

# **Perinatal Rapid HIV Testing Implementation: A Guide for Implementing Rapid HIV Testing in Hospital Labor and Delivery Units**

Developed by the Perinatal Rapid Testing Implementation  
Initiative in Illinois (PRTI<sup>2</sup>)



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A Guide for Implementing Rapid HIV Testing in Hospital Labor and  
Delivery Units**

The Perinatal Rapid Testing Implementation Initiative in Illinois (PRTII<sup>2</sup>), with funding from the Illinois Department of Public Health, was created to assist hospitals in implementing rapid HIV testing in labor and delivery units as stipulated by the Illinois Perinatal HIV Prevention Act originally passed in 2003. PRTII<sup>2</sup> developed resources for the implementation of rapid HIV testing in labor and delivery units in all birthing hospitals in Illinois. This document represents a historical guide to the implementation of rapid HIV testing that was initiated in Illinois in 2004. The materials contained within do not necessarily reflect the current laws in Illinois, nor should they be interpreted as a guide to the laws of any state other than Illinois. Please consult with the public health department in your state for individual guidance.

# **Hospital Implementation Overview**

## **Ten Steps Necessary to Implement Perinatal Rapid Testing in Your Hospital**

### **1) Arrange Hospital Key Players Meeting with Regional Coordinator**

The key players' meeting is an essential first step towards successful implementation. All areas of the hospital that will be impacted by these policies and procedures should be represented so that a fully integrated system can be put into place. Pharmacy, laboratory, hospital administration, nursing staff (L&D and Nursery), medical staff (Pediatrics and Obstetrics) and case management should be present and have reviewed their relevant portions of the manual (**Hospital Planning Guidelines-Section 2**) and the Key Players Meeting Discussion Points. A power point presentation and discussion points for this meeting are provided. The Regional Coordinator will help to facilitate this meeting (**Section 4**). The essential tasks for this group are:

- a. review requirements set forth in the your state's law
- b. finalize plan for location of testing (point of care versus laboratory)
- c. determine start date for rapid testing and set timeline for implementation of policies, procedures and templates (standing orders/consent forms/admission forms)
- d. secure CLIA waiver and develop QA plan for point of care rapid testing
- e. discuss and plan for budget considerations
- f. determine plan for ordering test kits
- g. secure pharmacy 24/7 availability of AZT (IV and syrup)
- h. set follow-up plan and referral plan for preliminary positives and exposed newborns

### **2) Review and adopt rapid testing policies and templates.**

- a. Rapid Testing Implementation Policy
- b. Rapid Testing Consent Template
  - 3 versions (Maternal Consent / Infant Refusal Form / Combined)
- c. HIV Status Identification Template
  - can use template or modify current admission forms
  - review and revise your hospitals L&D and newborn nursery admission forms to insure space to document maternal HIV status
- d. Rapid Testing Log / QA Data Form
  - must use this version to maintain consistent data collection

### **3) Review and adopt standing L&D/Nursery admission orders.**

Standing orders are important to enable initiation of the rapid testing process upon arrival to L&D or immediately after delivery; *rapid* testing is key.

- a) L&D order template: "*counsel, consent and conduct rapid HIV test on arrival to L&D if undocumented prenatal HIV test*".
- b) Newborn nursery order template: "*conduct rapid HIV test on newborn as soon as possible after delivery if undocumented maternal HIV status, unless mother refuses in writing*".

### **4) Notify nursing, medical and administrative staff of policy and procedure changes**

Notification and buy-in of staff is important for uniform and integrated implementation simultaneously across all departments. RN / MD memos are provided

**5) Arrange L&D and Nursery staff trainings with Regional Coordinator**

In-hospital training will be provided for as many L&D/nursery staff as possible. Remaining staff, new hires and on-going proficiency will utilize self-directed training packets with nurse manager oversight. Training of all staff must be completed by rapid testing start date.

**6) Set a formal start date for L&D/Nursery rapid HIV testing and assemble resources**

Insure coordination across departments for complete and full implementation. Plan to start formal rapid testing at end of 2-4 week HIV Status identification period on L&D. Finalize AZT (IV & syrup) 24/7 availability with pharmacy. Order rapid test kits through the hospital lab. Finalize plans for referral for specialized HIV Care and Case Management / Social Services in your area and plan for follow up of Western Blot results for identified preliminary HIV positive women and exposed infants.

**7) Begin maternal HIV status identification data collection in L&D: 2-4 week period prior to starting formal rapid testing on L&D/newborn nursery**

- a. Use HIV Status Identification Template or your hospital's modified admission form for data collection (collect HIV status on every L&D patient, try to determine barriers to having documented HIV status for every patient, address barriers).
- b. Set up point of care rapid testing station on L&D/Newborn Nursery (**Section 2, p19**) Need counter space with good lighting, space to store test kits (majority of test kit inventory can be stored in lab)
- c. Set up HIV rapid test log at rapid testing station – data collection must be completed for every pregnant patient on L&D with undocumented HIV status
- d. Insure all staff not previously trained complete self-directed rapid testing training by L&D rapid test start date

**8) Initiate rapid HIV testing in L&D and Nursery units**

Insure all departments (pharmacy, lab, social work, ob, pediatrics, neonatology, and nursing) ready for formal start date.

**9) Initiate rapid HIV testing surveillance data collection**

Use monthly summary data collection sheet to summarize data from rapid test logs; summary data sheets will be submitted monthly to IDPH through the PRTII Regional Coordinator. Fax or email the monthly summary sheet to your Regional Coordinator. Any preliminary positive data forms should also be sent to the Regional Coordinator. A permanent mechanism for transmission of data to IDPH is pending.

**10) Arrange follow-up site visit with Regional Coordinator**

Review progress of implementation. Review surveillance/data collection. Identify problem areas, need for intervention/education and improvement goals / timeline.

# Regional Coordinator Responsibilities Hospital Implementation Plan

## 1. Conduct **Perinatal Network Training and Implementation**

- a. Train and review hospital implementation with the nurse educators/managers at the network meetings.
- b. Distribute implementation materials (contained in PRTII Resource Binder and accompanying CD)
  - a. PRTII Executive summary
  - b. Perinatal HIV Law
  - c. AIDS Confidentiality Act
  - d. One page legal fact sheet on acceptable documentation of HIV status
  - e. Draft Hospital Implementation Policy
  - f. Memo Template for Distribution to Staff
  - g. Training slide show
  - h. HIV Consent Template/refusal form
  - i. Flip Chart for counseling and testing (separate material)
  - j. HIV Status Identification - HIV identification Template Form (revised triage, L&D log/admission and newborn form)
  - k. Rapid Testing Log
  - l. Summary Data Collection Sheet
  - m. Positive Patient Packet - (IV AZT administration policy – mom & baby, care recommendations, nursery medication administration, websites, etc)
  - n. Letter to Ob/Peds providers
  - o. Laminated flow chart

## 2. Conduct **Hospital Specific Implementation and Training**

- a. Send introductory hospital letter and information packet to hospital CEO in order to obtain buy-in.
  1. Provide information on the Illinois Perinatal Prevention Act, documentation and availability of HIV test results, laboratory considerations for Point of Care Testing, and information about antiretroviral availability.
  2. Describe timeline for implementation and available training resources
- b. Contact Hospital OB or Mother Baby Nurse Manager (identified by Perinatal Network Regional Administrators) to be liaison for PRTII
  1. Review Hospital Needs Assessment summary
  2. Review Perinatal Rapid HIV Counseling /Testing Implementation Policy and

determine hospital-specific changes

3. Examine hospital flow of patients, blood, information and work areas

c. Organize and meet with hospital based “Key Players Working Group” with representatives from

Administrators from: L&D, Postpartum, Nursery, NICU and ID

Physician OB staff

Nursing Staff Labor& Delivery, Postpartum, Nursery

Midwifery Staff

OB Nurse Educator

Laboratory/Point of Care Contact/CLIA

Phlebotomy Liaison

Pharmacy Administrator

Risk Manager

Forms

Information System Liaison

Social Workers

1. Discuss or show PowerPoint PRTII presentation for baseline information

2. Distribute executive summary to group

3. Obtain feedback and record barriers to implementation on Key Players System Questionnaire.

4. Get commitments from each representative regarding their responsibilities toward policy implementation

5. Visit each area to ensure feasibility of implementation

6. Review piloting of HIV identification

7. Determine responsibility and location of rapid testing (i.e. point-of-care versus laboratory)

d. Institute HIV determination using documentation form or revision of L&D admission log. Track documented status of HIV for 4 weeks and evaluate weekly to determine barriers (i.e. record availability and insufficient documentation of maternal HIV status at L&D)

e. Conduct trainings of all labor and delivery and newborn staff designated to perform Rapid Testing (Regional Coordinator and MATEC/PRTII trainers obtain consent and will assist with two in-hospital trainings)

f. Organize, as needed, physician presentations (OB monthly meeting, grand rounds, and Morbidity/Mortality rounds)

g. Set start date for rapid testing after all trainings and form approvals are completed.

**3. Schedule Follow-Up Site Visit to Review** hospital implementation adherence and data

collection/surveillance within perinatal network

#### **4. Secure Hospital System Sustainability**

- a. Provide self-directed training material/resource binder
- b. Continued QA and data collection per statewide perinatal directives
  1. Incorporate monthly review of Rapid HIV testing practices into standing OB meetings
  2. Monthly/quarterly presentations of data sheet at Perinatal Management meetings. Collect monthly summary data sheets, keep copy and send to IDPH. Collect preliminary positive data collection forms; submit to IDPH with no identifiers.
  3. Track at state level; provide feedback to hospitals that fall below statewide perinatal HIV testing target goals
  4. Revise operations/policy as needed



# **Hospital Planning**

To: Chief Executive Officers  
Director of Obstetrical Services  
Director of Pediatrics and Neonatology Services  
Director of Women's Services

From: Eric E. Whitaker, M.D., M.P.H.  
Director, Illinois Department of Public Health

Re: Perinatal Rapid Testing Implementation in Illinois

Date:

The new Illinois HIV Prevention Act, signed by Governor Blagojevich, is nearing implementation. The Act mandates that 1) all women in the state of Illinois must be counseled and offered an HIV test as early in pregnancy as possible; 2) HIV counseling and test results must be documented in the prenatal, labor & delivery and newborn nursery medical record; 3) **all labor and delivery and newborn nursery units must provide the opportunity for rapid HIV testing to any pregnant woman who presents for delivery without documented HIV status**; and 4) if a woman declines HIV testing, her newborn will have a rapid HIV test unless the patient requests, in writing, that the infant not be tested.

For pregnant women who arrive in labor without a documented HIV test, rapid tests are a necessary safety net. **When a positive HIV result is obtained, the more quickly the result is identified and antiretrovirals are administered, the more likely HIV transmission to the infant can be prevented.** Intervening as late as labor can still reduce transmission by over 50%.

While this new law provides the opportunity to essentially eliminate pediatric HIV disease in Illinois, it creates a challenge for us all. In order to equip each hospital with the necessary tools to comply with the new Illinois HIV Prevention Act, **the State of Illinois Department of Public Health has created the Perinatal Rapid Testing Implementation in Illinois (PRTII) initiative.** PRTII will coordinate rapid testing implementation in every labor & delivery unit and newborn nursery in Illinois.

A PRTII Regional Coordinator will be contacting your hospital to initiate staff training and assist with implementing policies and procedures for rapid HIV testing. Perinatal nurse managers and educators from every hospital will participate in a Regional Rapid Testing Training Session in each Perinatal Network this summer. Training and rapid test training kits

will be provided for Labor and delivery and newborn nursery staff at each hospital to ensure capability for point of care rapid testing.

Implementation will require the participation of staff from many areas including labor and delivery, nursery, pharmacy and laboratory services. In addition to staff training, **key issues to be addressed include:**

- 1) **reducing barriers to consistent access to prenatal HIV results on Labor & Delivery** (target goal > 90% patients, documented prenatal HIV test available on arrival to L&D)
- 2) **documentation of maternal HIV status** on L&D and newborn nursery admission forms
- 3) **CLIA-waived point of care rapid HIV testing** in labor and delivery and the newborn nursery
- 4) **24-hour availability of antiretroviral medications**
- 5) **follow-up / referral plan** for women with preliminary positive rapid test results and exposed infants

Attached are several appendices that will allow your hospital's planning committee to begin to address the necessary steps for successful initiation of perinatal rapid HIV testing. Your contact person for rapid testing can reach the PRTII project coordinator, Yolanda Olszewski at 312-560-1451 ([yonodey@ameritech.net](mailto:yonodey@ameritech.net)) for more information and to schedule an initial meeting. Thank you for your attention to this important initiative.

Enclosures:

1. Perinatal Rapid Testing Implementation in Illinois
  - a. Executive Summary
  - b. Rapid Testing Implementation Resources Provided
2. Illinois HIV Perinatal Prevention Act
3. L&D / Nursery considerations
4. Pharmacy considerations
5. Lab Considerations

<b>Executive Summary</b> <b>Perinatal Rapid Testing Implementation in Illinois (PRTI<sup>2</sup>)</b>
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**Goal**

To implement perinatal rapid HIV testing in every labor & delivery unit and newborn nursery in the state of Illinois. To use HIV Rapid Testing technology and the recently passed Illinois Perinatal HIV Prevention Act as opportunities for reducing HIV perinatal transmission in Illinois.

1. To carry out a state needs assessment to identify barriers to implementation of perinatal rapid HIV testing.
2. To develop and implement standard policy and procedures and best practice guidelines for rapid HIV testing in labor & delivery units and newborn nurseries.
3. To develop and implement hospital specific labor & delivery, postpartum, newborn nursery systems for rapid HIV testing.
4. To monitor and evaluate statewide implementation.

**Rationale**

Complete and effective statewide implementation of Perinatal Rapid HIV Testing is an essential step towards eliminating pediatric HIV in Illinois. This goal is obtainable for the first time given the confluence of opportunity (new state law and accurate rapid test), need (incomplete prenatal HIV testing is leading to preventable pediatric HIV), and proven, effective interventions (if maternal HIV status is known, effective treatment in labor, delivery and the newborn period can prevent perinatal transmission of HIV).

The *Illinois Perinatal HIV Prevention Act* states that all pregnant women in Illinois will be counseled and offered an HIV test. HIV test results will be documented in the prenatal, L&D and newborn pediatric chart. If there is no documented maternal HIV status on arrival to L&D, the patient will be offered a Rapid HIV test. If maternal status is not known at delivery, the newborn will be given a rapid HIV test unless the mother declines.

The *FDA approved rapid HIV test* can be performed at point of care using a blood drop from a finger stick. A state counseling and consent template form can be used. The test can be conducted easily by nurses, physicians or other health care providers and results are available in 20 minutes. The test is inexpensive and highly reliable with sensitivity and specificity slightly better than the standard ELIZA HIV test now used.

In Illinois currently approximately 30% of pregnant women arrive in labor & delivery not knowing their HIV status. Of the approximately 370 HIV infected infants born in this country last year, 40% were born to women who did not know their HIV status prior to delivery. We know that without appropriate therapy in labor 25% of HIV women will transmit HIV to their infants, with appropriate therapy <2% will transmit HIV. Since New York state implemented rapid testing, prenatal HIV testing in New York has increased from 65 to 95% and the perinatal HIV transmission rate has been reduced from 10.9 to 3.9%.

### **Structure and Collaborators**

The Illinois Department of Public Health

State of Illinois Perinatal HIV Taskforce

State of Illinois Regionalized Perinatal Network Administrators

MATEC (Midwest AIDS Training and Education Center)

PRTI<sup>2</sup> (Perinatal Rapid Testing Implementation in Illinois)

- Mardge Cohen, MD, Pat Garcia MD, MPH, Ann Bryant MD, MSc  
Yolanda Olszewski, MPH, MSc, Ram Yogev, MD
- PACPI (Pediatric AIDS Chicago Prevention Initiative) staff

### **Work Plan**

- 1) State Needs Assessment ► Survey of all hospitals in the state regarding current practice around perinatal HIV testing and documentation and staff training needs. Focus groups to identify and correct barriers to rapid testing implementation involving key staff in 7 hospitals geographically dispersed and representative of different sized hospitals around the state.
- 2) Preliminary Implementation Plan ► Draft training material, counseling & consent state templates and the preliminary state implementation model.
- 3) Pilot Projects ► One downstate and one in the Chicago area to test the preliminary implementation plan and materials.
- 4) Finalize Implementation Plan ► Statewide implementation and evaluation plan finalized based on findings from the state needs assessment and pilot projects.
- 5) Implementation ► State Perinatal Network Administrators and 4 funded Regional Perinatal Rapid Testing Coordinators will implement hospital specific protocols and work with MATEC to provide hospital specific training.
- 6) Evaluation ► Evaluation of implementation process. Perinatal HIV testing surveillance / QA incorporated into state perinatal system.

### **Timeline**

- 1) Spring 2004
  - State Needs Assessment and Preliminary Implementation Plan
- 2) Summer 2004
  - Pilot Projects (2) and Final Implementation Plan
- 3) August 2004 – July 2005
  - Rapid Testing Implementation and Evaluation Statewide

## **Resources Provided to Illinois Hospitals**

### **1) Implementation Coordination:**

PRTII Regional Coordinators will assist Nurse Managers with hospital specific implementation via site visits and telephone support.

### **2) Rapid Testing Resource Binder and CD:**

Includes all implementation, technical assistance, training material

### **3) Implementation Packets:**

- a) Rapid Testing Policy Template
- b) Counseling Flip Chart /Consent Templates
- c) HIV Status Identification Templates
- d) HIV test result Documentation Fact Sheet
- e) Rapid Testing Logs
- f) AZT Treatment Protocols
- g) Labor and Newborn Management of HIV + Patients
- h) Positive Results Protocol: counseling, confirmation testing, follow- up, and referral

### **4) Technical Assistance:**

- a) Laboratory considerations for Point of Care testing
  - Information on CLIA Waiver
  - Rapid Testing QA Plan: recommended use of controls
  - System ordering OraQuick Rapid Test Kits at bulk rate
  - Confirmatory testing preliminary positive with Western Blot
- b) Pharmacy consideration regarding AZT availability
  - Efficacy, protocols, cost, side-effects, product return policy

### **5) Staff Training:**

- a) Regional Training for nurse manager/educators (2hrs)
- b) In-Hospital Formal Staff training sessions (1 hr)
- c) Self-Directed Staff Training materials (forthcoming video, packet, test)
  - staff that can not attend formal staff training, new staff and yearly staff competency training
  - proficiency check list completed with nurse educator
- d) Rapid Test Kits and Controls provided for point of care proficiency training for all staff during implementation period.

