatives		EDTA, Heparin, Citrate	EDTA, Heparin, Citrate
Time that the specimen can wait		24 hours	8 hours
Sensitivity	99.6%	98.6%-99.1%	99.7%
Specificity	100%	99.8%	100%
Reproducibility	99.8%-100%	100%	“excellent”

* Although the OraQuick ADVANCE and Uni-Gold are approved as waived tests, they are unavailable for use as such pending FDA approval of package inserts.

B. Testing for HIV or Viral Components

RECOMMENDATIONS:

Clinicians should test children younger than 18 months of age who are born to an HIV-infected mother for HIV using one of the following methods:

- **HIV DNA PCR (preferred method) (II)**
- **HIV culture (acceptable method) (II)**

Because infection can only be confirmed with two positive test results performed on samples collected at different times, a repeat sample should be obtained promptly for any child with a single positive test result. (III)

In an infant younger than 18 months of age, HIV can be reasonably excluded with two negative HIV viral tests, one at 1 month of age or older, and the other at age 4 months or older. (II)

Ideally, a DNA PCR should be obtained for HIV-exposed infants at each of the following time points:

- **at birth** (II)
- **at 2 weeks of age** (II)
- **at 4 to 6 weeks of age** (II)
- **at 6 to 12 weeks of age** (II)
- **at 4 to 6 months of age** (II)

The ideal testing schedule includes PCR testing at birth to obtain the earliest possible identification of infants infected *in utero*; at 2 weeks to enable earliest identification of some infants infected during the intrapartum period; and at 4 to 6 weeks, 6 to 12 weeks, and 4 to 6 months of age to identify all perinatally infected infants. While the Committee recognizes that not all pediatric HIV Specialists perform both of the recommended initial DNA PCR tests (at birth and at 2 weeks), the current guidelines recommend that clinicians adhere to the testing schedule outlined above. One advantage of including the test at birth is that the results of this test can help determine if the infant was infected *in utero* or during labor and delivery. This information is essential in improving strategies to prevent perinatal transmission. Earlier identification can also be beneficial when initiating ARV therapy for the infant (see Chapter 5: *Pediatric Antiretroviral Therapy* for guidelines on initiating ARV therapy).

All tests that require amplification of genetic material are dependent on a specific DNA or RNA sequence being present in the patient's virus. Because of the diversity in HIV, the sensitivity of a specific test for the patient's isolate should always be considered. Optimal sensitivity is achieved if multiple sequences are amplified or if the sequence to be amplified is conserved across all viral species. Specific tests are discussed in the following sections.

1. HIV DNA Polymerase Chain Reaction

DNA PCR is a sensitive technique used to detect specific HIV proviral sequences in DNA of patients' peripheral blood mononuclear cells (PBMC). Extracted DNA from patients' PBMC is incubated with a thermostable DNA polymerase, deoxynucleotide triphosphates, and oligonucleotide primers that correspond with the portion of the HIV genome to be amplified. In a series of temperature shift cycles, an exponential increase in the copy number of the HIV sequence occurs. Amplified DNA sequence of HIV can then be detected using a number of techniques. DNA PCR is a much more rapid procedure than HIV co-culture and can provide results in 48 hours. As with HIV culture, samples obtained at birth (<48 hours of age) may be negative in 50% or more of infants who are eventually determined to be HIV infected because infants who are infected during delivery may not have developed detectable quantities of viral DNA yet. By 4 weeks of age, the DNA PCR test results are positive in more than 90% of infected infants. In infants older than 4 weeks of age, sensitivity of DNA PCR is consistently high, ranging between 91% and 99%.^{8,9}

Because DNA PCR involves the amplification of minute quantities of DNA, false-positive results may occur, particularly if testing laboratories do not take extreme precautions to prevent contamination. Experienced laboratories follow procedures to minimize false-positive results.¹⁰ A positive test result at any age is a presumptive indicator of HIV infection but must be confirmed by a second DNA PCR test or HIV co-culture as soon as possible. Negative tests also should be confirmed. Current CDC guidelines for reasonable exclusion of HIV in an infant require two negative DNA PCR tests—one of which should be performed at 1 month of age or older, and the other at 4 months of age or older.¹¹ Many centers continue to follow children beyond 4 to 6 months of age to confirm the loss of maternal antibody, which usually occurs between 9 and 15 months of life. A positive DNA PCR at any time requires a repeat test on a second blood sample as soon as possible for confirmation. Two positive DNA PCRs at any time confirm infection. Once infection is confirmed, further DNA PCR testing is not required.