## L&D / Nursery Considerations

- Key steps to work on prior to implementation
- **Maximize number of patients with documented HIV status available at time of admission to labor and delivery**
  - target goal > 90% patients HIV status known at admission
  - work with clinics / prenatal care providers to improve testing rates, documentation and timely transfer of prenatal records
  - create a system to ensure access to prenatal HIV results regardless of the gestational age at which patients present to labor and delivery (example: copy of all prenatal lab results sent to L&D after first prenatal visit)
- **In accordance with the Illinois Perinatal HIV Prevention Act (and essential for identifying who needs a rapid HIV test) ensure that labor and delivery admission forms and newborn nursery admission forms have a space to document maternal HIV status**
  - start forms revision process
  - consider need to document both prenatal maternal HIV status and (if HIV status unknown) preliminary rapid HIV test result
  - consider documentation of counseling along with test acceptance or refusal
  - template admission forms are available
- **Revise standing admission order templates**
  - add “counsel, consent and conduct rapid HIV test for undocumented maternal HIV status” to standing L&D admission orders
  - add “conduct rapid HIV test for undocumented maternal HIV status unless mother declines in writing” to newborn nursery admission orders
- **Allocate space on labor and delivery unit and newborn nursery for point of care rapid testing**
  - potential location is counter space in “dirty utility”
- **Name a point of care rapid testing contact person in your hospital**
  - will work directly with your Rapid Testing Regional Coordinator to coordinate implementation and training

# Pharmacy Considerations for 24/7 AZT Availability

Generic: ZIDOVUDINE

Brand: Retrovir (Manufacturer: Glaxo-SmithKline)

## Efficiency of Treatment

- The risk of maternal to infant HIV transmission is approximately 25% with no antiretroviral treatment<sup>1</sup>
- Transmission rates can be reduced by as much as 50% (to 9-13%) if AZT treatment begins during the intrapartum (labor) or neonatal period<sup>2-3</sup>
- Transmission rates can be reduced to <2% with antiretroviral administration in the antepartum, intrapartum and neonatal periods and appropriate obstetric interventions<sup>1</sup>

Protocol	Regimen
Labor	During labor, intravenous administration of ZDV in a 1-hour initial dose of 2 mg/kg body weight, followed by a continuous infusion of 1 mg/kg body weight/hour until delivery.
Newborn	Oral administration of ZDV to the newborn (ZDV syrup at 2 mg/kg body weight/dose every 6 hours) for the first 6 weeks of life, beginning as soon after birth as possible but at least by 8-12 hours after birth. (Note: intravenous dosage for infants who can not tolerate oral intake is 1.5 mg/kg body weight intravenously every 6 hours.) Preterm infants should have a dose adjustment. <34 wks: 1.5 mg/kg Q12 hrs birth to 2 wks, 2mg/kg Q8 hrs from age 2wks – 6 wks.

Public Health Service Task Force Recommendations for the Use of Antiretroviral Drugs in Pregnant Women Infected with HIV-1 for Maternal Health and for Reducing Perinatal HIV-1 Transmission in the United States June 23, 2004, <http://aidsinfo.nih.gov/guidelines/perinatal>

	IV (Vial containing 200mg in 20ml solution)	Syrup (240 ml) bottle	Tablets (300mg) bottle of 60	Capsules (100mg) bottle of 100
<b>Cost*</b>	Hospital cost \$18.00	Hospital cost \$41.00	Hospital Cost \$301.63	Hospital Cost \$167.57
<b>Average Shelf-life</b>	Diluted for administration: 8 hrs room temp, 24 hrs refrigeration Vial: 36 months	36 months	36 months	48 months
<b>Side-effects</b>	<ul style="list-style-type: none"> <li>• <b>Most serious reactions include:</b> anemia, neutropenia and leukopenia, when used over a significant period of time.</li> <li>• <b>Common:</b> Anemia, neutropenia, leukopenia, dizziness, nausea, raised blood levels of liver enzymes and bilirubin, myalgia, malaise.</li> <li>• <b>Less Common:</b> Thrombocytopenia and pancytopenia with marrow hypoplasia, dyspnea, myopathy</li> </ul> Rare: Urinary frequency, cough, cardiomyopathy, insomnia, aplastic anemia • <b>Short term use minimal side effects</b>			

Glaxo-SmithKline Electronic Medicines Compendium 2004 (Retrieved at: [http://www.gsk.com/products/retrovir\\_uk.htm](http://www.gsk.com/products/retrovir_uk.htm))

1. Lampe, C., Branson, B., Burr, C., et al. (2004) Centers for Disease Control Rapid HIV-1 Antibody Testing during Labor and Delivery for Women of Unknown HIV Status: A Practical Guide and Model Protocol
2. Wade, A., Birkhead, S., Warren, L. et al. (1998) Abbreviated regimen of zidovudine prophylaxis and perinatal transmission of the human immunodeficiency virus. *New England Journal of Medicine*, 339, 1409-14.
3. Guay, L., Musoke, P., Fleming, T. et al. (1999) Intrapartum and neonatal single-dose nevirapine compared with zidovudine for prevention of mother-to-child transmission of HIV-1 in Kampala, Uganda: HIVNET 012 randomized trial. *Lancet*, 354, 795-802.



## The Challenge

### The Challenge

- 24/7 availability of IV AZT and AZT syrup for every L&D / nursery unit
- Rapid pharmacy response to positive rapid HIV test on L&D
- Protocol for nursing staff access to AZT if 24/7 pharmacists not available in hospital

**\*AZT Costs** - per Illinois Level III Hospital Pharmacy approximated cost 6/04

<b><u>70kg woman / 6 hour labor</u></b>	<b><u>Newborn</u></b>
Dose = 2mg/kg loading dose, 1mg/kg/hr maintenance	Dose = 2mg/kg Q 6 hrs
<b>Approximately 500 mg IV dose</b>	<b>10 mg / dose</b>
= \$45 hospital cost	= \$0.17 hospital cost
	<b>12 doses (4 doses/day x 3 days)</b>
	= \$2.04 hospital cost

## Refund Available if AZT Expires

### **Information provided directly from Glaxo-SmithKline Pharmacist (888-825-5249)**

- Syrup sold in 8oz (240ml) bottle. Each teaspoon=50mg=5ml Approximately 48 doses/bottle
- Hospitals have contracts with Glaxo-SmithKline, cost varies per state and institution
- Those facilities that purchase Retrovir / AZT through Glaxo-SmithKline wholesalers who have products that expire can return product and receive credit for purchase price. This is done so by, the “Return Goods Policy” These can be sent from the facilities to:

Return Capital Returns Capone  
4066 N. Port Washington Road  
Milwaukee, WI 53212  
800-950-5479

## Point of Care Perinatal Rapid HIV Testing

*In most cases is superior to lab based testing in the perinatal setting*

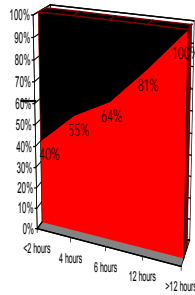
### 1) Point of care has faster turnaround.

#### Turnaround Time for Rapid HIV Testing Results

*CDC. Rapid Point of Care Testing for HIV-1 During Labor and Delivery – Chicago IL, 2002; MMR, Sept 12, 2003*

	Median	Range
Point-of-Care	45 minutes	20-120 minutes
Laboratory Based	120 minutes	75-300 minutes

### 2) Patients with no prenatal care on average deliver quickly after arrival to L&D. (Patients without prenatal care are the most at risk group for unknown HIV status)



#### Patients without PNC

patients delivering over time after admission

N = 557 deliveries to women without PNC  
6 L&D units in Chicago (34 pts missing data)  
*HRSA/SPINS MCH/HIV Integration Project, 1998, Chicago*

Delivered

### 3) A faster test result is the key to prevention of perinatal transmission.

40% of women with no prenatal care deliver in less than 2 hours. Transmission of HIV from mom to baby can be cut in half by completing a rapid HIV test on admission, receiving point of care test results on average in 45 minutes and starting AZT immediately for a positive result. Point of care testing has the same sensitivity and specificity as lab based testing, but on average point of care is almost 3 times faster.

Point of care rapid HIV testing is recommended in the perinatal setting because the faster a positive HIV result is identified for a laboring woman, the more quickly AZT can be started and therefore the more likely the woman will not transmit HIV to her baby.

**4) Each hospital must decide how it can best provide rapid test results.**

Whether point-of-care or laboratory-based testing is used, rapid results and rapid intervention are the goals.

# General and Laboratory Considerations: Rapid HIV Tests Currently Available in the United States

Rapid HIV tests are simple to use and require little or no specialized equipment. They make it possible to provide test results at the time the test is done. Six rapid HIV tests approved by the U.S. Food and Drug Administration (FDA) are commercially available for use in the United States (listed in chronological order of their FDA approval dates):

1. OraQuick Rapid HIV-1/2 Antibody Test
2. Reveal G3 Rapid HIV-1 Antibody Test
3. Uni-Gold Recombigen HIV Test
4. Multispot HIV-1/HIV-2 Rapid Test
5. Clearview HIV 1/2 Stat Pak
6. Clearview Complete HIV 1/2

Test Kit Name	Manufacturer	Specimen Type	CLIA Category	Shelf Life
OraQuick Advance Rapid HIV-1/2 Antibody Test	<a href="#">OrasureTechnologies, Inc</a> ■	Whole Blood, Oral Fluid	Waived	6 months
		Plasma	Moderate Complexity	
Reveal G3 Rapid HIV-1 Antibody Test	<a href="#">MedMira, Inc.</a> ■	Serum, Plasma	Moderate Complexity	1 year
Uni-Gold Recombigen HIV Test	<a href="#">Trinity BioTech</a> ■	Whole Blood	Waived	1 year
		Serum, Plasma	Moderate Complexity	
Multispot HIV-1/HIV-2 RapidTest	<a href="#">Bio-Rad Laboratories</a> ■	Serum, Plasma	Moderate Complexity	1 year
Clearview HIV 1/2 Stat Pak	<a href="#">Inverness Medical Professional Diagnostics</a> ■	Whole Blood	Waived	2 years
		Serum, Plasma	Moderate Complexity	
Clearview Complete HIV 1/2	<a href="#">Inverness Medical Professional Diagnostics</a> ■	Whole Blood, Serum, Plasma	Waived	2 years

\*Manufacturer has applied for waiver for use with whole blood.

## Requirements for Performing Rapid HIV Tests

Any organization that performs a rapid HIV test in order to provide results to patients is considered a laboratory under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). All laboratories must comply with the regulations of the CLIA program and with applicable state requirements. (For more information on CLIA, which is administered by the Centers for Medicare & Medicaid Services (CMS), and a list of laboratory contact persons in each state, visit the [CMS CLIA Web site](#). An organization can either apply for its own CLIA certificate or, if authorized by CMS, make arrangements to be included with a CLIA-certified laboratory under a multiple-site exception.

The sale of rapid HIV tests is restricted to clinical laboratories that have an adequate quality assurance program and where persons who use the test will receive and use the instructional materials provided with the tests. The FDA also requires that persons tested with the rapid tests receive the "Subject Information" pamphlet provided with the test. Details about other restrictions that apply to the rapid HIV tests are outlined in the package inserts provided with the test kits.

Currently available rapid HIV tests are either "waived" or [categorized](#) as "moderate complexity" under the CLIA program. CLIA requirements for laboratories differ depending on the category of the test.

### Waived Testing

OraQuick is a waived test when it is used with whole blood or oral fluids. Uni-Gold and Clearview HIV 1/2 Stat Pak are waived tests when used with whole blood. The manufacturer of Clearview Complete HIV 1/2 test has applied for a CLIA waiver.

For waived tests, there are no federal requirements for personnel, quality assessment, or proficiency testing. Waived tests can be done in traditional laboratories or clinical settings and also in settings such as doctors' offices, HIV counseling and testing sites, mobile vans, and health fairs. To perform waived tests, an organization must obtain a certificate of waiver from the CLIA program (or, if authorized by CMS, be included with a CLIA-certified laboratory under a multiple-site exception) and follow the manufacturer's instructions for the test procedure. For laboratories that plan to perform waived testing, more information on CLIA requirements is outlined in the [CLIA Certificate of Waiver Fact Sheet](#) and at the [CDC CLIA Web site](#). CDC also has developed guidelines on [quality assurance practices](#) for laboratories planning to use waived HIV rapid tests.

### Moderate Complexity Testing

Reveal and Multispot are categorized as moderate complexity tests. OraQuick is categorized as moderate complexity when used with plasma. Uni-Gold, Clearview HIV Complete HIV 1/2, and Clearview HIV 1/2 Stat Pak are categorized as moderate complexity when used with serum or plasma.

A laboratory that performs moderate complexity tests must register with the CLIA program and meet specific CLIA standards for personnel, quality assessment, proficiency testing, and inspections. For organizations that plan to perform moderate complexity testing, more information on CLIA requirements and the steps necessary to obtain a certificate for moderate complexity testing are outlined in the [moderate complexity overview section of the CDC](#)

[CLIA Web site.](#)

## Summary of the Testing Procedures

### OraQuick Advance Rapid HIV 1/2 Antibody Test

[The OraQuick test](#) is approved for use with whole blood specimens obtained by fingerstick or by venipuncture, with oral fluid specimens, and with plasma. It is intended for use at point of care, in medical and nonmedical settings. However, it can also be performed in a laboratory after the specimen has been obtained.

To conduct the test, place a vial of developer solution in the plastic stand. The reusable stand holds the test device at the correct angle to ensure accurate test results. When testing a fingerstick specimen, clean the fingertip with alcohol and prick the fingertip with a lancet (needle) to get a small drop of blood. The blood is collected with a specimen loop and transferred to a small plastic vial containing a premeasured volume of developing solution, into which the sample is mixed. The testing process is the same for whole blood or plasma obtained by venipuncture. For whole blood, insert the specimen loop into the tube of blood after the tube has been inverted to ensure that the blood is thoroughly mixed. For plasma, first centrifuge the blood to separate the blood cells from plasma, and insert the specimen loop into the plasma. Then insert the specimen loop into the test vial and mix. Collect oral fluid specimens by using the absorbent pad on the end of the test device to swab the outer surface of the upper and lower gums. Then insert the test device into the test vial. Test results must be read no sooner than 20 minutes, but no later than 40 minutes, after the OraQuick device is added to the developer solution.

[The test result](#) is read directly from the OraQuick device.

- If 1 reddish band appears at the control (C) location the test result is negative for HIV antibodies.
- If 2 reddish bands appear, one at the control (C) location and one at the test (T) location, the test is "reactive" (that is to say, the test result is preliminary positive for HIV-1 or HIV-2 antibodies).
- If no band appears at the C location, if any bands appear outside the C or T locations, or if a pink-red background appears in the device window, the test is invalid and must be repeated.

The OraQuick test includes an internal control that verifies that specimen has been added and that the test has been run correctly. Positive and negative external controls must be run by each new operator before performing testing on patient specimens, whenever a new lot of test kits is used, if the conditions of testing or storage (e.g., temperature) fall outside the range recommended by the manufacturer, and at periodic intervals specified in the laboratory's quality assurance program. External controls are not included with the test kits and must be ordered separately from the manufacturer.

Shelf Life of Kits: 6 months from data of manufacture if stored at room temperature

Shelf Life of Controls: 1 year unopened or 8 weeks after opening if refrigerated

For more information on the OraQuick test, see the test kit [package insert](#)  or visit the [manufacturer's Web site](#). 

### Reveal G3 Rapid HIV-1 Antibody Test

[The Reveal G3 test](#) is intended for use as a point-of-care test, but it requires some laboratory equipment. Positive and negative external controls (supplied with the test) must be reconstituted with buffer solution. These control reagents, each sufficient for 5 tests, can be stored refrigerated for up to 7 days after they are reconstituted.

To do the test, draw a blood specimen from a vein and centrifuge the specimen to separate the blood cells from the serum or plasma. Place a buffer solution in the test cartridge, and allow it to be absorbed. Add the serum or plasma specimen to the test cartridge and allow it to be absorbed. Then place the InstaGold cap in the cartridge and add 12 drops of buffer. Then remove the cap and read [the test result](#) directly from the cartridge. An additional 3 drops of buffer may be added to clarify the test results

- A red band on the test cartridge indicates the test result is "non-reactive," that is, negative for HIV-1 antibodies.
- A red dot with a red band on the test cartridge indicates the test result is "reactive," that is, preliminary positive for HIV-1 antibodies.
- Absence of the red band on the test cartridge after the test has been run, or a pinkish-red background throughout the window of the cartridge indicates that the test is invalid and must be repeated.

Unlike the Reveal test initially approved by the FDA, the Reveal G3 test contains an internal procedural control that verifies that the specimen has been added and the test has been run correctly. External controls (known HIV-positive and -negative specimens supplied with the test kit) must be run by each new operator before performing testing on patient specimens, whenever a new lot of test kits is used, if the conditions of testing or storage (e.g., temperature) fall outside the range recommended by the manufacturer, and at periodic intervals specified in the laboratory's quality assurance program.

Shelf Life: 12 months from date of manufacture if stored at room temperature.

For more information on the Reveal G3 test, see the test kit [package insert](#)  or visit the [manufacturer's Web site](#). 

### Uni-Gold Recombigen HIV

[The Uni-Gold test](#) is a single-use rapid test for the detection of HIV-1 antibodies in plasma, serum, or anticoagulated whole blood obtained by fingerstick or venipuncture. It is intended for use as a point-of-care test.

To conduct the test, draw an adequate specimen (serum, plasma, or whole blood) to the first gradation on the pipette supplied with the kit, or obtain a fingerstick blood specimen with the pipette supplied for this purpose. Hold the pipette vertically over the sample port and add 1 drop of specimen. Add 4 drops of the wash solution from the dropper bottle to the sample port. Set timer for 10 minutes..

[The test result](#) is read directly from the device 10 to 12 minutes after the specimen is added.

- A reddish line at the “control” region with no line at the “test” region indicates that the test is negative for HIV-1 antibodies.
- A reddish line of any intensity at both the “test” and “control” regions indicates the test is “reactive”, that is, preliminary positive for HIV-1 antibodies.
- No line at the “control” region (irrespective of a line forming at the “test” region) or lines not adjacent to the respective regions indicate the test is invalid and must be repeated

The Uni-Gold test includes an internal control that indicates whether the test is functioning correctly. However, the formation of the control line on the Uni-Gold test does not validate that the specimen has been added to the test. Consequently, a test with no specimen added may appear the same as a test with a negative result (that is, a band in the control region and no band in the test region). When testing whole blood, you must observe the red color at the specimen sample port to validate that specimen was added. Positive and negative external controls should be run by each new operator before performing testing on patient specimens, whenever a new lot of test kits is used, if the conditions of testing or storage (e.g., temperature) fall outside the range recommended by the manufacturer, and at periodic intervals specified in the laboratory’s quality assurance program. External controls are not included with the test kits and must be ordered separately from the manufacturer. The controls require refrigeration and can be stored for 21 days after they are opened.

Shelf Life of Kits: 1 year from date of manufacture if stored at room temperature

For more information on the Uni-Gold test, see the test kit [package insert](#)  or visit the [manufacturer’s Web site](#) .

### Multispot HIV-1/HIV-2 Rapid Test

[The Multispot test](#) is a single-use rapid test that detects and differentiates circulating antibodies to HIV types 1 and 2 in fresh or frozen human serum and plasma. It has been approved by FDA to differentiate HIV-1 from HIV-2 antibodies. Multispot requires a refrigerator for the reagents and some laboratory equipment for processing and diluting the specimen.

To conduct the test,

- Dilute the specimen in specimen diluent and then add it to the test cartridge through a prefilter.
- After the diluted specimen has been completely absorbed, remove the prefilter. If antibodies against HIV-1 and/or HIV-2 are present in the specimen, they bind to the antigens on the microparticles in the specific spots on the cartridge membrane.
- Add the conjugate to the cartridge. The conjugate binds to the human antibody-antigen complexes that are immobilized in the spots on the cartridge membrane.
- Perform a wash step to remove the unbound conjugate
- Add development reagent and a stop solution to the cartridge.
- Examine the membrane visually for the presence of the color purple on the procedural control spot and on the test spots.