Since April 1995, all physicians in New York State have had free-of-charge access to HIV DNA PCR tests for infants born to HIV-infected mothers via the Pediatric HIV Testing Service at the New York State Department of Health's Wadsworth Center in Albany (phone: 518-486-9605). Physicians who have not yet used this service should contact the Wadsworth Center to obtain test materials and mailing kits before sending specimens.

2. HIV Culture

HIV can be cultured from PBMCs. Current methods use small blood volumes and have excellent sensitivity. PBMCs from patients are co-cultured with healthy donor mitogen-stimulated PBMCs. Supernatant fluid is periodically sampled and tested for p24 antigen. The sensitivity of the PBMC culture is similar to the sensitivity of DNA PCR with PBMC culture detecting nearly 50% of infected infants at birth and more than 90% by 3 months of age.¹² PBMC culture is, however, technically demanding and time-consuming. Positive results may be available as soon as 1 to 2 weeks, but negative results are not reported until there has been no evidence of HIV replication for 30 days. As with DNA PCR, negative results from a single test cannot exclude infection, and positive test results presumptively indicate HIV infection but must be confirmed as soon as possible with a second HIV co-culture or DNA PCR.

3. Plasma HIV RNA

Although HIV RNA quantification has been carefully studied and validated as a prognostic marker in individuals who are already known to be HIV infected, none of the RNA tests are licensed for use in diagnosing infection, and published data are limited regarding performance characteristics when used in this manner. Because HIV RNA quantification is exquisitely sensitive and may be falsely positive in the low copy number range in exposed, uninfected individuals, a low positive test result should not be assumed to indicate infection. Repeat testing using DNA PCR or culture should be used to confirm all results. Similarly, negative RNA results in infected infants who have received ARV therapy *in utero* or postnatally can occur. Even untreated, infected individuals can have "undetectable" HIV RNA, although such a finding would be unusual in a neonate.

Some centers use HIV RNA quantification, despite the limitations, to assist in the diagnosis of infection in exposed neonates or acute retroviral syndrome. For an untreated infant, RNA tests may be more sensitive than either DNA PCR or culture, and, in most centers, the RNA test is readily available with a rapid turnaround time.¹³ If RNA PCR is to be used, *it is not acceptable as a sole diagnostic test.*

4. HIV Antigen Detection

In the past, p24 antigen detection was used by some centers. Because of sensitivity and specificity problems, it is no longer considered a reliable method and should not be used for diagnosis.

IV. HIV COUNSELING AND TESTING

RECOMMENDATIONS:

In New York State, written informed consent from the child's biological parent or legal guardian must be obtained before HIV testing can be performed in children except in certain specific circumstances, such as expedited testing, newborn screening, and follow-up PCR testing, and when testing is urgently necessary to provide medical care for a life-threatening condition. (III)

When HIV testing of a child is performed, the parents should be considered for testing as well. (III)

If a child is found to be perinatally HIV infected, his/her siblings also should be tested. (III)

If HIV infection is newly diagnosed in a woman, all of her children should be strongly considered for testing, even if they are asymptomatic. (III)

New York State Public Health Law §2504 states that “medical, dental, health and hospital services may be rendered to persons of any age without the consent of a parent or legal guardian when, in the physician’s judgment, an emergency exists and the person is in immediate need of medical attention and an attempt to secure consent would result in delay of treatment which would increase the risk to the person’s life or health.”¹⁴

A. Pre-Test Counseling

RECOMMENDATIONS:

The clinician should counsel the child’s parent or guardian or the child/adolescent with capacity to consent prior to HIV testing (see Table 2). (III)

In New York State, a minor’s right to consent for or refuse HIV testing is based on his/her capacity to understand, without regard to chronological age, what an HIV antibody test actually tests for, the implications/consequences of being HIV infected, and why he/she is at risk for HIV. (III)

The clinician should arrange for follow-up visits at the time of testing and should note in the patient’s medical record that counseling was provided and written consent was obtained when required. (III)

When rapid testing is obtained and will yield a preliminary result during the visit, the clinician should first ensure that the patient/parent is emotionally able to receive a positive result and that mental health services are available for patients receiving a positive result. (III)

Although the counseling session does not need to be lengthy, more time should be allowed for patients who need it.