[The test result](#) is read directly from the device at any time after the test is completed.

- The purple color on the test spots is proportionate to the amount of antibodies against HIV-1 and/or HIV-2 that have been bound to the antigen-coated microparticles and detected by the conjugate.
- The procedural control spot will turn purple when the test has been performed correctly. If no color appears at the control spot, the test is invalid and must be repeated with a new cartridge.

Shelf Life of Kits: 1 year refrigerated, 3 months at room temperature

For more information on the Multispot test, see the test kit [package insert](#)  or visit the [manufacturer’s Web site](#) .

### ClearView HIV 1/2 Stat Pak

[The Clearview HIV 1/2 Stat Pak](#) is a single-use rapid test that detects antibodies to HIV-1 and HIV-2 in fingerstick whole blood, venous whole blood, serum, or plasma specimens. The Clearview HIV 1/2 Stat Pak assay is intended for use as a point-of-care test to aid in the diagnosis of infection with HIV-1 or HIV-2



To conduct the test,

- Place the Clearview HIV 1/2 Stat Pak cartridge on a flat surface.
- Label the test device with patient name or identification number.
- Touch the 5 µL sample loop (provided in kit) to the specimen, allowing the specimen to fill the opening of the loop.
- Holding the sample loop vertically, touch it to the sample pad in the center of the sample (S) well of the device to dispense about 5 µL of specimen onto the sample pad.
- Invert the bottle of running buffer bottle and hold it vertically over the sample well. Add 3 drops (about 105 µL) of buffer slowly, drop by drop, into the sample (S) well.
- Wait 15 minutes.

[The test result](#) is read directly from the device.

- Read the test results after 15 to 20 minutes. Reactive test results may be observed and read earlier than 15 minutes. To verify a nonreactive test result, wait the entire 15 minutes. Do not read results after 20 minutes.
- A reactive test will show two pink or purple lines—1 in the test area and 1 in the control area. The line in the test area may look different from the line in the control area. Intensities of the test and control lines may vary, but a test result with visible lines in both the test and control areas, regardless of intensity, is considered reactive, which means that HIV-1 and/or HIV-2 antibodies have been detected in the specimen. The test result is interpreted as preliminarily positive for HIV-1 and/or HIV-2 antibodies.
- A nonreactive test will have 1 pink/purple line in the control area, but no line in the test area. A nonreactive test result means that neither HIV-1 nor HIV-2 antibodies were detected in the specimen. The test result is interpreted as negative for both antibodies.
- The test is invalid if there is no pink-purple line in the control area. Similarly, the test is invalid if any lines appear outside the control area or test area. An invalid test cannot be interpreted. An invalid test must be repeated with a new device.

Shelf Life of Kits: 24 months from the date of manufacture if stored at room temperature

For more information on the Clearview HIV 1/2 Stat Pak, see the test kit [package insert](#)  or visit the [manufacturer's Web site](#) .

### ClearView Complete HIV 1/2

[The Clearview Complete HIV 1/2](#) is a single-use rapid test that detects antibodies to HIV-1 and HIV-2 in fingerstick whole blood, venous whole blood, and serum or plasma specimens. It is intended for use as a point-of-care test to aid in the diagnosis of infection with HIV-1 or HIV-2. The shape of the device resembles a syringe with a narrow sampler tip and the test strip enclosed in the barrel. The single-use vial of buffer is stored in the base of the barrel.



To conduct the test,

- For fingerstick whole blood: touch the blood drop with the test sampler tip until the blood flows into and fills the tip.
- For venous whole blood, serum, or plasma: invert sampler and pipette 2.5 µL of specimen into sampler tip.
- Firmly press the sampler tip into the buffer vial through the foil cover until sampler and buffer vial snap together.
- Wait 15 minutes, keeping the sampler tip/buffer vial mechanism upright in the cardboard rack supplied with the kits.

[The test result](#) is read directly from the device.

- Read the test results after 15 to 20 minutes. Reactive test results may be observed and read earlier than 15 minutes. To verify a nonreactive test result, wait the entire 15 minutes. Do not read results after 20 minutes.
- A reactive test will show two pink/purple lines—1 in the test area and 1 in the control area. A test result with visible lines in both the test and control areas, regardless of intensity, is considered reactive, which means that HIV-1 and/or HIV-2 antibodies have been detected in the specimen. The test result is interpreted as preliminarily positive for HIV-1 and/or HIV-2 antibodies.
- A nonreactive test will have 1 pink/purple line in the control area, but no line in the test area. A nonreactive test result means that neither HIV-1 nor HIV-2 antibodies were detected in the specimen and the test result is interpreted as negative for both antibodies.
- The test is invalid if there is no pink-purple line in the control area. Similarly, a test is invalid if any lines appear outside the control area or the test area. An invalid test cannot be interpreted. An invalid test must be repeated with a new device.

Shelf Life of Kits: 24 months from the date of manufacture if stored at room temperature

For more information on the Clearview Complete HIV 1/2, see the test kit [package insert](#)  or visit the [manufacturer's Web site](#) .

### Interpretation of Rapid HIV Test Results

The results of rapid HIV tests are interpreted the same way as the results of other HIV screening tests.

- A nonreactive result from a single test is considered negative. However, if the person whose test result is negative may have been exposed to HIV within the past 3 months, it may be too early for the test to detect HIV antibodies. A repeat test at a later time is recommended.
- A reactive result from a rapid test is considered a preliminary positive result. The test does not have to be repeated before the result is reported as "preliminary positive." It must be followed up with another type of test a Western blot, an immunofluorescence assay, or an RNA test to confirm the result. The person is considered HIV-positive only if the confirmatory test result is positive. A small proportion of specimens produce indeterminate results in the confirmatory test. If this happens, the test should be repeated after 1 month.

**Special Note:** Specimens from HIV-infected persons receiving highly active antiretroviral therapy may produce false-negative results on rapid tests.

For more information see CDC's [Revised Counseling, Testing, and Referral Guidelines](#).

Last Modified: November 20, 2007

Last Reviewed: November 20, 2007

Content Source:

[Divisions of HIV/AIDS Prevention](#)

[National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention](#)





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## Quality Assurance Guidelines for Testing Using the OraQuick<sup>®</sup> Rapid HIV-1 Antibody Test

*Use of trade names and commercial sources is for identification only and does not imply endorsement by the Centers for Disease Control and Prevention or the U.S. Department of Health and Human Services.*

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## Introduction and Background

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### **Purpose**

This document provides guidance on quality assurance (QA) practices for sites using or planning to use the OraQuick<sup>®</sup> Rapid HIV-1 Antibody Test to detect antibodies to the human immunodeficiency virus (HIV).

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### **Background**

The OraQuick Rapid HIV-1 Antibody Test is the first rapid HIV point-of-care (i.e., testing and results are available in one visit) test approved by the U.S. Food and Drug Administration (FDA). It is also the first test for HIV that the FDA has waived under the Clinical Laboratory Improvement Amendment regulations (CLIA). The OraQuick test uses whole blood obtained from puncture of a finger. Results are available within 20 to 60 minutes.<sup>1</sup> Positive results with the OraQuick rapid test are preliminary, however, and must be followed up with an acceptable confirmatory test. Although the OraQuick test device is simple to use and can provide reliable results when the manufacturer's directions are followed, mistakes can occur at any point in the testing process. To reduce mistakes and to ensure that the FDA restrictions for sale of the test are followed (see Appendix A for information on the FDA sales restrictions), a site must have a QA program in place before offering OraQuick testing. The guidelines in this document outline the basic parts of a QA program.

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### **How these guidelines were developed**

These guidelines were developed after many discussions on quality assurance for rapid HIV testing within the Centers for Disease Control and Prevention (CDC) and culminated from the discussions at a meeting of experts convened by the CDC at the end of January 2003. This working group included individuals from Federal agencies—CDC, FDA, U.S. Department of Defense (DOD), and the Centers for Medicare & Medicaid Services (CMS)—as well as individuals outside the Federal government with expertise in rapid point-of-care testing, QA, HIV prevention programs, and private and public health laboratories.

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### **How to use these guidelines**

This document outlines the basic processes and procedures that should be in place before a site offers rapid HIV testing. It describes steps that can be taken to identify and prevent errors in the testing process. Because the OraQuick test will be used in many different settings, each site needs to decide how to fit the various QA elements into its own workflow and system of operation. For example, following these guidelines in a large clinic or hospital environment where on-site laboratory support is available may be quite different from using them in a small voluntary counseling and testing site or outreach setting with few staff and resources. These guidelines are intended to assist a range of providers in developing policies, processes and procedures to ensure

high quality HIV testing services.

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### How this document is organized

This document includes text and appendices that provide basic information that staff in sites offering OraQuick testing should know. It includes information on:

- The basics of a QA program for testing using the OraQuick test.
  - An overview of government rules that apply to using this test.
  - Examples of forms/checklists that can be used to keep track of QA outcomes.
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## Basic Elements of a Quality Assurance Program

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### What is quality assurance?

Quality assurance (QA) refers to planned, step-by-step activities that let one know that testing is being carried out correctly, results are accurate, and mistakes are found and corrected to avoid adverse outcomes. Quality assurance is an ongoing set of activities that help to ensure that the test results provided are as accurate and reliable as possible for all persons being tested. Quality assurance activities should be in place during the entire testing process; this means from the time a person asks to be tested using the rapid HIV test to providing the test result.

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### How does quality assurance differ from quality control?

As described above, QA is an overall program of activities throughout the entire testing process. Quality control (QC) is one part of the QA program. See [Quality Control](#) for details on quality control testing for the OraQuick test. Here are definitions for both terms<sup>2</sup>:

Term	Definition and activities performed
Quality assurance	Planned and organized activities to help ensure that certain requirements for quality will be met
Quality control	Operational techniques or tasks that are in place to find and correct problems that might occur Basic

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### Basic elements of a QA program for OraQuick Rapid HIV-1 Antibody testing

Even though the OraQuick test is simple to use, things can go wrong. To help find and prevent problems, the basic elements of a QA program should be in place before offering testing. These basic elements are the building blocks of a QA program and are listed below. More detail on these five elements is provided in this document.

1. Organization of the QA program
  2. Testing personnel
  3. Process control
    - a. Before testing
    - b. During testing
    - c. After testing
  4. Documents and records
  5. Troubleshooting
- 

## Organization of the QA program

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### Establishing a QA program

Resources are needed to establish and maintain a QA program, no matter how simple. Someone must oversee the program and ensure the necessary staff and supplies are available. Each organization must:

- Identify the person(s) responsible for managing the QA program (this could be a senior staff member, outside consultant or a network of individuals who oversee different aspects of the QA program).
- Write procedures (step-by-step instructions) and make them available to all staff involved in testing (see the list of recommended procedures below).
- Verify the testing process (see below).
- Ensure staff know how to perform processes and procedures (see the section on [personnel](#) who conduct testing).
- Create mechanisms for communication so that those who need to know are informed about QA issues, as well as all staff, when appropriate.
- Develop and implement mechanisms to ensure the site meets all applicable Federal, State, and other regulatory requirements. Each site offering testing must have a CLIA Certificate of Waiver if they are performing only the OraQuick test or the OraQuick test and other waived tests, or be included under an organization with a CLIA exception for limited public health or mobile testing. Each site must also meet Federal requirements for biohazard safety, as well as applicable State rules. See Appendix A for more information on regulatory requirements.

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### Verifying the testing process

Before offering the test to clients or patients, each site should make sure (verify) that the testing process works as planned. This verification should be completed before testing is offered. Verification includes ensuring that staff have been trained and are able (competent) to perform their assigned tasks, the test kits work as expected (e.g., make sure the test gives accurate results for a referenced panel of non-reactive, weakly reactive and reactive specimens), and the logistics for providing confirmatory testing (if a person tests positive, he or she still has to have a test to confirm the finding) and biohazardous waste handling are in place.

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### Providing written procedures

It is strongly recommended that step-by-step, written instructions be made available to all staff performing testing. This will help to ensure that personnel know how to perform specific tasks and testing success is not left to chance. Testing personnel must follow instructions provided by the manufacturer. Additional procedures, as listed below, should be provided along with the manufacturer's instructions. Text from the current OraQuick package insert may be used for some of the items denoted by an asterisk (\*) in the list below. Written instructions should describe how to:

- Train new employees, assess their ability to do the testing and document training.
- Provide information to persons being tested before testing.\*
- Use gloves and other personal protective equipment.
- Safely dispose of biohazardous waste, including used lancets.
- Maintain sufficient supplies and unexpired test and control kits, follow the manufacturer's instructions for storage, and check performance of new test kit lots and shipments with external controls (see section on ["Checking inventory and test kits"](#)).
- Maintain and document the temperature of the room and refrigerator where the tests and controls are stored and testing is performed.
- Perform quality control testing and take action (e.g., contact the manufacturer) if controls don't work.
- Collect the OraQuick specimen. \*
- Perform steps in the test procedure. \*

- Report results.
  - Refer specimens or persons being tested for confirmatory testing and manage confirmatory test results.
  - Record test and quality control results.
  - Conduct external quality assessment (see "[External assessment](#)").
  - Review records and store and destroy them when they are outdated (how long test result records are kept as part of a medical record may be subject to State or other requirements).
  - Troubleshoot and take corrective action when things go wrong.
- 

## Testing Personnel

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### Overview

Having qualified, trained staff to perform and supervise OraQuick testing and the various activities in the QA program is one of the most important factors for ensuring accurate and reliable results. Key aspects of this element include:

- Qualifications
  - Training
  - Competency assessment (i.e., how well they are doing their job)
- 

### Personnel qualifications

Since the OraQuick test is waived under CLIA, there are no specific Federal requirements on who can perform the test. Each site should find out if there are State or other requirements for personnel that they must meet. Beyond any regulatory requirements, it is recommended that certain qualities be considered when selecting personnel to perform the OraQuick test. The following list of qualities resulted from practical considerations and expert opinion:

- *Sincerity and commitment* – A dedication to performing testing according to defined procedures.
  - *Literacy* – The ability to read instructions and record results is critical.
  - *Organizational skills* – The need for this quality will depend on the number and complexity of tasks an individual performs in the testing process. If test volume is high and the individual performing testing is doing several tests or managing several other tasks simultaneously, organizational skills can be critical.
  - *Decision-making skills* – Testing personnel should be able to interpret results and be able to recognize and handle problems that might come up.
  - *Communication skills* – If the person performing the test also is the one who shares results or other information with the person being tested, being able to communicate clearly is important.
- 

### Components of training

Training is crucial to ensuring quality testing.<sup>3</sup> Training is also required to be able to purchase the OraQuick test kit (see Appendix A for details on the FDA sales restrictions). Staff should be fully trained on how to perform their assigned tasks and responsibilities. Training should be documented for each staff member; using training checklists is one way to handle this documentation (see Appendix B for an example of a training checklist). The key components to include in a training program are:

- How to perform the test, including procedures performed before, during and after testing.
  - How testing is integrated into the overall counseling and testing program.
  - The importance of QA and the elements of the site's QA program.
  - The use and importance of Universal (or Standard) Precautions/biohazard safety.
- 

### **Training method**

Experience with training to perform the OraQuick test (CDC unpublished data) shows that a training method should optimally include the following activities:

- Read the instructions for performing the test.
  - Watch someone perform the test or view a video of someone performing the test.
  - Practice performing the test with positive and negative control materials.
  - Practice performing the finger-stick collection procedure.
  - Review the procedures and forms on how to document testing.
- 

### **Competency assessment**

Before a trainee is permitted to perform testing alone for the first time, his or her ability to conduct the test should be demonstrated and documented. This assessment should also be carried out at periodic intervals after training, such as every six months or other interval as determined by the testing site. This assessment can be carried out in many ways, but regardless of the method, every task for which a staff member is responsible should be evaluated. A supervisor or trainer should perform the assessment, using a combination of methods to determine competency. Examples of these methods are presented below.

---

### **Assessing performance of tasks done before testing**

To assess the task performance before testing, staff should be observed as they:

- Check and record the temperatures of the testing and storage areas.
  - Set up the testing area, label the device and prepare control and test results log sheets.
  - Run the external controls and record results.
- 

### **Assessing performance of tasks done during testing**

To assess staff's ability to perform the test and interpret results

- Observe the staff member performing the finger-stick, collecting the blood on a test loop and placing it into the testing vial.
  - Observe how the test is performed on a client/patient. If such observation will interfere with actual client-provider interactions, observe test performance on a volunteer.
  - Evaluate the use of Universal or Standard Precautions and procedures for biohazard and sharps (e.g., lancets, needles) waste disposal.
  - Review results obtained on a panel of referenced specimens that show a range of results, such as five specimens that include non-reactive, weakly reactive and reactive results. Control materials supplied by the manufacturer may be used as a source of specimens in the panel. In addition, specimens may be obtained from laboratories performing confirmatory testing or from other commercial sources.
  - Appraise the individual's ability to interpret results. This might include using previously used test devices or pictures of devices that show non-reactive, weakly reactive, reactive and invalid results.
- 

### **Assessing performance of tasks done after testing**

To assess task performance after testing:

- Review test records and quality control results documentation.
- Observe oral reporting of results to a test subject (if trainee's responsibility).
- Observe venous blood and/or oral fluid specimen collection and handling for confirmatory

testing. If the frequency of OraQuick reactive results is low, the trainee should be observed collecting blood and/or oral fluid from a staff volunteer and demonstrate how it is processed for confirmatory testing.

- Verify that confidentiality is maintained.

## Process Control

### What is process control?

Process control refers to the activities and techniques that are carried out to ensure that the testing procedures are performed correctly, the environment is suitable, and the test kit works as expected to produce accurate and reliable results.

### Steps in the testing process

Steps in the testing process follow the path of workflow beginning with tasks before testing, followed by those conducted during and after testing. This path of workflow and the associated steps are shown in the table below. Detailed descriptions about each of the steps listed in this table are provided in the remainder of this document.

Steps in the testing process



Before testing	During testing	After testing
<ul style="list-style-type: none"> <li>▪ Check storage and room temperatures daily</li> <li>▪ Check inventory and test kit lots, as needed</li> <li>▪ Receive request for testing</li> <li>▪ Provide HIV/AIDS information to the test subject</li> <li>▪ Set up test area, label test device</li> <li>▪ Perform external quality control according to the manufacturer's and the site's instructions</li> </ul>	<ul style="list-style-type: none"> <li>▪ Follow biohazard safety precautions</li> <li>▪ Collect the finger-stick specimen</li> <li>▪ Perform the test</li> <li>▪ Interpret test results</li> </ul>	<ul style="list-style-type: none"> <li>▪ Clean up and dispose of biohazardous waste</li> <li>▪ Report results to client</li> <li>▪ Document results</li> <li>▪ Collect, process and transport confirmatory test specimens</li> <li>▪ Manage confirmatory test results</li> <li>▪ Participate in external quality assessment (periodically)</li> </ul>

## Before Testing

## Overview

As shown in the table above, there are a number of steps that must be followed before testing the blood sample for HIV. These activities are in place to ensure that the conditions in which the tests are stored and performed are suitable, the test area and the test subject are prepared, and the test is working appropriately.

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### Temperature control: test kits and control kits

Test kits and controls must be stored in an environment within the temperature ranges specified by the manufacturer. Store test kits at 2° to 27° C (35° to 80° F). If test kits are refrigerated, the pouch containing the test device and developer solution must be brought to room temperature (15° to 27° C or 59° to 80° F) before opening. Control kits must be refrigerated at 2° to 8° C (35° to 46° F). To ensure these temperature ranges are maintained, monitor and document temperatures of the storage areas each day testing is performed. If the temperature falls outside of the specified range, take action as needed to adjust the temperature. To monitor the temperatures, place thermometers in the storage areas (e.g., in the refrigerator and on the shelf in the room where kits are stored). Check and record temperatures on a log sheet each day testing is performed. An example temperature log is provided in Appendix C.

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### Temperature control: testing area

The temperature in the area where the test will be performed must be within the range of 15° to 27° C (59° to 80° F). If the test must be performed at a temperature below 15°C/59°F or above 27°C/80°F, run external controls that have been stored within the proper temperature range to find out if the test can be performed at another temperature (see the section below on external controls). If testing is carried out in the field, monitor the temperature of the test and control kits in their portable storage containers and check the temperature where testing will be performed if it appears to be outside the specified range. If there are doubts about the testing area temperature or whether test kits have stayed within the appropriate temperature range, run a positive and negative external control as described in the quality control section below.

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### Checking inventory and test kits

Procedures should be in place to ensure that an adequate supply of unexpired test kits, controls, and supplies is available. Test kits and controls have a defined shelf life. Use the oldest first. Never use test or control kits beyond their expiration dates. It is helpful to use a log sheet to document when test and control kits are received, their lot numbers and expiration dates. Also, once control vials are opened, they are stable for 21 days. Therefore, record on the vial the date it is opened and discard unused opened controls after 21 days. As described in the package insert and in the section on quality control below, run the positive and negative controls with new lots and new shipments of test kits before using them for testing, to verify that they work as expected.

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### Setting up the testing area and labeling the test device

Before testing, the testing area should be prepared according to the specific site procedure, which should include directions for setting up the workspace listed in the test kit instructions, as well as instructions for how to label testing devices and complete report forms, including the method for identifying each person to be tested to ensure specimens are not mixed up during the testing process. Labeling is especially important when more than one test is being performed at the same time. Label components of the test with the name or identifying number of the person being tested before collecting the specimen. These components include the developer solution vial, test device, and documents for recording results. Using preprinted labels improves the efficiency of performing this task.

**Note:** Do not place a label over the two holes on the back of the test device as this can cause an invalid result.



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### Providing information to test subjects

OraSure Technologies, Inc., provides a "Subject Information" pamphlet that must be given to each person getting tested prior to performing the HIV rapid test. Each site may provide additional information. For further details, see the CDC website <http://www.cdc.gov/hiv/pubs/rt-counseling.htm>, the *Revised Guidelines for HIV Counseling, Testing, and Referral*, MMWR Recommendations and Reports, RR-19, vol. 50, November 9, 2001<sup>4</sup> and applicable State or local rules.

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### Quality control

There are two types of quality control (QC) for the OraQuick test. These are described in the table below.

Type of quality control	Description of activity
Internal Controls	A control is built in to each testing device to verify that the specimen was adequate and the solution flowed through the device as intended.
External Controls	Known reactive and non-reactive specimens (controls) are available from the manufacturer to sites purchasing the OraSure Rapid HIV Test. They are used to evaluate the accuracy of the test in detecting antibody to HIV and to check if the person conducting the test performs it correctly.

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### External quality control

To verify that the test device is accurately detecting HIV-1 antibodies, external positive and negative controls must be tested from time to time. The test kit manufacturer provides external controls in the form of the OraQuick Rapid HIV-1 Antibody Test Kit Controls. This control kit must be ordered separately from the test kit. It includes one vial each of an HIV antibody-negative (non-reactive) and positive (reactive) human plasma control. How often controls are run to verify the accuracy of the test will depend on the number of tests carried out by the site, how often new test kit shipments or lot numbers are received by a site, changes in how the tests are stored and testing area temperatures, and how often staff who conduct the testing change. An example of a log for control testing results is available in Appendix D.

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### Run external controls according to the manufacturer's instructions

The manufacturer has set guidelines for the minimum number of times to run the negative and positive controls. This is described in the test kit instructions, which specifies running controls under the following circumstances:

- By each new operator prior to performing testing on patients,
  - When opening a new test kit lot (a test kit lot is defined as the boxes of test devices that contain either 25 or 100 tests that have the same lot number labeled on the outside of the boxes),
  - Whenever a new shipment of test kits is received (even if it is the same kit lot number in current use),
  - If the temperature of the test storage area falls outside of 2°-27° C (35°-80° F),
  - If the temperature of the testing area falls outside of 15°-27° C (59°-80° F), and
  - At periodic intervals as dictated by the user facility.
- 

### Frequency of running external controls on the basis of test volume

In addition to the specific circumstances listed in the manufacturer's instructions, testing sites should determine the optimal frequency for running controls on the basis of their test volume. When external controls provide incorrect results, none of the tests that were run since the last time

control results were correct can be considered valid. This means that everyone who was tested since the last time controls ran correctly will need to be called back and retested (unless a confirmatory test was ordered). Sites testing large numbers of persons, and especially those that offer anonymous testing, should plan to run controls more often than facilities that conduct fewer tests. Each site needs to decide how often to run controls based on its own situation and testing practices. Instructions for some other waived tests recommend running external controls each time a new box of 25 tests is opened. Facilities that test 25 or more subjects a day should run controls every day. Low volume sites, such as those testing fewer than 25 subjects per month, should run external controls every two to four weeks at a minimum. Controls should be run more often if new lots or shipments are opened or if storage or testing temperatures fluctuate.

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## During Testing

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### Overview

This phase of the testing process involves running the test and interpreting the results. Activities during testing include collecting the specimen, performing the test, interpreting the internal control and client/patient test results, and following biohazard safety guidelines.

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### Collecting the OraQuick specimen

Follow the written procedure for finger-stick specimen collection. Further information on collecting blood by skin puncture can be found in *Procedures and Devices for the Collection of Diagnostic Blood Specimens by Skin Puncture*.<sup>5</sup>

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### Performing the test and interpreting results

Follow the manufacturer's instructions for performing the test and interpreting the results. Results can be one of the following:

- *Nonreactive* (negative)
  - *Reactive* (preliminary positive)
  - *Invalid* (the test result is inconclusive and cannot be interpreted; see below for information on handling invalid results)
- 

### Evaluating internal control results

Each OraQuick device includes a built-in (internal) control. When an appropriate line develops at the center of the "C" location on the device, the patient's specimen has been correctly loaded and traveled through the test strip, indicating a valid test. Additional information is provided in the test kit package insert. These controls are included in every device, and control results are evaluated with every test. If the internal control does not produce the expected result, the test result for the patient is not valid, cannot be reported, and the test must be repeated. If a second invalid result occurs, external controls should be evaluated as described below before repeating the test a third time.

---

### Running external controls to troubleshoot invalid results

CDC experience (unpublished data) has shown that external controls should be run to help find out if repeated invalid test results are due to the test device, test performance, or the patient specimen. If the same test kit lot yields repeated invalid results, the test kit may have gone bad. It is important to run the positive and negative controls whenever two consecutive invalid test results are obtained on a person being tested.

---

### Biohazard safety/Universal (Standard) Precautions

All specimens and materials contacting specimens must be handled as if they are capable of transmitting an infectious organism. As described in Appendix A, each site must ensure that the Occupational Safety and Health Administration (OSHA) bloodborne pathogens standards are met,

that is persons doing the testing must know how to safely handle potentially infectious specimens. Also, according to Universal (Standard) Precautions, all human blood should be treated as if known to be infectious for HIV, hepatitis B virus, and other bloodborne pathogens. Sites must have available and follow procedures for biohazard safety to include instructions for the use of gloves, hand washing, sharps and biohazardous waste disposal, spill containment and disinfection. A different pair of gloves should be worn for collecting a specimen from each person being tested. Used gloves should be handled as biohazardous waste. For further details on these precautions see the OraQuick package insert, OSHA regulations and guidelines on Universal and Standard Precautions. <sup>1, 6, 7, 8</sup>

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## After Testing

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### Overview

Quality assurance extends to those activities completed following the performance of the test. Each site should have established procedures for:

- Reporting and recording results,
  - Referring specimens (or test subjects, if specimens are not collected on-site) for confirmatory testing,
  - Managing confirmatory test results, and
  - Conducting external quality assessment.
- 

### Reporting results

Reporting procedures should describe how results are provided to the person being tested (verbal and/or written results) and how results are documented in the person's chart and in the test result logs. Some States have laws and regulations that include certain reporting criteria for HIV testing results. Check with your State agency for more information on these requirements. See Appendix A for State agency contact information and Appendix E for an example of a test result log.

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### Referral for confirmatory testing

Whenever the OraQuick test result is reactive (preliminary positive), a confirmatory test must be performed to confirm that the person being tested is infected with HIV. Therefore, each site must have established procedures for referral of either test specimens or persons being tested for confirmatory testing when OraQuick results are reactive. If specimens are collected on-site, the site must establish procedures describing how to collect, label, process, store and document specimen transfer; transport the confirmatory test specimens to the site(s) where they will be tested; and obtain the confirmatory results to give to the client/patients. It should be indicated on the specimen transfer sheet that the specimen is from an individual who had a reactive OraQuick rapid test result. See the Appendix F for an example of a specimen transfer sheet. Collecting confirmatory specimens on-site may improve follow-up, since some clients may not go elsewhere for the testing or to obtain results. However, if the site is not able to collect confirmatory test specimens, a procedure must be in place for referring persons to another site to obtain this testing.

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### Confirmatory testing protocols

For confirmatory testing, the current standard testing algorithm should be followed, with the following exceptions:

- All OraQuick reactive (preliminary positive) results must be followed up with either a Western blot or immunofluorescent assay (IFA) for confirmation.
- Confirmatory testing can be done on blood (plasma, serum or dried blood spots) or oral fluid specimens. Urine testing should not be performed due to its lower sensitivity (i.e., ability to detect positive results).
- With blood specimens, enzyme immunoassay (EIA) screening tests prior to the Western blot or IFA confirmatory test are optional. If an EIA is performed, even if it is non-reactive, the specimen must proceed to Western blot or IFA testing (reactive EIA specimens will automatically be tested by Western blot or IFA). For oral fluid testing, both EIA and Western

blot testing should be performed to confirm results.

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### **Follow up testing for negative confirmatory result**

Most confirmatory test results will be positive; however, some may be negative or indeterminate. If the confirmatory test result is negative, specimen mix-up needs to be ruled out versus a false positive OraQuick result. If the Western blot or IFA test is negative, it is recommended that:

- For blood specimens, a confirmatory test should be repeated with a new specimen to rule out specimen mix-up.
  - For oral fluid specimens, a repeat confirmatory test with a blood specimen should be done, since the oral fluid test is less sensitive than the blood test.
- 

### **Follow up testing for indeterminate results**

Occasionally, confirmatory test results are indeterminate. If the Western blot or IFA is indeterminate, it is recommended that:

- For blood specimens, the person should be advised to return for repeat testing in one month. See CDC's Revised Guidelines for HIV Counseling, Testing and Referral found at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5019a1.htm>. 
  - For oral fluid specimens, the Western blot or IFA test should be repeated using a blood specimen.
- 

### **Managing confirmatory results**

OraQuick testing sites that refer specimens for confirmatory testing should have established procedures describing how to:

- Match the client's/patient's confirmatory test results with their OraQuick results to find potential discrepancies and to ensure that testing was performed according to the protocol described above,
  - Report the test result to the person being tested, and
  - Obtain any additional specimens needed to resolve potential specimen mix-up and for retesting, as needed.
- 

### **Handling result discrepancies**

Procedures should describe how to handle result discrepancies when the OraQuick result was reactive and the confirmatory test negative or indeterminate. If the laboratory providing confirmatory testing performed an EIA test only and reported a non-reactive or negative result, the OraQuick testing site should contact the confirmatory testing laboratory and request a Western blot test or IFA test. If the original specimen is not available, a new specimen will need to be collected from the person in question to be used for confirmatory testing.

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### **External assessment**

External assessment, or an evaluation of the testing process by a source outside the testing site, can look at how testing is being performed and whether it is being performed reliably. It can also help to identify existing or potential problems. Moreover, information gathered can provide an educational tool to improve performance. Some form of external assessment is highly recommended, but it is not required by Federal (CLIA) regulations since the test is waived and the test kit manufacturer does not specifically require it.

---

### **Methods for external assessment**

Every reactive OraQuick test is externally assessed by a second, confirmatory test. However, if there is a low prevalence of HIV infection in the population being tested, these assessments may be rare and will not provide an external check for the majority of the results, i.e., those that are nonreactive. Other ways to assess performance may be needed. Some external assessment mechanisms include:

- Comparing the OraQuick reactive results with the confirmatory test results.

- Arranging for someone outside the organization to observe testing.
- Participating in a proficiency testing or external evaluation program (for more information on these programs, see Appendix G).

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## Documents and Records

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### Overview

One of the hallmarks of a QA program is comprehensive documentation. Sites using the OraQuick test should have policies and procedures describing what QA records are required and how and when they are reviewed, stored and destroyed. Having a supervisor review records periodically is recommended. State regulations or other governmental or accrediting agencies may require facilities to have specific record retention policies. QA records include the following:

- Training documentation (Appendix B)
- Temperature logs (Appendix C)
- External control result logs (Appendix D)
- Test result logs (Appendix E)
- Specimen transfer logs (Appendix F)

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### Temperature logs

Temperature logs should include a daily record of the refrigerator temperature in which controls are stored, the temperature where test kits are stored and the temperature of the testing area. Thermometers should be placed in each location. Laboratory grade thermometers (can be purchased from medical or laboratory supply houses) are recommended and their accuracy checked periodically (e.g., every six months) by comparison with another thermometer.

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### External control result logs

External control records should include the date and time of control testing, lot number and expiration of the test kit, lot number and expiration date of the controls, control results, and corrective action taken if control results are unacceptable. Control records should be kept in the order in which they were completed so they can be easily compared with the test records. This will help find answers if there are questions about testing performed within a specific time frame.

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### Test result logs

Test result records should include the date and time of testing, an identifier for the person being tested, a test kit lot number and expiration date, test result, action taken if the result was invalid, identification of the person who performed the test, whether confirmatory testing was requested, including the type of specimen sent for confirmation (e.g., oral fluid, blood), and the confirmatory test results when they are available. If more than one person is conducting testing, there should be a mechanism to chronologically link the test record log sheets to detect problems, such as invalid results occurring repeatedly with the same kit lot number.

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## Troubleshooting

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### Overview

Each site should have a method to detect and resolve problems that occur at any point in the testing process, especially those that may affect the accuracy of test results. Significant problems should be immediately reported to the appropriate supervisory personnel.

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### Procedures

Procedures should be available to all testing personnel for the following:

- When to discontinue testing, e.g., when the external control results are unacceptable as described in the package insert.


How to take corrective action, or an action taken in response to a problem, such as contacting the manufacturer when the external control results are unacceptable and following the advice provided.

- How to document problems and actions taken, such as a logbook where problems and corrective actions taken can be recorded.
- How to verify the corrective actions taken addressed the problem.

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## [Appendixes: Government Regulations and Sample Forms \(PDF only - 407 KB, 9 pages\)](#)

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## CLIA Certificate of Waiver Fact Sheet

### How to Obtain a Clinical Laboratory Improvement Amendments (CLIA) Certificate of Waiver

The Clinical Laboratory Improvement Amendments of 1998 (CLIA) establishes quality standards for laboratory testing to ensure the accuracy, reliability, and timeliness of patient test results. CLIA requires that any facility examining human specimens for diagnosis, prevention, treatment of a disease or for assessment of health must register with the federal Centers for Medicare & Medicaid Services (CMS) and obtain CLIA certification.

Because the OraQuick® Rapid HIV-1 Antibody Test is simple and accurate, the Food and Drug Administration (FDA) approved it as a waived test. Waived tests are determined to be easy to use and have little risk of an incorrect result. So far, more than 1,400 test systems have been waived. A Certificate of Waiver is one of four types of required certificates and is the type to request if you plan to conduct only waived tests, such as the OraQuick test.

As a waived test, the OraQuick test can be used at many clinical and non-clinical testing sites, including community and outreach settings. Non-clinical testing sites that plan to provide the OraQuick test **must** either apply for their own CLIA Certificate of Waiver or establish an agreement to work under the CLIA Certificate of an existing laboratory. Any agency that has a CLIA Certificate of Waiver and is performing the OraQuick test is considered a clinical laboratory.

FDA restrictions also require that any facility planning to perform the OraQuick test **must** have a quality assurance plan – step-by-step activities that ensure testing is carried out correctly, results are accurate, and mistakes are found and corrected. Quality assurance guidelines for OraQuick testing can be found at: <http://www.phppo.cdc.gov/DLS/default.asp>. 

All sites ordering the OraQuick test will receive a letter from its manufacturer, OraSure Technologies, indicating that they agree to various requirements and restrictions, including:

- Sale is restricted to clinical laboratories (Any agency that has a CLIA Certificate of Waiver and performs the OraQuick test is considered a clinical laboratory.)
- A quality assurance plan is in place
- Staff have been trained to perform the test using manufacturer's instructions
- Clients receive a "Subject Information" pamphlet before the test is given and receive appropriate information when results are provided


### State Involvement

Many states have additional regulations that apply to laboratory testing, and some require separate applications to the state agency. Some regulations also apply specifically to HIV testing. These regulations may require training to provide counseling, testing, and referral services, draw blood, or perform the test. Some states regulate who may provide HIV testing, perform the test, or give test results. For example, even for the OraQuick test, some states require a written HIV test order from


a licensed medical professional.

Before applying, you should consider these applicable requirements and the best method for receiving the authority for testing, including contacting your state health department and your local CMS inspector for guidance. CLIA contacts for all states can be found at the following Web site:

<http://cms.hhs.gov/clia/ssa-map.asp>. 

**Exceptions** : Washington State is exempt from CLIA regulations. New York is also exempt from CLIA, except for physicians' office labs, which are required to have a CLIA certificate. Both states have their own requirements that meet or exceed CLIA requirements. Traditional and non-traditional sites that want to perform OraQuick testing should contact their CLIA representative, listed at: <http://cms.hhs.gov/clia/ssa-map.asp>. 