TABLE 2 ELEMENTS OF PRE-TEST COUNSELING
<ul style="list-style-type: none"> • An explanation of the nature of HIV infection • Discussion about prior history of HIV test counseling • The nature and purpose of the HIV test • Information about anonymous testing options, the confidentiality of test results, discrimination that may arise from disclosure of those results, and existing legal protections • Information regarding HIV transmission and risk-reduction behaviors • Implication of a positive test result for the child and the biological mother and father • Potential benefits of early diagnosis, medical monitoring, care and treatment, including ARV therapy and other medications to prevent serious infections • Information on HIV reporting and partner notification • Risk assessment, if not already obtained. Possible elements of a risk assessment include the following: <ul style="list-style-type: none"> - information about parental illness or death from unknown causes - whether the child was born prior to routine HIV screening at birth - childhood illnesses that may be indicative of HIV infection - history of sexual abuse or assault that may not have previously resulted in an HIV test being obtained - for adolescents, see Chapter 3: <i>Identification and Ambulatory Care of Adolescents</i>

B. Obtaining Consent

In New York State, written informed consent from the child's biological parent or legal guardian must be obtained before HIV testing can be performed in children, with the following exceptions:

- Testing may be performed without consent if the test result is needed in an emergency to provide appropriate medical care to the child.
- Testing may be performed without consent in a newborn as part of the New York State Comprehensive Newborn Testing Program, which may include rapid testing at birth and/or newborn HIV antibody testing performed on all infants through Wadsworth Center and diagnostic DNA PCR testing performed at Wadsworth Center through 6 months of age.
- Testing may be performed with the consent of the child/adolescent if he/she is deemed to have the capacity to consent. A minor's right to consent for or refuse HIV testing is based on his/her capacity to understand, without regard to chronological age, what an HIV antibody test actually tests for, the implications and consequences of being HIV infected, and why he/she is at risk for HIV.

C. Post-Test Counseling

1. Counseling After a Patient Receives a Positive Test Result

RECOMMENDATIONS:

Positive HIV test results should be presented in person to the appropriate individual (patient, parent, or guardian). A clinician should not communicate results to a patient or family member by telephone or mail. (III)

Clinicians must respect an adolescent's right to confidentiality concerning HIV status. (III)

The clinician should explain the test results and should provide general information about available treatment. (III)

The clinician should discuss the implications of the HIV Reporting/Partner Notification law (see Section D: *HIV Reporting and Partner Notification*). (III)

The clinician should provide or arrange for necessary referrals for treatment and supportive services. (III)

The clinician should discuss methods of risk reduction and advise the family to inform medical personnel of the child's HIV status during any medical care visit. (III)

2. Counseling After the Patient Receives a Negative Test Result

RECOMMENDATION:

When telling a patient that his/her test result is negative, the clinician should educate the patient on how to reduce the risk of transmission in the future. (III)

The clinician should explain to the patient that the negative test result almost always means that he/she does not have HIV. However, if the patient feels that he/she has been exposed to HIV through unprotected sex (vaginal, oral, or anal sex without a condom) or by sharing needles within the last 3 months, the clinician should schedule a repeat test.

D. HIV Reporting and Partner Notification

RECOMMENDATIONS:

Since June 2000, New York State has required HIV reporting and partner notification for all confirmed positive HIV tests (unless testing occurred at an anonymous site) and HIV-related tests (available at <http://www.health.state.ny.us/nysdoh/hiv aids/hivpartner/intro.htm>). (III)

During pre-test counseling, parents/children should be informed that if their HIV test result is positive, their names will be reported to the New York State Department of Health. (III)

Parents/children should be informed during pre-test counseling that if they provide the names of sexual or needle-sharing partners, the provider is required to report these names to the State Health Department. They should also be informed that if the test results are positive, their partners will be notified that they have been exposed to HIV. (III)

All sexually active HIV-infected adolescents should be informed about the importance and benefits of notifying partners of their possible exposure to HIV. (III)

Adolescents who are undergoing HIV testing should be questioned regarding the potential for domestic violence if their partners were notified. If domestic violence is a concern, partner notification should be deferred until the risk of harm to the patient (or one close to the patient, e.g., child) is eliminated. (III)

The New York State Department of Health uses the information from HIV reporting for tracking the epidemic and for planning prevention, health care, and other services. Exceptions to the mandatory reporting include infants who undergo antibody testing as part of newborn screening or expedited testing. In addition, a woman's HIV-positive status will not be reported based on her infant's test result. Mothers tested under the expedited testing program will be reported but only after a confirmatory test has verified the preliminary positive test result. Infants born to HIV-infected women who then undergo subsequent testing will be reported if they have a positive HIV DNA PCR test result.