## How to Apply for a CLIA Certificate of Waiver

Obtaining a Certificate of Waiver is generally a straightforward process. An application (form CMS-116) can be obtained at the CMS Web site at <http://www.cms.hhs.gov/clia>  or from your state health department. The application is four pages and requests the following information:

- I. **General Information** – provide information about your organization, including street address, name of director, and federal tax identification number. Don't fill out the CLIA identification number if this is an initial application.
- II. **Type of Certificate Requested** – request a Certificate of Waiver.
- III. **Type of Laboratory** – indicate the facility or setting in which you will perform the rapid test, e.g., community clinic, health fair, mobile laboratory (van). If none of the categories apply to your setting, check "other."
- IV. **Hours of Laboratory Testing** – indicate the times you plan to do testing.
- V. **Multiple Sites** – indicate if you will be doing testing at more than one site. If you will have multiple sites, provide the number of sites and complete the remainder of this section. In general, a mobile van is considered a multiple site if it is not in a fixed location and moves from site to site for testing. If that is the case, the name and address of the testing site for that van would be the same as the organization it operates under or the physical location where the van is housed.
- VI. **Waived Testing** – estimate the number of tests you will be performing annually.
- VII. **Non-Waived Tests** – skip this section if you are performing a waived test only.
- VIII. **Type of Control** – check the type of organization for which you are making this application (private non-profit, for-profit, government).
- IX. **Director Affiliation With Other Laboratories** – provide the name and address of other laboratories (facilities) that your director also directs. (CLIA regulations allow a director to direct a maximum of five laboratories.)
- X. **Individuals Involved in Laboratory Testing** – indicate the total number of individuals involved in testing (those who are directing, supervising, consulting, or testing). Include counselors only if they will perform or supervise testing.
- XI. **Consent and Signature** – carefully read the consent information at the bottom of p. 4 before signing and dating.



- [Sample completed form \(PDF 82.2 KB, 4 Pages\)](#)

The Certificate of Waiver application should be forwarded to the address of the local state agency of the state in which the testing will be performed. CMS has a list of these agencies by state at <http://cms.hhs.gov/clia/ssa-map.asp>. You can also contact your local state agency for assistance in filling out the application. You will need to submit the \$150 fee with the application.

The Certificate of Waiver is valid for two years. A renewal application will need to be completed and sent to the state agency not less than 9 months before the certificate's expiration date.

**For additional information or assistance in filling out the CLIA waiver application, please call CMS Toll-Free: 877-267-2323; Local: 410-786-3000; TTY Toll-Free: 866-226-1819; TTY Local: 410-786-0727. Or visit the following Web site: <http://www.cms.hhs.gov/clia>**

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*Weekly*

September 12, 2003 / 52(36);866-868

# Rapid Point-of-Care Testing for HIV-1 During Labor and Delivery --- Chicago, Illinois, 2002

On November 7, 2002, the Food and Drug Administration (FDA) approved the OraQuick Rapid HIV-1 Antibody Test (OraSure Technologies, Inc., Bethlehem, Pennsylvania) ([1](#)). Rapid human immunodeficiency virus (HIV) testing during labor and delivery allows pregnant women who were not tested previously during pregnancy to be tested and, if HIV-infected, to begin antiretroviral therapy immediately to prevent perinatal transmission ([2,3](#)). To evaluate whether point-of-care rapid HIV testing during labor and delivery expedites the diagnosis of HIV infection in pregnant women, CDC assessed turnaround testing times at three hospitals in Chicago, Illinois, in which obstetric staff performed rapid tests on whole blood specimens at point of care, and at a fourth hospital in which testing was performed in the hospital laboratory ([4](#)). This report summarizes the results of that analysis, which indicate that point-of-care rapid testing provided HIV test results faster than laboratory testing, resulting in prompt administration of intrapartum and neonatal antiretroviral prophylaxis. Hospitals should assess the costs and benefits of implementing point-of-care HIV testing within their institutions.

The four Chicago hospitals with the city's highest HIV-1 prevalence among childbearing-aged women participated in the Mother Infant Rapid Intervention at Delivery (MIRIAD) study. MIRIAD is a multisite study funded by CDC to 1) determine the feasibility of rapid HIV testing in labor and delivery units of women with undocumented HIV status, 2) provide timely therapy to reduce perinatal transmission, and 3) facilitate follow-up care for HIV-infected mothers and their infants. Women eligible for MIRIAD do not have documentation of HIV status in their health-care records and are expected to deliver either during that hospitalization or at >34 weeks' gestational age.

For the MIRIAD study, FDA allowed use of the OraQuick rapid test before its formal licensure. After institutional review board approval, hospital staff were trained to recruit eligible women, obtain informed consent, perform the OraQuick rapid test, and counsel participants about their test results. Three of the four hospitals received approval from their respective point-of-care testing committees for obstetric staff to perform the OraQuick test onsite in labor and delivery units; one hospital sent specimens to its 24-hour laboratory for OraQuick rapid testing. At each hospital, duplicate specimens were sent for standard HIV testing (enzyme immunoassay and, when necessary, Western blot) as part of the study protocol.

Hospital staff performing point-of-care testing in labor and delivery units used timers attached to their clothing to continue other work during the 20 minutes necessary for development of test results. In the hospital in which testing was performed in the laboratory, staff delivered specimens to the laboratory and reported test results to patients when the results were available. Staff recorded the time of each step in the testing protocol. Median times were analyzed by using the Wilcoxon rank-sum test.

During January--July 2002, a total of 5,771 women were evaluated in the labor-and-delivery units of all four hospitals; 514 (9%) were deemed eligible for rapid HIV testing. Of the 514 women, 30 (6%) were not offered participation, 104 (20%) declined participation, and 380 (74%) gave informed consent and were enrolled. A total of 225 women were tested at the three hospitals using point-of-care testing, and 155 were tested at the hospital using laboratory testing. Standard enzyme immunoassay and, when necessary, Western blot testing, confirmed 100% of the rapid test results. Three women were identified as HIV-infected, and antiretroviral therapy was administered to

mothers and infants during labor and delivery. None of these infants became HIV-infected.

Turnaround testing time was measured as the time that elapsed between obtaining the participant's blood and the participant receiving the test results. Median turnaround time at the three hospitals using point-of-care testing was 45 minutes (interquartile range: 30 minutes--2.5 hours), substantially less than at the hospital using laboratory testing (median time: 3.5 hours; interquartile range: 94 minutes--16 hours) ( $p<0.0001$ ).

**Reported by:** *MH Cohen, MD, Y Olszewski, MPH, M Robey, F Love, CORE Center, Cook County Bur of Health Svcs, Chicago, Illinois. Mother Infant Rapid Intervention at Delivery (MIRIAD) Study Group; B Branson, MD, DJ Jamieson, MD, M Bulterys, MD, Div of HIV/AIDS Prevention---Surveillance and Epidemiology, National Center for HIV, STD, and TB Prevention, CDC.*

## Editorial Note:

The findings in this report indicate that point-of-care rapid testing provided valid HIV test results faster than laboratory testing. The median turnaround time for point-of-care testing was less than one fourth that for laboratory testing. With rapid testing, three pregnant women who had not received an HIV diagnosis previously were able to learn their HIV status quickly, resulting in prompt administration of intrapartum and neonatal antiretroviral therapy, measures proven to reduce vertical HIV transmission ([3,5,6](#)).

The majority of pregnant women are offered HIV testing early during prenatal care, which is the optimum approach to HIV prevention and care. However, women who do not receive prenatal care are at increased risk for HIV infection ([3](#)). FDA's approval of the OraQuick rapid test now provides health-care providers with an opportunity to test for HIV infection and inform patients of their HIV status rapidly. This can have a profound benefit for the care of women who have not been tested for HIV during pregnancy. Women can be informed about a negative rapid test result without further testing (pending state-specific regulations). Reactive rapid test results require confirmation but can be used to initiate therapy in this setting.

The findings in this report complement the new CDC initiative aimed at reducing barriers to early diagnosis of HIV infection, which includes a goal to further decrease perinatal HIV transmission in the United States ([7](#)). Rapid HIV testing of pregnant women not screened during prenatal care will help achieve this goal by increasing the proportion of infected women and their infants receiving intrapartum and neonatal antiretroviral drug prophylaxis. As rapid HIV testing becomes more available in labor and delivery settings, implementation will require training and logistic planning ([8](#)). FDA waived the OraQuick rapid test under the Clinical Laboratory Improvement Amendments on the basis of the test's simplicity and accuracy.

Data from this study indicate that point-of-care testing was feasible and support using nonlaboratory personnel to perform this rapid test. However, adequate training and quality-assurance procedures are necessary. Point-of-care testing also requires coordination with the laboratory information system to ensure test results are documented correctly. Hospitals will need to assess the costs and benefits of implementing point-of-care HIV testing within their institutions ([9,10](#)).

## Acknowledgments

This report is based on data contributed by the following MIRIAD Study principal investigators: S Nesheim, Atlanta, Georgia; MH Cohen, Chicago, Illinois; MJ O'Sullivan, Miami, Florida; R Maupin, New Orleans, Louisiana; and MP Webber, New York, New York. The following persons provided data management and analysis: A Podolanczuk, CORE Center, Chicago, Illinois. S Danner, S Wei, J Wiener, Div of HIV/AIDS Prevention---Surveillance and Epidemiology, National Center for HIV, STD, and TB Prevention, CDC.

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# **Key Players Meeting**

# **Key Players Meeting Summary Steps**

- 1) **Arrange Hospital Key Players Meeting with Regional Coordinator.**
- 2) **Send out the *Questionnaire Sheets for Key Departments* and review the answers prior to the meeting.**

The key players' meeting is an essential first step towards successful implementation. All areas of the hospital that will be impacted by these policies and procedures should be represented so that a fully integrated system can be put into place.

**Pharmacy, laboratory, hospital administration, nursing staff (L&D and Nursery), medical staff (Pediatrics and Obstetrics) and case management should be present** and have reviewed their relevant portions of the manual (**Hospital Planning Guidelines-Section 2**) and answered the **Questionnaire Sheets for Key Departments**.

A power point presentation and discussion points for this meeting are provided. The meeting will be facilitated with the Regional Coordinator.

## **The essential tasks for this group are:**

- a. review requirements set forth in the Illinois Perinatal HIV Prevention Act
- b. finalize plan for location of testing (point of care versus laboratory)  
determine start date for rapid testing and set timeline for implementation of policies, procedures and templates (standing orders/consent forms/admission forms)
- c. secure CLIA waiver and develop QA plan for point of care rapid testing  
discuss and plan for budget considerations
- d. determine plan for ordering test kits
- e. secure pharmacy 24/7 availability of AZT (IV and syrup)
- f. set follow up plan for preliminary positives and exposed newborns

## **Key Players Power Point Presentation**

- explains rationale behind POC Perinatal Rapid HIV Testing
- reviews key steps of implementation

## **Key Players Implementation Questionnaire**

- questions for L&D nurse manager to review with key players from departments involved

# Key Player Implementation Questionnaire

- use as a guide to facilitate the key players meeting

## Questions for L&D Managers

Nurse Manager: \_\_\_\_\_

Hospital: \_\_\_\_\_

### STAFF ISSUES/ TRAINING

	YES	NO	NOTES
Number on Staff			
Types of Shifts			
Are Staff Cross Trained?			
When/Where Staff Meet			
Charge Nurses Names			
Are Registry RN's Used?			
Nurse Educator on Unit?			
Where is POC Testing Done?			
Who Obtains Blood?			

### HIV POLICY ISSUES

How is HIV Testing Done?			
Are results currently documented on the following forms?			
Triage?			
L&D Admission?			
H+P?			
Labor Summary?			
Nursery admission?			

**HIV POLICY ISSUES (Cont...)**

<b>Who</b>	
<b>When</b>	
<b>Where</b>	

**HIV POLICY ISSUES (Cont...)**

<b>ITEMS</b>	<b>COMMENTS</b>
<b>Policies for ZDV Administration for Mother Baby Currently in Place?</b>	
<b>Policies for ZDV Administration for Baby Currently in Place?</b>	
<b>Staff trained re: ZDV Administration Policies</b>	
<b>Where Are Policies located on unit?</b>	
<b>Names of L&amp;D Charge RNs</b>	<b>Names of Nursery Charge RNs</b>
<b>7:00 am</b>	<b>7:00 am</b>
<b>3:00 pm</b>	<b>3:00 pm</b>
<b>11:00 pm</b>	<b>11: 00 pm</b>
<b>Average Time Patient is on L&amp;D Prior to Being Transferred to Postpartum.</b>	
<b>Who Offers HIV Test/Consent?</b>	
<b>Who gives HIV Results to Patient?</b>	
<b>How is Testing Documented?1</b>	
<b>How are Results Documented?</b>	
<b>Who Offers HIV Test/Consent?</b>	



**POSTPARTUM ISSUES**

ITEMS	YES	NO	COMMENTS
Where is Postpartum Located (in Relation to L&D?)			
Is There a Need for a Separate Testing Area Within the PP?			
Home Deliveries: Who Will Offer?			
How Long is Usual Patient Stay?			

**NURSERY ISSUES**

ITEMS	COMMENTS
Where is Nursery Located (in relation to L&D?)	
Is There a Need for a Separate Testing Area Within the Nursery?	

**CONFIRMATORY TESTING OF PRELIMINARY POSITIVE RESULTS**

What is Current System for Requesting Western Blot Tests?			
What Tube is Used to Collect Specimen?			
What is the hospital process for getting Sample in Lab?			
What is the Follow-up if Result is Positive?			
Who Follows-up Positive Results?			
Is Phlebotomist Available 24hrs? If No What is System?	Yes	No	

**CONFIRMATORY TESTING (Cont...)**

ITEMS	YES	NO	COMMENTS
Is Lab requisition Required?			
Where are lab requisitions located? (Include Sample)			

**PHYSICIAN/MIDWIFERY STAFF ISSUES**

ITEMS	YES	NO	NUMBER
Number of Physicians with Delivery Privileges at Hospital			
Number of Private Offices/ Clinics/ Health Departments Attached/ Affiliated with the Hospital			
Number of Midwives with Delivery Privileges at Hospital			
Number of Residents at Hospital			
Number of Family Practice Physicians with Delivery Privileges at Hospital			

**LABORATORY/ POINT OF CARE CONTACT/CLIA ISSUES**

ITEMS	YES	NO	NUMBER/ COMMENTS
Will rapid testing occur at point-of-care or lab based?			
What Competency Will Lab Require for Staff in Relation to POC and Rapid HIV Testing?			
Does Hospital have CLIA Status?			
What is Hospital CLIA #?			

**LABORATORY/ POINT OF CARE CONTACT/CLIA ISSUES (Cont...)**

<b>What Will Lab Do To Ensure Proper Documentation of Rapid HIV Test Log?</b>			
<b>Who Will Receive Lots of Rapid HIV Tests, Run/Document Controls &amp; Record Lot #'s and Inventories?</b>			
<b>Choose a rapid test kit (training provided on OraQuick) order test kits to be ready for rapid testing start date?</b>			

**PHARMACY ISSUES**

<b>ITEMS</b>	<b>YES</b>	<b>NO</b>	<b>COMMENTS</b>
<b>Is AZT/ZVD (IV and syrup Available in the Pharmacy?</b>			
<b>Is the Pharmacy open 24 Hours?</b>			
<b>Is There 24 Hour Pharmacy Storage?</b>			
<b>If the pharmacist is not available, do nurses on L&amp;D have access to AZT and instructions for diluting for administration? Do the nursery nurses have access to stat syrup AZT 24 hr/day?</b>			
<b>What is the Protocol for a Stat Pharmacy Delivery During Daytime and Night Hours?</b>			
<b>Can Mother be D/C With Full RX for Infant?</b>			

## FORMS

ITEMS	COMMENTS
<b>When/How Can New HIV Consent be Printed &amp; Available for Rapid HIV Testing on the OB Unit?</b>	
<b>Do L&amp;D and newborn admission forms have a space to document prenatal HIV status and rapid HIV test results?</b>	
<b>Can stand L&amp;D / newborn nursery admission orders be revised to account for rapid HIV testing if undocumented maternal HIV status on arrival or at delivery?</b>	
<b>What/How Long is the Revision of Forms Process?</b>	
<b>Can Process be Expedited?</b>	

## INFORMATION SYSTEMS

ITEMS	YES	NO	NUMBER/ COMMENTS
<b>Are HIV Results Currently Available on Computer?</b>			
<b>Which Staff is allowed to View HIV Results?</b>			
<b>What is the Process to Obtain Staff Access for Results?</b>			
<b>How can this Training be Arranged?</b>			
<b>Who is responsible for changing access/screens on computer?</b>			

<b>How is this process accomplished?</b>			
<b>How Can a POC Preliminary Results Screen be Added to Computer?</b>			
<b>How Can POC Preliminary HIV Test Result and WB be Correlated on the Computer?</b>			
<b>Can this Process be Expedited?</b>			
<b>Can Electronic L&amp;D and Nursery Admission and Discharge Forms be Revised to include HIV Status?</b>			

**INFECTIOUS DISEASE ISSUES**

<b>ITEMS</b>	<b>YES</b>	<b>NO</b>	<b>NUMBER/ COMMENTS</b>
<b>Is There an HIV Specialist Available?</b>			
<b>How/When are Referrals for Follow-up Care Made for HIV &amp; OB Patients?</b>			
<b>What will be the specific referral plan for specialized HIV care for HIV+ women identified on L&amp;D and exposed newborns? Who will confirm linkage to care has occurred?</b>			
<b>What will be the specific plan for follow-up of confirmatory Western Blot results?</b>			
<b>How can the Illinois Perinatal HIV Hotline be incorporated into your hospital's follow-up plan / referral plan? (with release of information the Hotline can assign case management and assist with follow-up and linking to care)</b>			

<b>How can the Local Health Dept assist the attending of record with this responsibility?</b>	
<b>Who is Liaison with Local Health Dept.?</b>	
<b>Who is Responsible for Reporting Efforts?</b>	
<b>How should Current Reporting Practice be Revised?</b>	
<b>How can the Preliminary Positive Data Collection Form be collected and transferred to the PRTII Regional Coordinator? (will be sent on to the IDPH Perinatal HIV Database)</b>	

**Risk Manager:**  
**Make aware of new law and involve as needed to engage process.**

<b>COMMENTS</b>

# Key Players Working Group: Draft Presentation

Hospital Name

Date

# Rationale

- **Opportunity**
  - New Illinois law
  - FDA approved Rapid HIV Test
- **Need**
  - Incomplete prenatal testing
  - Unknown maternal HIV status = preventable pediatric HIV
- **Intervention**
  - If maternal HIV status known = effective treatment on labor & delivery to prevent perinatal transmission
- **Goal**
  - Eliminate Pediatric HIV in Illinois



# An Opportunity: Illinois Perinatal HIV Prevention Act

- All pregnant women in Illinois will be counseled and offered an HIV test.
- HIV test results will be documented in prenatal, L&D and newborn pediatric chart.
- If there is no documented maternal HIV status on arrival to L&D, the patient will be offered a Rapid HIV test. (Opt-In)
- If maternal status not known at delivery, newborn will be given rapid HIV test unless mother declines. (Opt-Out)