All sexually active adolescents should be informed about the importance and benefits of notifying partners of their possible exposure to HIV. Although patients can opt not to disclose the names of sexual contacts, they should be made aware that once they have provided the healthcare provider with contact information (past and present), the provider is required to report the names to the Health Department. Adolescents and adults who are diagnosed as HIV infected should be given available options for partner notification, including self-notification [the patient directly notifies his/her partner(s)] as well as notification through the New York State Department of Health's Partner Notification Assistance Program (PNAP) or Contact Notification Assistance Program (CNAP). Patients are not required to disclose names of partners. PNAP can be reached by providers outside of New York City at 1-800-541-2437, and CNAP can be reached by providers in New York City at 212-693-1419.

Adolescents who are undergoing HIV testing should be questioned regarding the potential for domestic violence if their partner were notified. If domestic violence is a concern, partner notification may be deferred. Further information on domestic violence screening is available through the New York State Domestic Violence Hotline (1-800-942-6906) and the New York City Domestic Violence Hotline (1-800-621-HOPE).

E. HIV Testing of Older Children and Adolescents With the Capacity to Consent

RECOMMENDATIONS:

Clinicians should be knowledgeable about New York State laws pertaining to adolescent consent and confidentiality and should educate their patients about these laws (see Chapter 3: *Identification and Ambulatory Care of Adolescents*). (III)

In New York State, older children and adolescents who are judged capable of understanding the informed consent process may give written informed consent for HIV testing. (III)

Parents cannot be informed of their child's HIV test results without the explicit consent of the child or adolescent who is deemed capable of providing consent. (III)

Ideally, HIV testing of older children and adolescents should occur in a comprehensive care setting that provides social support, ancillary services, and ongoing health care. (III)

Parents may not be informed of their child's HIV test results without the explicit consent of the child or adolescent who is deemed capable of providing consent (i.e., the provider has used his/her best judgement to determine that the patient is able to comprehend the nature and consequences of HIV testing). However, HIV test results of children and adolescents in foster care, including those children with the capacity to consent, must be transmitted to the local department of social services, foster care agency, and foster parent(s). Counselors should ascertain that information is provided at an appropriate cognitive level. If the child is determined to be HIV-infected, testing of siblings also should be discussed.

F. HIV Testing of Children in Foster Care

RECOMMENDATIONS:

Within 5 days of entering the foster care system, all children must be assessed for capacity to consent for HIV testing. If a child is determined not to have capacity to consent, an HIV risk assessment must also be completed within the first 5 days of entering foster care. Children already in foster care must be assessed for HIV risk factors at least 60 days prior to their next scheduled periodic medical examination. If it is determined that a child may have the capacity to consent, an assessment of capacity to consent must be made and documented by authorized foster care agency staff within 30 days of the child's entry into foster care. An HIV risk assessment must also be completed within this timeframe. (III)

If one or more risk factors are present, a child in foster care should be offered HIV testing, or if the child lacks capacity to consent, he/she should be tested for HIV infection. (III)

Adolescents and older children in foster care with the capacity to consent for HIV testing have the right to either consent for their own test or refuse testing. (III)

Children in foster care have a relatively high prevalence of HIV infection. All children entering the foster care system must be assessed for capacity to consent and must be given an HIV risk assessment within 5 days of entering the system. Children already in foster care must be assessed for HIV risk factors at least 60 days prior to their next required medical examination. HIV testing is recommended for any child having one or more risk factors for HIV infection. Foster care agencies must take steps to obtain the necessary legal consent for testing the child and arrange for testing within 30 days once the consent is obtained. If, after a good-faith effort, a parent cannot be located, or if parental rights have been terminated, the local commissioner of social services may grant consent for HIV testing. Adolescents and older children deemed to have the capacity to consent may grant consent. Copies of the New York State Office of Children and Family Services regulations can be obtained from the office of the local commissioner of social services.

In New York City, requests for HIV testing of children in foster care should be sent or faxed to the New York City Administration for Children's Services Pediatric AIDS Unit, where copies of the testing policy are available (phone: 212-341-8943; fax: 212-341-8972).