**OraQuick: Oral fluid, serum, whole blood**



**Obtain finger stick specimen...**

**B. Branson**



**Or whole blood**

**CDC\_B. Branson**



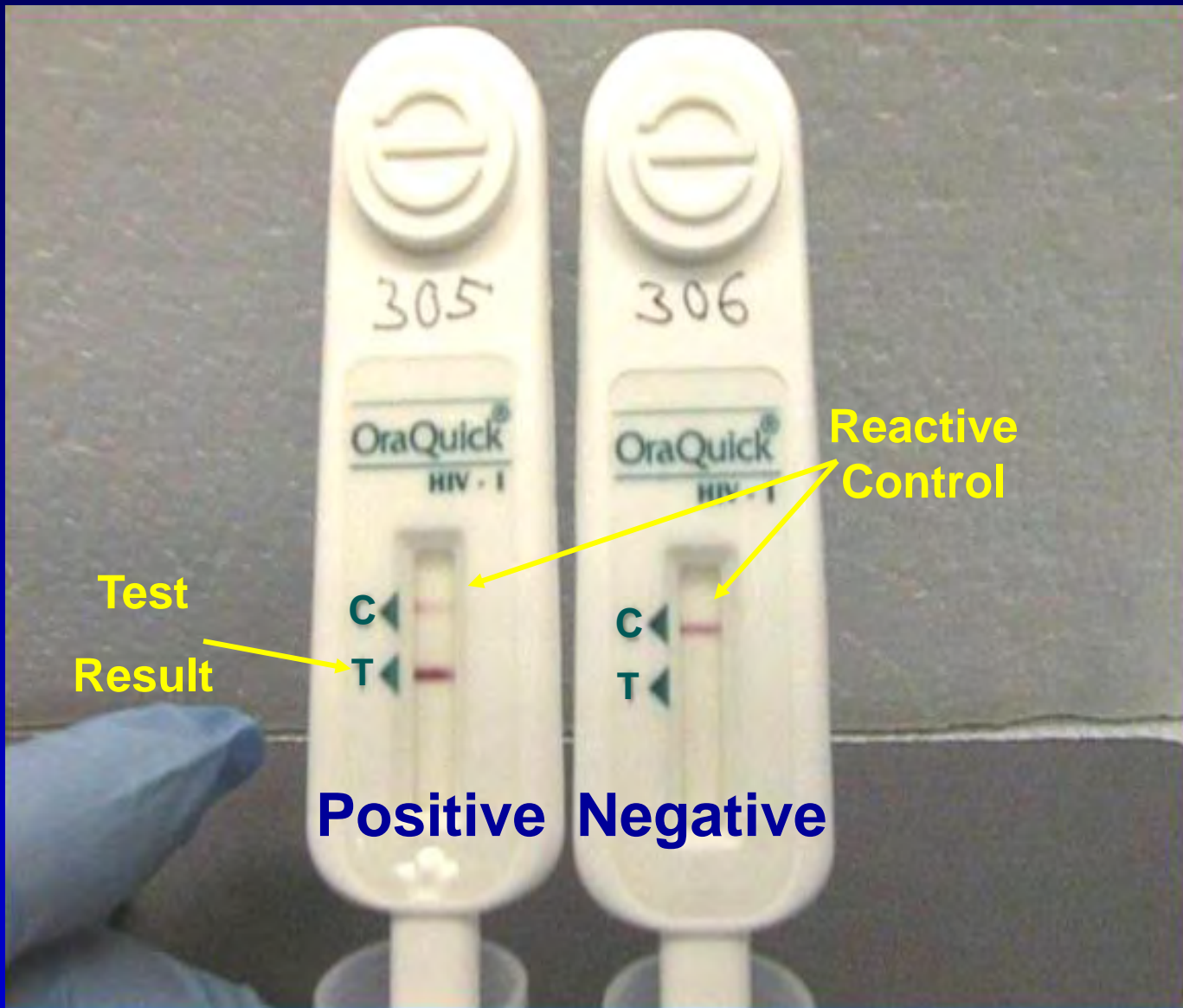
**Insert loop into vial and stir**

**CDC\_B. Branson**



**Insert device; test develops in 20  
minutes**

**CDC\_B. Branson**



Read results

CDC\_B. Branson

# Rationale

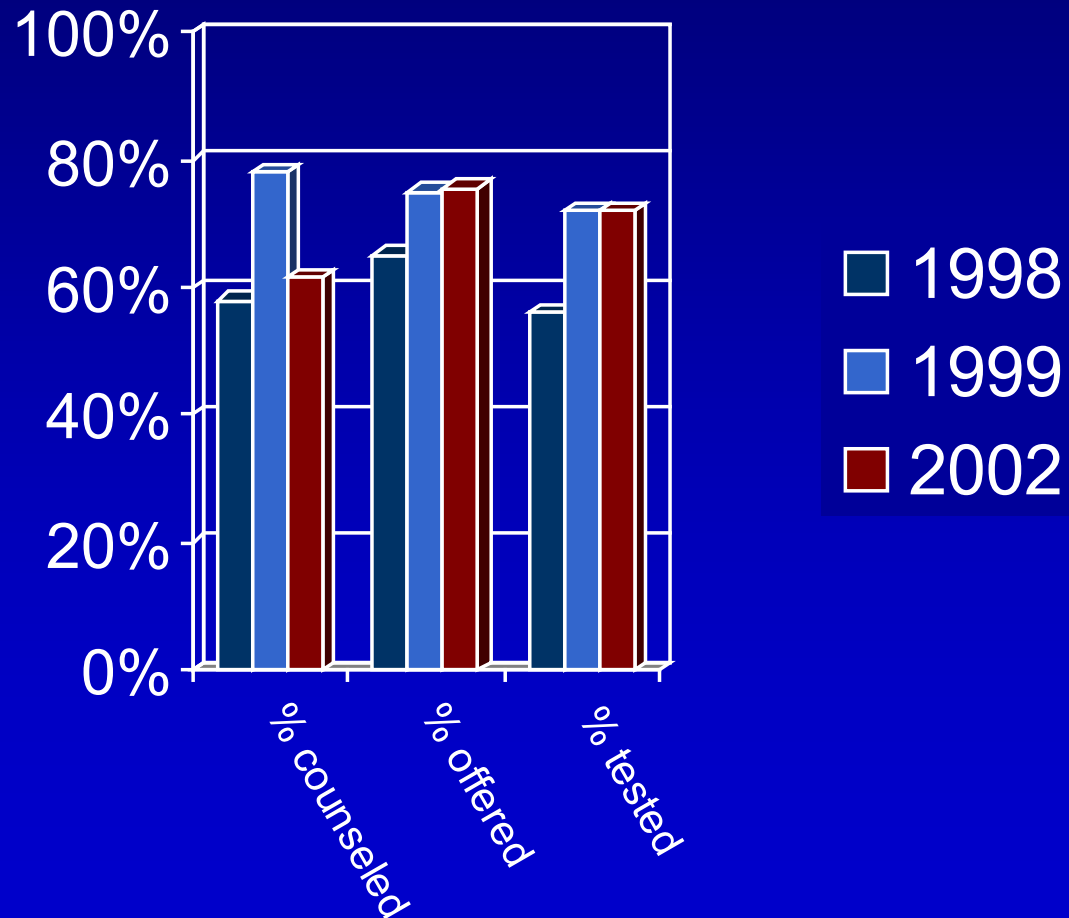
- **Opportunity**
  - New Illinois law
  - FDA approved Rapid HIV Test
- **Need**
  - Incomplete prenatal testing
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- **Intervention**
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- **Goal**
  - Eliminate Pediatric HIV in Illinois



# A Need: Untested Pregnant Women

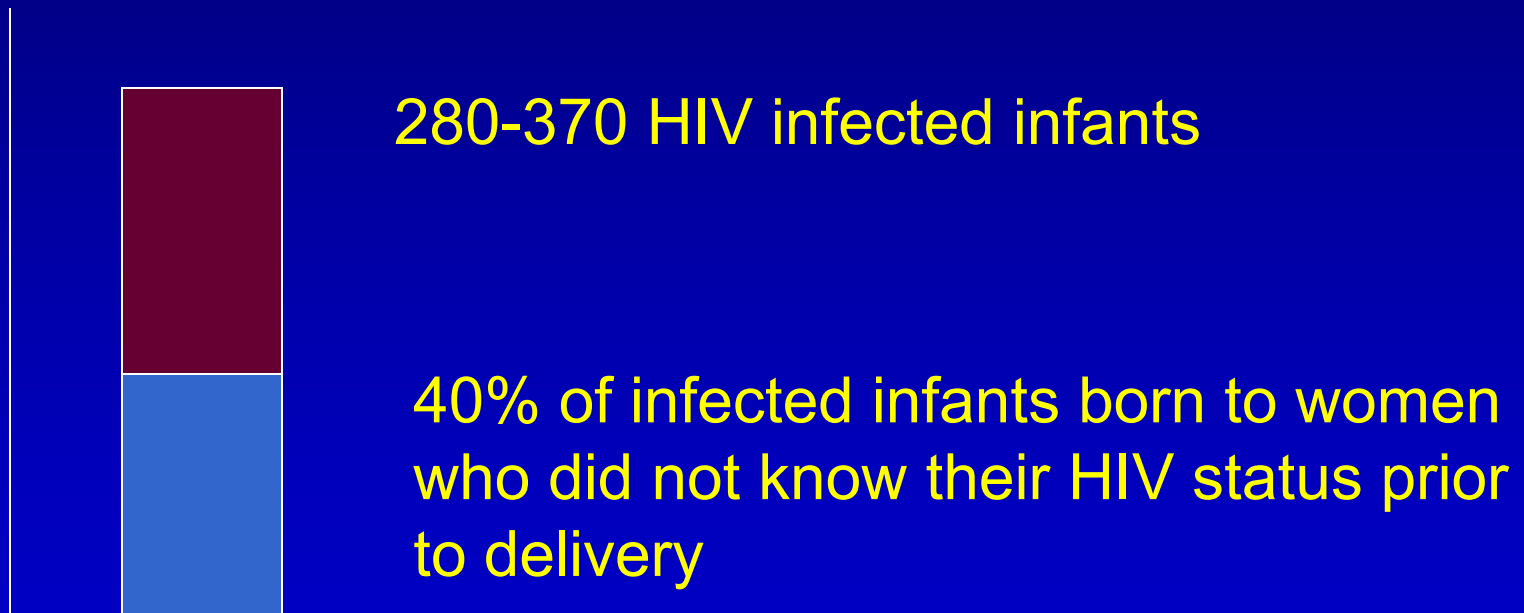
## Status of Prenatal HIV C/T in Chicago

- 66 hospitals surveyed
- 1 month: 1998,1999,2002
- 1999 9,115 /10,063 women
- 2002 5,031/6,135  
(82% completion rate)



# Unknown status = preventable pediatric HIV

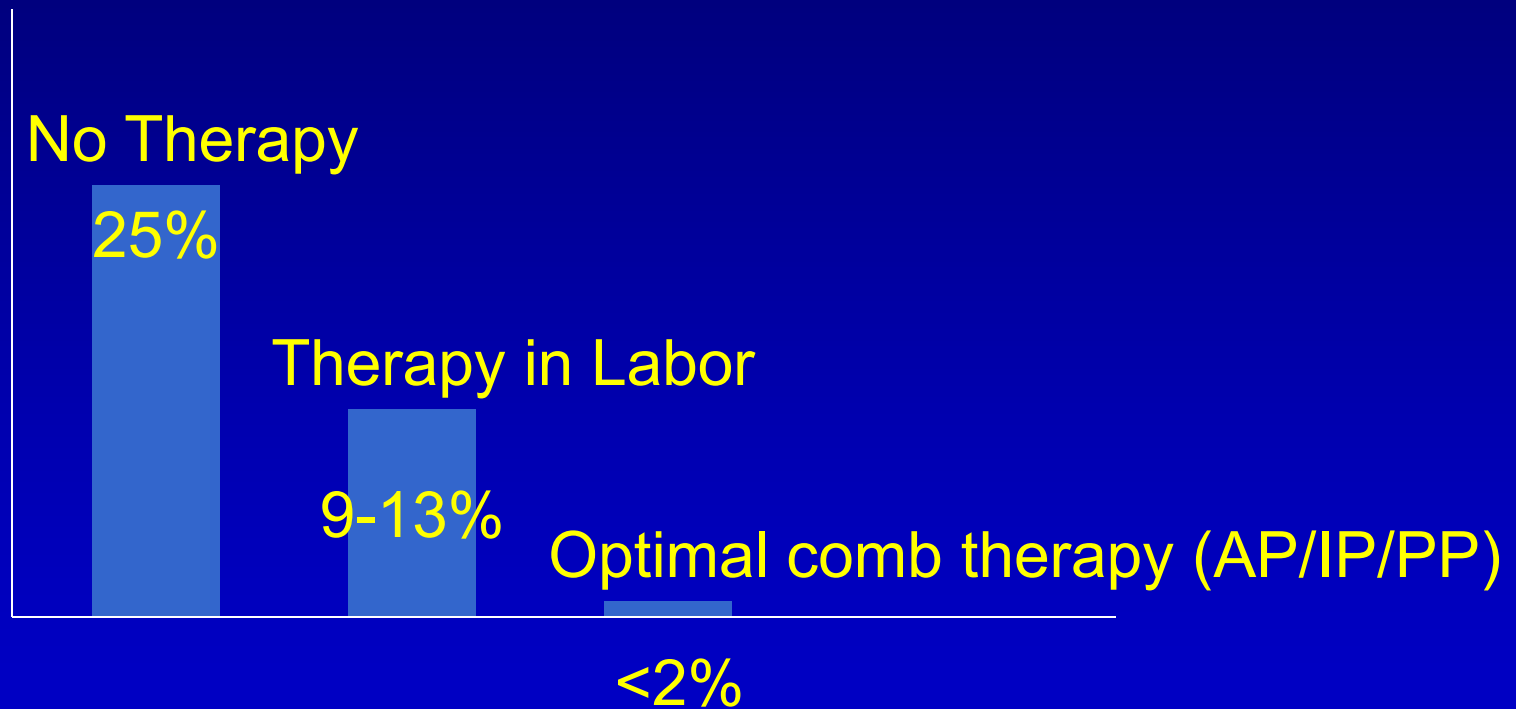
- 6,000 - 7,000 HIV infected women gave birth in 2000



# Rationale

- **Opportunity**
  - New Illinois law
  - FDA approved Rapid HIV Test
- **Need**
  - Incomplete prenatal testing
  - Unknown maternal HIV status = preventable pediatric HIV
- **Intervention**
  - If maternal HIV status known = effective treatment on labor & delivery to prevent perinatal transmission
- **Goal**
  - Eliminate Pediatric HIV in Illinois

# An Intervention: treatment to prevent transmission



Wade, et al. 1998 NEJM 339;1409-14

Guay, et al. 1999 Lancet 354;795-802

Fiscus, et al. 2002 Ped Inf Dis J 21;664-668

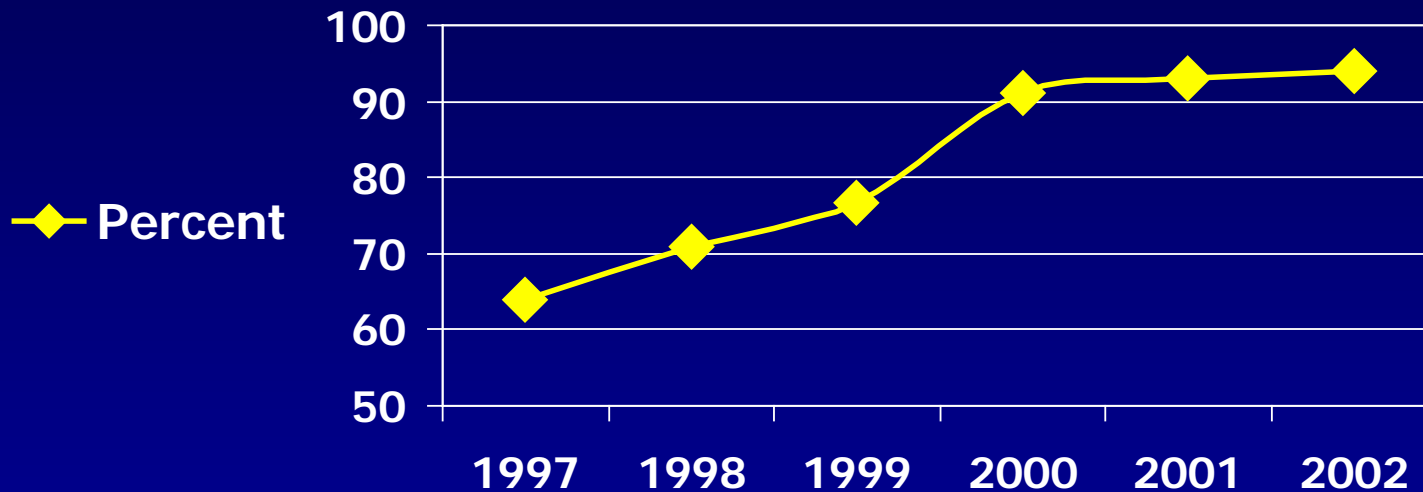
Moodley, et al. 2003 JID 167;725-735

# Rationale

- **Opportunity**
  - New Illinois law
  - FDA approved Rapid HIV Test
- **Need**
  - Incomplete prenatal testing
  - Unknown maternal HIV status = preventable pediatric HIV
- **Intervention**
  - If maternal HIV status known = effective treatment on labor & delivery to prevent perinatal transmission
- **Goal**
  - Eliminate Pediatric HIV in Illinois

# Women in NYS Aware of HIV Status Before Delivery

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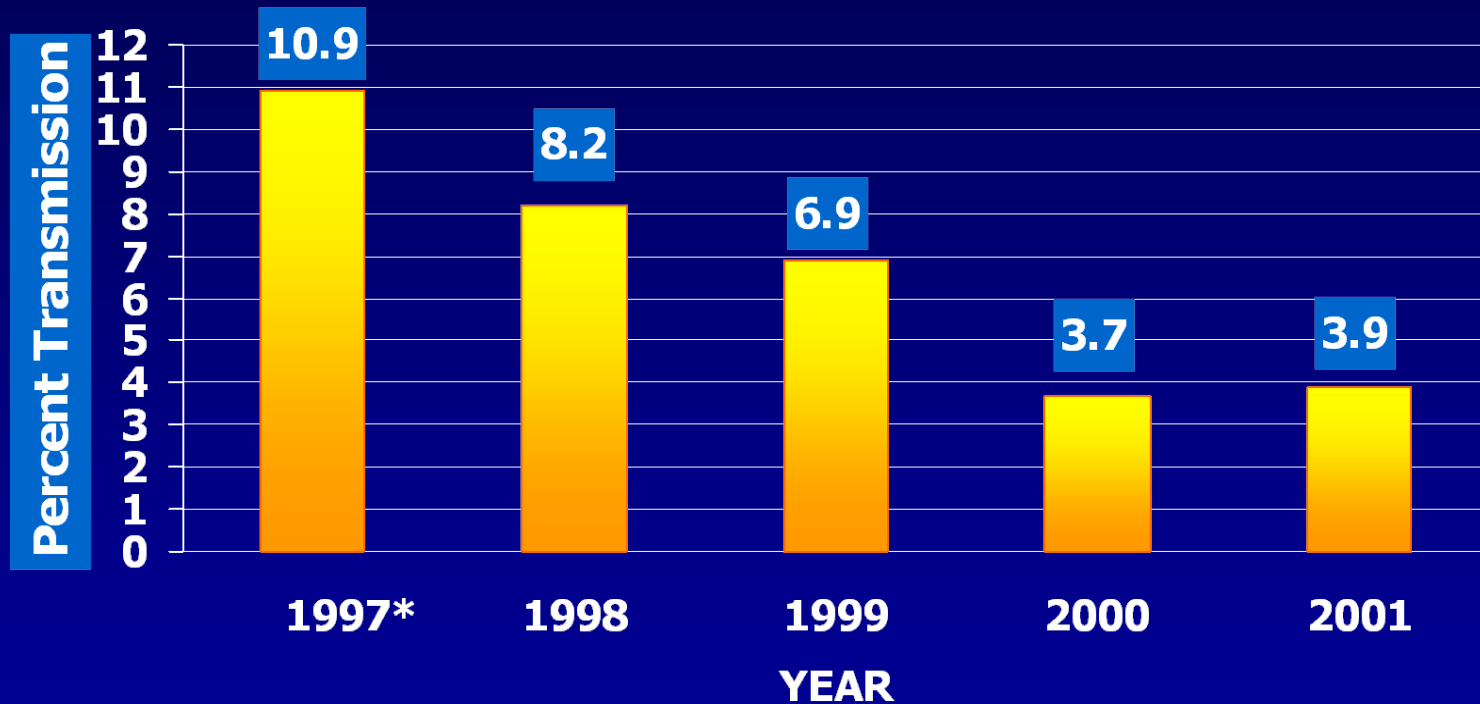