V. CONFIDENTIALITY OF HIV TEST RESULTS

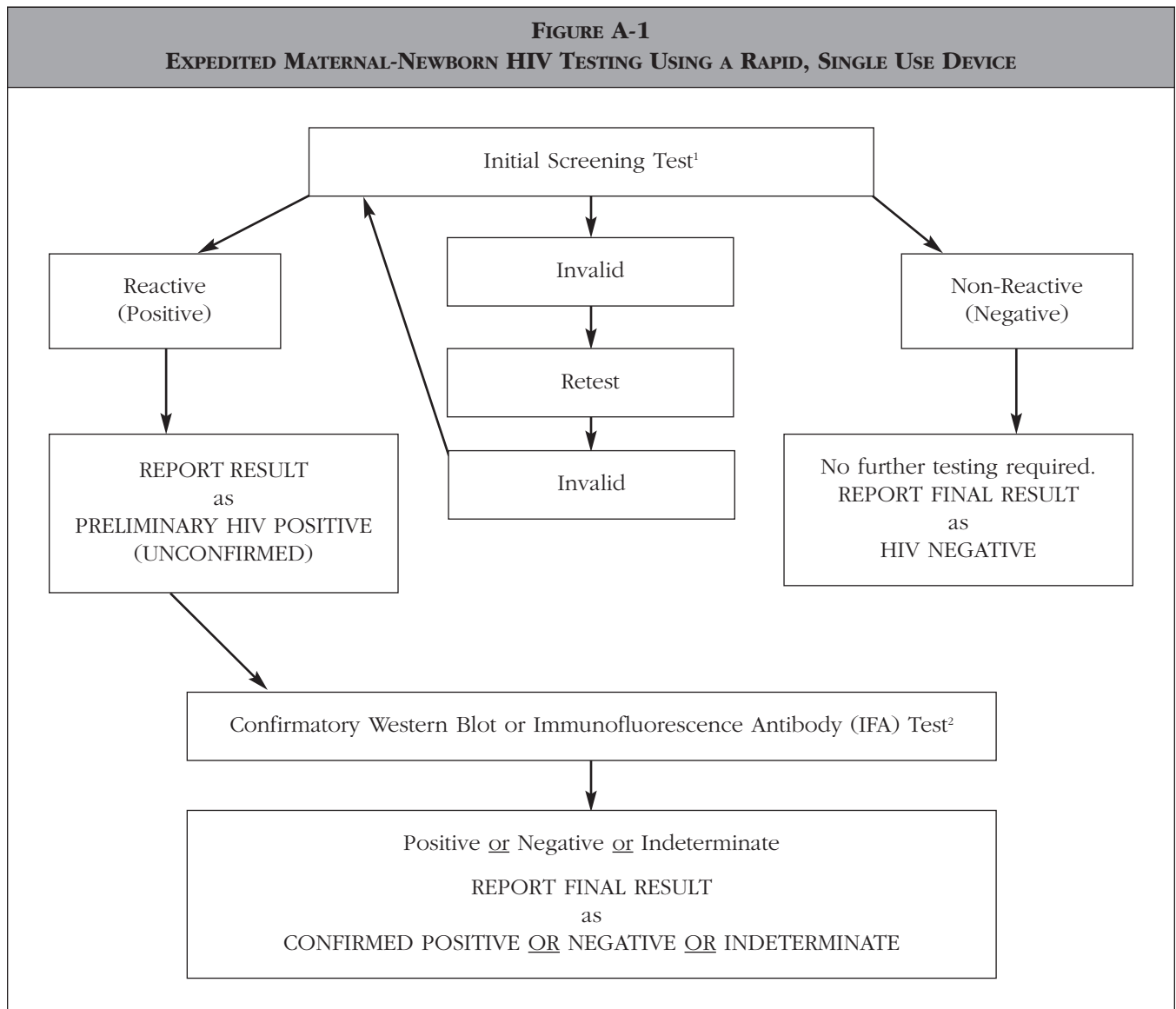
The results of HIV testing are confidential, as outlined in New York State Public Health Law, Article 27-F and in New York State Public Health Code, Part 63.