**Since 1997, there has been a 30% increase in the number of women aware of their HIV status before delivery (64 – 94%)**

Source: New York State Perinatal HIV Surveillance Program

# Perinatal HIV Transmission Rate New York State, 1997-2001\*\*

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**Percent of deliveries by HIV positive mothers that resulted in HIV transmission to the baby**

\* Feb-Dec, 1997; \*\* $p < 0.05$  using chi square for trends

# Work Plan

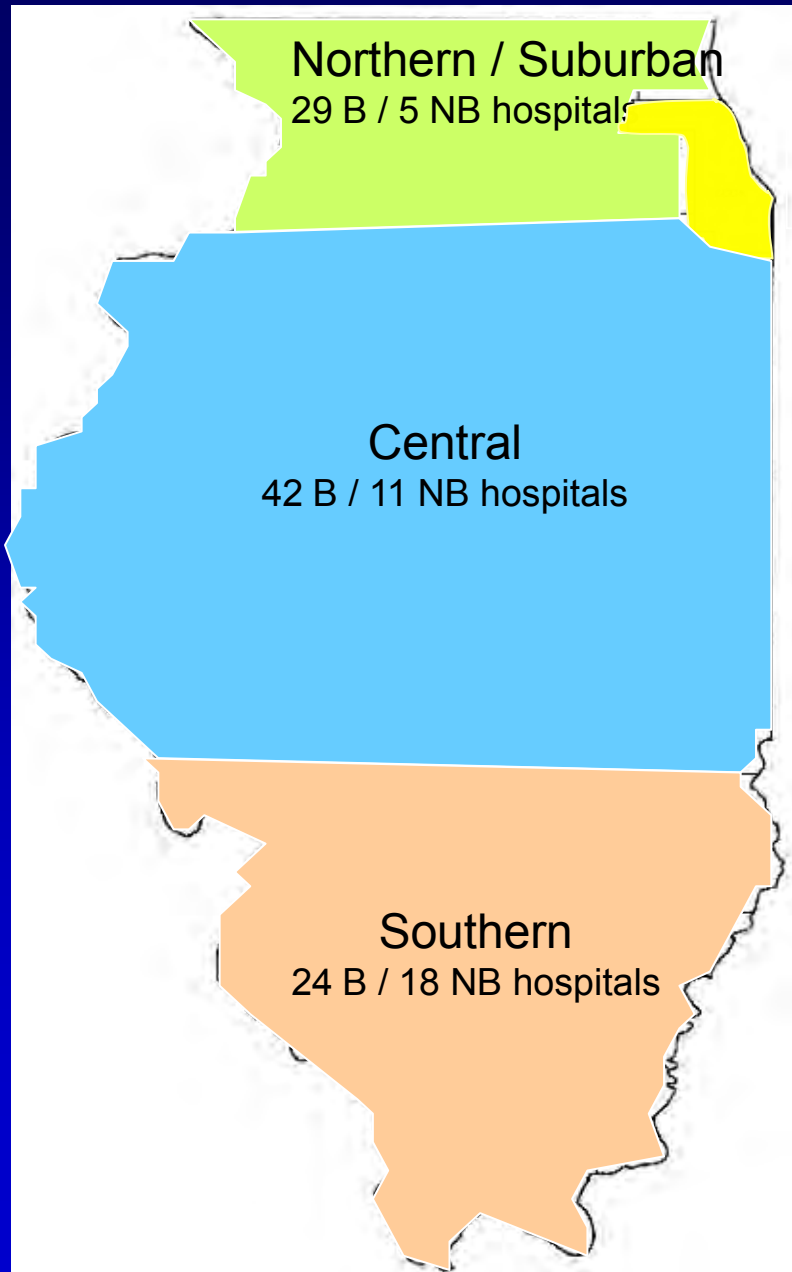
- **Needs Assessment**
  - Survey all hospitals in state (via perinatal coordinators)
  - Focus Groups (7) geographically dispersed
  - Pilot Projects in 2 hospitals
- **Implementation**
  - Implementation packets, education packets, technical assistance packets, counseling/consent templates to be available to every hospital.
  - Hospital Specific Implementation / Training via Regional Coordinators and MATEC Trainers.
- **Evaluation**
  - Implementation process
  - Ongoing state QA / surveillance



# Timeline

- **Feb – May 2004**
  - Needs Assessment: Survey/ Focus Groups
- **May-July 2004**
  - 2 Pilot Projects (Chicago area and Downstate)
- **July 2004 - June 2005**
  - Statewide training / implementation / evaluation\*
  - QA incorporation into statewide perinatal system.

# Regional Rapid Testing Coordinators



**Chicago**  
50 B / 8 NB hospitals

Network	Birthing hospitals	Non-birthing hospitals	Number of births
University of Chicago	11	2	
Cook County Hospital	9	0	
Northwestern	14	4	
University of Illinois	13	2	
Loyola	6	1	
Rush	15	1	
Suburban Combined*	(18)	(2)	
Rockford	11	3	
Peoria	27	10	
Springfield	15	1	
St. Louis	24	18	
<b>Totals</b>	<b>145</b>	<b>42</b>	

# Training and Implementation Model

## Each birthing hospital (5 days in-hospital, day administrative):

Time 0	Protocol implementation Review with Nurse Manager
2-4 weeks	Start 2-4 week Identification Process Staff training session #1 Staff training session #2
2-3 months	Quality assurance follow-up visit

## Each non-birthing hospital (1/2 day administrative)

- Send CEO letter
- Contact ER Director
- Contact Gyne/OB director

# Hospital Specific Implementation

- PRTII RC will conduct Key Players meeting and coordinate policy/procedure review & training
- Implementation Packet
  - PRTII Summary
  - Illinois Prevention Act
  - AIDS Confidentiality ACT
  - Illinois Legal Fact sheet on Documentation
  - Power point RT Training Module with Flip Charts
  - Templates
    - RT Implementation Policy
    - HIV Status Identification Form
    - Staff Memo Introducing RT Implementation
    - Summary Data Collection Sheet
    - HIV RT Consent Form
    - RT Log/QA Data Sheet
    - Laminated flow sheet
  - Positive Packet
  - Proficiency Training pre test/post test and check list

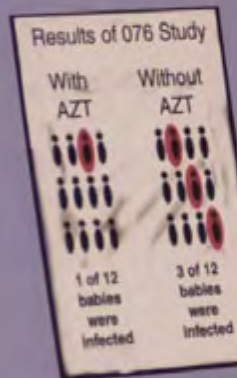
# MIRIAD (Nov 01-Jun 03)

## Mother and Infant Rapid Intervention at Delivery

- Of the 5,374 eligible women on L&D, **1,044 (19.4%)** could not be approached by the staff
- Of the remaining **4,330** women who were approached for rapid HIV testing, consent was obtained from **3,660 (84.5%)**

## THE BENEFITS OF TAKING AN HIV TEST

- All pregnant women should know if they have HIV.
- You can pass HIV to your baby during pregnancy, childbirth and breastfeeding.
- If you have HIV and are pregnant, you have about a 1 in 4 (25 %) chance of passing HIV to your baby.
- If you have HIV, you can take medicine to keep you healthy and to lower the chances of passing HIV to your baby. You can also choose not to breastfeed since babies can get HIV from their mother's milk.



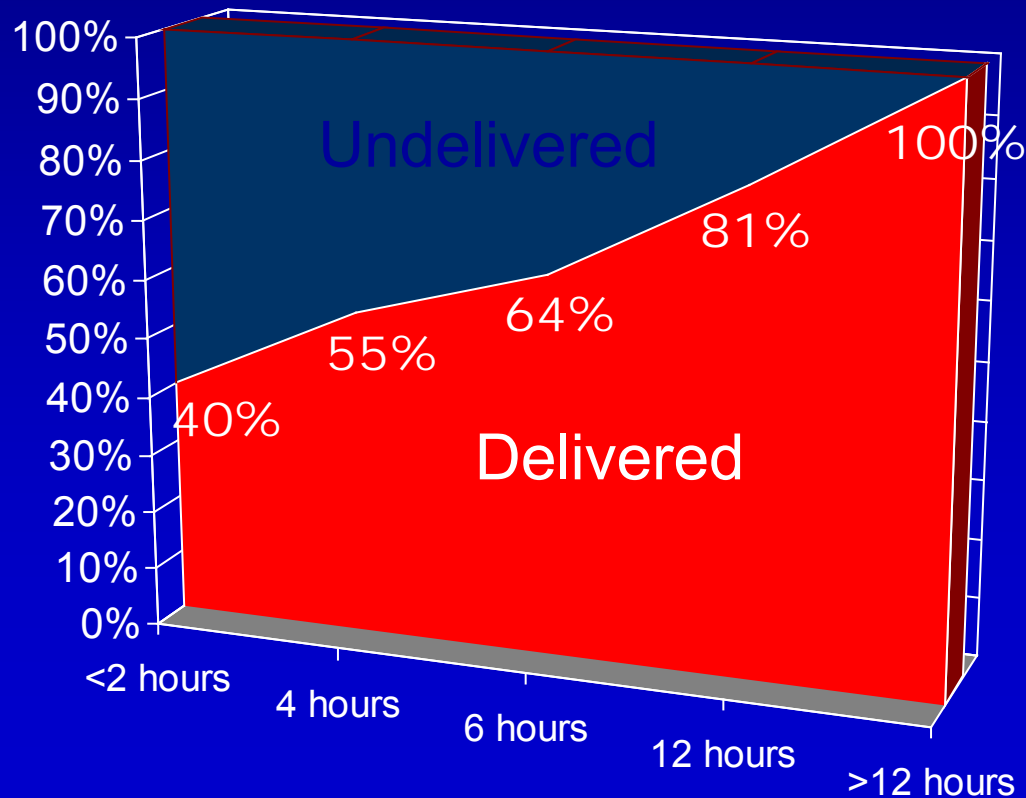
# Turnaround time for results

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	<b>Median</b>	<b>Range</b>
<b>Point-of-Care</b>	45 minutes	20 – 120 minutes
<b>Laboratory-based</b>	120 minutes	75 minutes – >300 minutes

# Patients without PNC – percent of patients delivering over time after admission

N = 557 deliveries to women without PNC  
6 L&D units in Chicago (34 pts missing data)





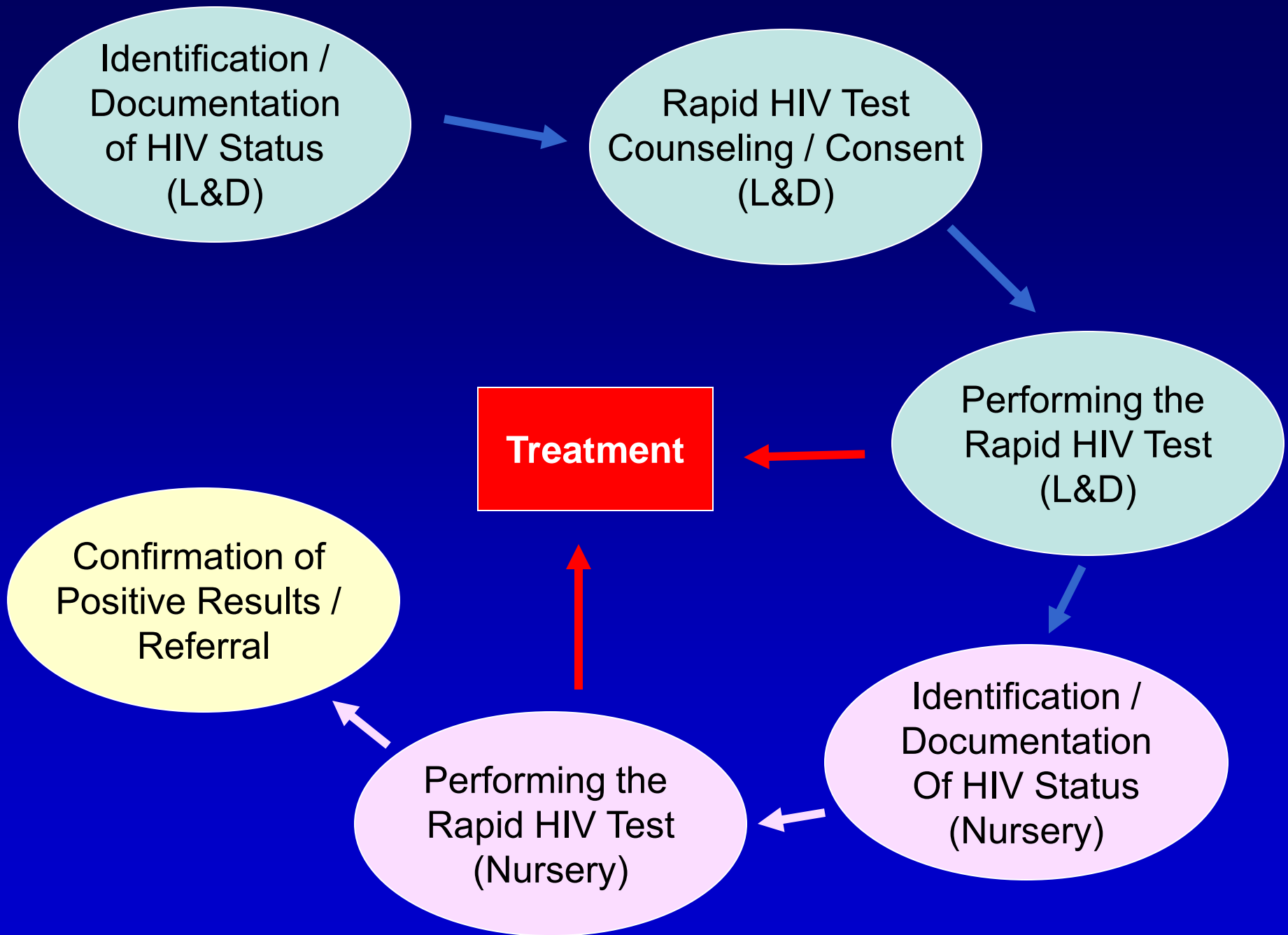
# Hospital Staff Reaction to Point of Care Rapid HIV Test

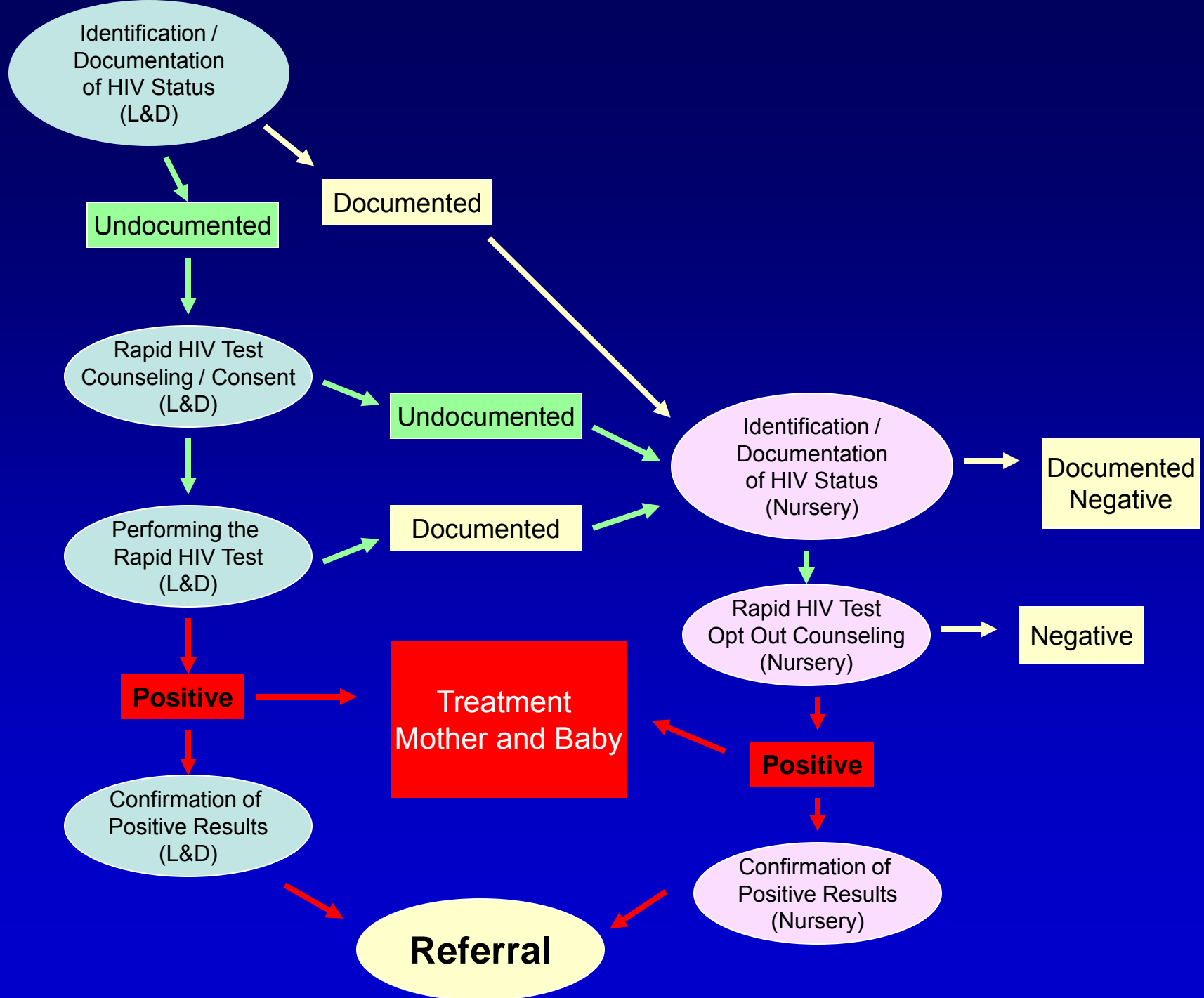
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- Utilizing a test that provided a fast turnaround time allowed providers more opportunities for getting the results to patients and for interventions
- Enjoyed being able to complete the test themselves
- Felt that they personally made a difference in the patient's care