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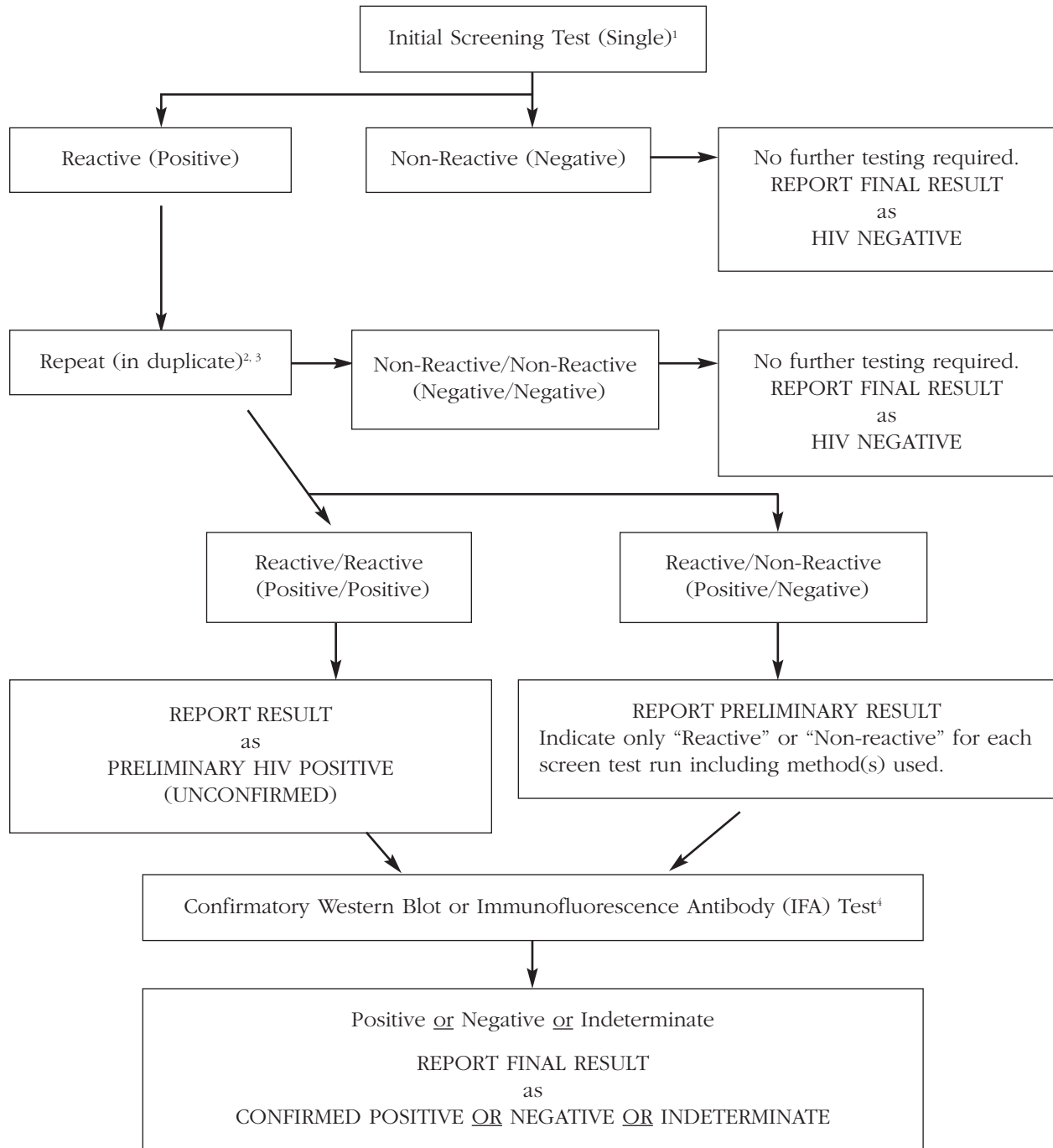
APPENDIX A

NYSDOH MATERNAL-PEDIATRIC HIV PREVENTION AND CARE PROGRAM



1. This algorithm applies to FDA-approved single use devices for rapid HIV screening, such as OraQuick, Reveal, and Uni-Gold.
2. Preliminary positives generated by combination HIV-1/2 test kits that produce negative or indeterminate results upon HIV-1 confirmatory test must be further tested with HIV-2 specific tests.

FIGURE A-2
EXPEDITED MATERNAL-NEWBORN HIV TESTING USING INSTRUMENTED METHODS



1. As of August 2004, FDA-approved screening tests for HIV using the EIA method (also known as ELISA) are available from several manufacturers; an FDA-approved test using an IFA method may be used, but is not routinely used, for screening in place of an EIA.
2. PPV can be greatly increased by re-testing with a different test, such as a second manufacturer's EIA or a rapid method.
3. The laboratory must follow the manufacturer's instructions for test performance; however, whenever an expedited result is required, the laboratory may begin at this step, with the analysis of duplicate specimens in the same run, in the interest of time.
4. Preliminary positives generated by combination HIV-1/2 test kits that produce negative or indeterminate results upon HIV-1 confirmatory testing must be further tested with HIV-2 specific tests.