# Evaluation/Surveillance System

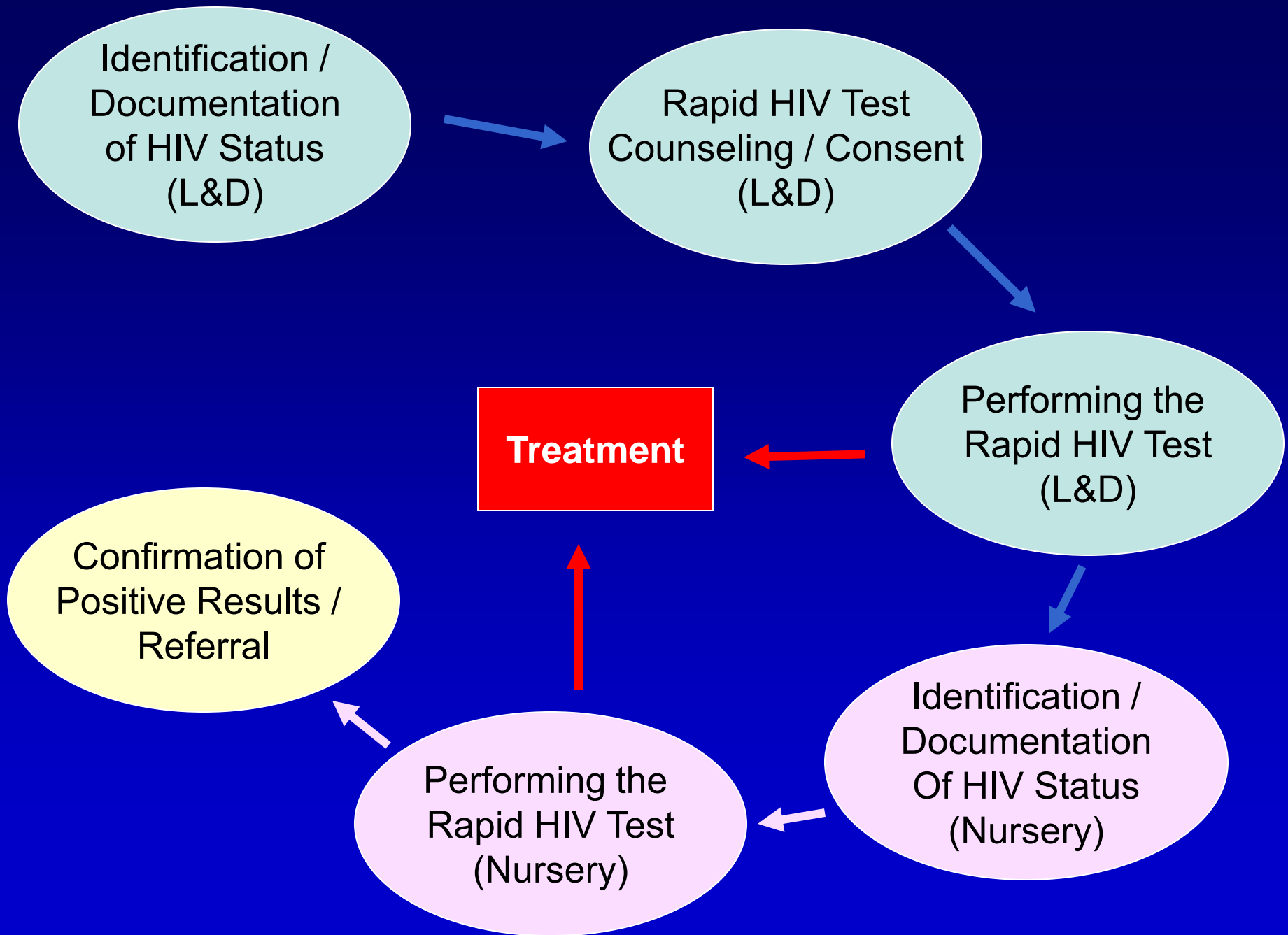
- Hospital QA system gathers data through chart review or L&D / nursery log book (or automated state birth data set when operational)
- Hospitals submit data on monthly basis to IDPH through Perinatal Networks (specific structure pending)
- Data analyzed by IDPH / SQC: trends tracked by hospital, county, Perinatal Network, state.
- Feedback / interventions to hospitals / providers if below state target perinatal HIV testing goals.





# Protocol Key Steps

- Enhance Prenatal HIV testing & have results on L&D
- Identify HIV status on arrival to L&D
- Counsel/Consent all women with undocumented HIV status for rapid HIV test.
- Perform point of care rapid HIV test on L&D
- Document results L&D and newborn chart
- Identify newborns with undocumented maternal HIV status
- Inform mother that their newborn will be HIV tested unless she declines.
- Perform rapid HIV test on newborn, document results
- If + results: counsel, treat, send confirmatory test, refer for follow up care



Identification /  
Documentation  
of HIV Status  
(L&D)

Rapid HIV Test  
Counseling / Consent  
(L&D)

Performing the  
Rapid HIV Test  
(L&D)

**Treatment**

Confirmation of  
Positive Results /  
Referral

Identification /  
Documentation  
Of HIV Status  
(Nursery)

Performing the  
Rapid HIV Test  
(Nursery)

## Infectious Disease Questionnaire

From: Perinatal Rapid Testing Initiative in Illinois

As part of the Illinois Perinatal HIV Prevention Act:

- All pregnant women in Illinois will be counseled and offered an HIV test.
- HIV test results will be documented in the prenatal, L&D, and newborn pediatric charts.
- If there is no documented maternal HIV status on arrival to L&D, the patient will be offered a Rapid HIV test.
- If maternal status is not known at delivery, the newborn will be given a Rapid HIV test unless the mother declines.

### **Follow Up / Referral for Preliminary Positives:**

- a. Insure that a referral plan for specialized HIV care for preliminary HIV positive patients and exposed infants is in place prior to the start of rapid testing in your hospital.
- b. Insure that a referral plan for case management of HIV positive patients and exposed infants is in place prior to the start of rapid testing in your hospital.
- c. All preliminary positive patients and exposed infants must be referred for immediate start of specialized HIV care.
  - i. Confirmation that the referral has been made should be the responsibility of the covering physician.
  - ii. The local community health nurses (contact local dept of public health) can be involved to insure that the patient and newborn have linked with follow-up care.
- d. All preliminary positive patients must be given the results of their confirmatory Western Blot test.
  - i. Follow-up of confirmatory results with the patient is the responsibility of the covering physician and must be documented.
  - ii. If the patient signs a release of information, the preliminary positive result and confirmatory result can be tracked through the Illinois Perinatal HIV Hotline (PACPI) 1-800-439-4079
  - iii. The local health department and public health nurses can be contacted to assist with patient notification of confirmatory result and need for continued AZT treatment. The mother and infant must be linked to care. The perinatal HIV Hotline can assist with identifying local resources for case management and HIV care.

1) Is there an Infectious Disease / HIV specialist available in your hospital? Who?

2) What will be the specific referral plan for specialized HIV care for HIV-positive women identified in labor and exposed newborns?

3) What will be the plan for follow-up of confirmatory Western Blot results?

**Name of Department Contact Person:**

**Phone Number:**

**Email Address:**

## Information Systems Questionnaire

From: Perinatal Rapid Testing Initiative in Illinois

As part of the Illinois Perinatal HIV Prevention Act:

- All pregnant women in Illinois will be counseled and offered an HIV test.
- HIV test results will be documented in the prenatal, L&D, and newborn pediatric charts.
- If there is no documented maternal HIV status on arrival to L&D, the patient will be offered a Rapid HIV test.
- If maternal status is not known at delivery, the newborn will be given a Rapid HIV test unless the mother declines.

- 1) Are HIV results currently available on the computer?
- 2) Which staff members are allowed to view HIV results?
- 3) What is the process to obtain staff access for results?
- 4) How can this training be arranged?
- 5) Who is responsible for changing access/screens on computer?
- 6) How is this process accomplished?
- 7) How can point of care preliminary results screen be added to computer?
- 8) How can point of care preliminary HIV Test Results and Western Blot Test Results be correlated on the computer?
- 9) Can this process be expedited?
- 10) Can electronic L&D / Nursery admission and discharge forms be revised to include HIV status?

**Name of Department Contact Person:**

**Phone Number:**

**Email Address:**



## **L&D Manager Questionnaire**

From: Perinatal Rapid Testing Initiative in Illinois

As part of the Illinois Perinatal HIV Prevention Act:

- All pregnant women in Illinois will be counseled and offered an HIV test.
- HIV test results will be documented in the prenatal, L&D, and newborn pediatric charts.
- If there is no documented maternal HIV status on arrival to L&D, the patient will be offered a Rapid HIV test.
- If maternal status is not known at delivery, the newborn will be given a Rapid HIV test unless the mother declines.

### **A. Staff Issues/Training**

1) Number on Staff

RN's

Tech's

2) Are staff cross-trained?

3) When/where are staff meetings?

4) Names of Charge Nurses for L&D:

5) Names of Charge Nurses for Nursery:

6) Are Registry/Traveling RN's used?

7) Nurse Educator's name:

8) Will rapid testing be POC or lab based?

9) If POC, where is POC testing done?

10) Who obtains blood?      Lab?    RN's?

### **B. HIV Policy Issues**

1) How is HIV testing done?

Who?

When?

Where?

2) Are results currently documented on the following forms?

3) Will there be a space for both prenatal HIV status and rapid HIV test result?

Triage?

L&D Admission?

H&P?

Labor & Delivery Summary?

Nursery Admission?

- 4) Are policies for AZT / ZDV Administration for women in labor currently in place?
- 5) Are policies for AZT / ZDV Administration for newborns currently in place?
- 6) Where are the policies located on the unit?
- 7) Where are the policies located in the nursery?
- 8) Average time patient is in L&D prior to being transferred to Postpartum?
- 9) Who offers HIV Test/consent?
- 10) Who gives HIV results to the patient?
- 11) How is testing documented?
- 12) How are results documented?

### **C. Postpartum Issues**

- 1) Where is postpartum located in relationship to L&D?
- 2) Is there a need for separate testing area within PP?
- 3) When a patient comes in who delivers at home, who will offer test?
- 4) How long is patient's usual length of stay?

### **D. Nursery Issues**

- 1) Where is nursery located in relationship to L&D?
- 2) Is there a need for separate testing area with the nursery?

### **E. Physician/Midwifery Staff Issues**

- 1) Number of OB physicians with delivery privileges?
- 2) Number of Midwives with delivery privileges?
- 3) Number of Family Practice physicians with delivery privileges?
- 4) Number of private offices/clinics/health departments attached/affiliated with the hospital?
- 5) Number of Residents at hospital?
- 6) What kind of Residents are in L&D?

**Name of Department Contact Person:**  
**Phone Number:**

**Email Address:**

## Laboratory Questionnaire

From: Perinatal Rapid Testing Initiative in Illinois

As part of the Illinois Perinatal HIV Prevention Act:

- All pregnant women in Illinois will be counseled and offered an HIV test.
- HIV test results will be documented in the prenatal, L&D, and newborn pediatric charts.
- If there is no documented maternal HIV status on arrival to L&D, the patient will be offered a Rapid HIV test.
- If maternal status is not known at delivery, the newborn will be given a Rapid HIV test unless the mother declines.

### **Lab Issues:**

- a. Responsibility for and site for conducting of Perinatal Rapid HIV Testing needs to be determined (lab-based or point of care). The key issue is ability to consistently (24 hrs per day 7 days per week) generate rapid results within 20 to 40 minutes.
- b. Training protocols and ongoing staff competency protocols are provided in the Hospital Rapid Testing Resource Binder (provided at nurse manager regional trainings) can be reviewed, revised and adopted as hospitals see fit. Regional and in-hospital staff training will be provided per the protocols accepted by the CDC and the makers of OraQuick rapid tests.
- c. QA protocols should be adopted by all hospitals. CDC recommendations are provided (**see laboratory considerations p. 34**).
- d. CLIA Waivers must be obtained for all point of care testing (**see laboratory considerations p. 49**) for the CDC CLIA Waiver Fact Sheet.
- e. Choose a rapid test kit (**see laboratory considerations p. 30**). Regional and in-hospital staff trainings will be provided using the OraQuick rapid HIV test kit from OraSure. Information regarding other available rapid HIV test kits is available in **Laboratory Considerations page 30**.
- f. Order sufficient test rapid test kits / controls to have available for the rapid testing start date set by your hospital.

### **A. QA issues:**

- 1) What competency will the lab require for staff in relation to point of care testing and Rapid HIV Testing?
- 2) Does the hospital have a CLIA status?
- 3) What is the hospital CLIA number?
- 4) What will Lab do to ensure proper documentation of Rapid HIV Test Log if testing is done in Lab? Will log stay on L&D to be completed by nursing?
- 5) Who will receive and store Rapid HIV Tests, run/document controls & record Lot #'s and inventories?

**B. Confirmatory Testing for Preliminary Positives:**

- 1) What is the current system for requesting a Western Blot test?
- 2) What tube is used to collect the specimen?
- 3) What is the hospital process for getting samples to lab?
- 4) What is the follow-up result if positive?
- 5) Who follows up positive results?
- 6) Is a Phlebotomist available 24 hours a day?  
If no, what is the system?
- 7) Is a lab requisition required for HIV test?  
Paper form?                      Computer requisition?
- 8) Where are the lab requisitions located in the department?  
(Please attach a sample if paper form)

**Name of Department Contact Person:**

**Phone Number:**

**Email Address:**

## NICU Questionnaire

From: Perinatal Rapid Testing Initiative in Illinois

As part of the Illinois Perinatal HIV Prevention Act:

- All pregnant women in Illinois will be counseled and offered an HIV test.
- HIV test results will be documented in the prenatal, L&D, and newborn pediatric charts.
- If there is no documented maternal HIV status on arrival to L&D, the patient will be offered a Rapid HIV test.
- If maternal status is not known at delivery, the newborn will be given a Rapid HIV test unless the mother declines.

1) How close is the NICU to Labor & Delivery?

2) How will maternal HIV status be transmitted to nursery staff?

3) How will information be transmitted from L&D to the NICU regarding the mother is informed her infant will be tested unless she refuses?

4) How will information be transmitted from L&D to NICU regarding if a mother refused infant testing in writing?

5) Who will be performing the rapid HIV test on newborns?

6) Where will point of care testing be done?

7) Who will tell the infant's mother the preliminary results?

8) Where are AZT therapy protocols located in the department?

**Name of Department Contact Person:**

**Phone Number:**

**Email Address:**

## Pharmacy Questionnaire

From: Perinatal Rapid Testing Initiative in Illinois

As part of the Illinois Perinatal HIV Prevention Act:

- All pregnant women in Illinois will be counseled and offered an HIV test.
- HIV test results will be documented in the prenatal, L&D, and newborn pediatric charts.
- If there is no documented maternal HIV status on arrival to L&D, the patient will be offered a Rapid HIV test.
- If maternal status is not known at delivery, the newborn will be given a Rapid HIV test unless the mother declines.

- 1) Is AZT / ZVD available in the pharmacy (in IV and syrup form)?
- 2) When can AZT (IV and syrup form) become available 24/7 to L&D and the newborn nursery?
- 3) Is the pharmacy open 24 hours / is a pharmacist available 24/7 to handle stat calls?
- 4) If a pharmacist is not available 24/7 for stat AZT, do the nurses on L&D have access to AZT and instructions for diluting for administration? Do the L&D and newborn nursery nurses have access to stat syrup AZT 24/7?
- 5) Is there 24-hour pharmacy storage?
- 6) What is the protocol for the STAT pharmacy delivery during daytime and nighttime hours? How quickly can AZT be hanging for a patient on L&D once a positive rapid HIV test is identified?
- 7) Can a mother be discharged with full AZT / ZVD prescription therapy for her infant?

**Name of Department Contact Person:**

**Phone Number:**

**Email Address:**

## Forms Questionnaire

From: Perinatal Rapid Testing Initiative in Illinois

As part of the Illinois Perinatal HIV Prevention Act:

- All pregnant women in Illinois will be counseled and offered an HIV test.
- HIV test results will be documented in the prenatal, L&D, and newborn pediatric charts.
- If there is no documented maternal HIV status on arrival to L&D, the patient will be offered a Rapid HIV test.
- If maternal status is not known at delivery, the newborn will be given a Rapid HIV test unless the mother declines.

1) When/how can new HIV consent be printed and available for Rapid HIV testing on the OB unit? (template for the consent and Spanish version is available in the binder)

2) Do L&D and newborn nursery admission forms have a space to document prenatal HIV status and rapid HIV test result?

3) How can standing L&D admission orders be revised to order: counsel, consent and conduct a rapid HIV test for all admission with undocumented prenatal HIV status?

4) How can standing newborn nursery admission orders be revised to order: conduct a rapid HIV test as soon as possible after delivery for all newborns with undocumented maternal HIV status at delivery?

5) What/how long is the revision of forms process?

6) Can process be expedited?

**Name of Department Contact Person:**

**Phone Number:**

**Email Address:**



## Rapid Testing Policy and Logistics Questions

- 1) Will rapid testing be done Point-of Care (POC) or Lab Based?  
Will results be back consistently, 24/7 between 20-40 minutes?
- 2) If POC is planned, where will staff do POC testing?  
Dirty utility room?  
Other?
- 3) Where will purple forms be kept in L&D?  
Box/folder/binder in nurse's station?
- 4) Where will the flip chart be kept in L&D?  
Nurse's station bookshelf?  
With tests?
- 5) Where will the tests and timer be kept in L&D?  
Dirty utility room?  
Clean utility room?
- 6) Where will Log be kept in L&D?  
Nurse's station bookshelf?  
With tests in dirty/clean utility room?
- 7) Who will be responsible for collecting data from the log to send monthly to the hospital PRTII Regional Coordinator (who will send it on to IDPH)?
- 8) Where will positive results packet be kept in L&D?  
Who will do post-test counseling with patients?
- 9) Policy for notifying Pharmacy of need for stat ARV therapy.  
Fax?                      Computer?
- 10) Policy for follow-up and referral:
  - notifying Social Services Dept of patient/baby with preliminary positive results
  - Follow-up of confirmatory Western Blot
  - Referral plan for women & newborn for specialized HIV care, confirming link to care
- 11) Will the testing be done in L&D prior to infant going to the Nursery?
- 12) If Nursery does test, where will they keep the tests and timers?  
Where will they keep the Log?  
Where will they do the test? Circumcision area?
- 13) Will NICU staff do rapid testing?  
Document in Log in L&D  
Tests kept in L&D

# **Documents for Implementation**

# **Documents for Implementation: Summary Steps**

## **1) Review and adopt rapid testing policies and templates**

- a. Rapid Testing Implementation Policy
- b. Rapid Testing Consent Template
  - 3 versions (Maternal Consent/Infant Refusal Form/Combined)
- c. HIV Status Identification Template
  - use to collect HIV status data on all L&D patients during the HIV status identification time period (2-4 weeks) prior to formal rapid testing start date
  - review and revise your hospitals L&D and newborn nursery admission forms to insure space to document maternal HIV status (prenatal and/or rapid test result) (required by the IL Perinatal HIV Prevention Act)
- d. Set standing admission orders:
  - L&D: to counsel, consent and conduct rapid HIV test for all patients with undocumented HIV status on arrival to L&D.
  - Newborn Nursery: to conduct a rapid HIV on all newborns with undocumented maternal HIV status as soon as possible after birth unless mother refuses in writing.
- e. Rapid Testing Log/QA Data Form
  - must use this version to maintain consistent data collection on ALL patients/newborns with undocumented HIV status on arrival to L&D.

## **2) Notify nursing, medical and administrative staff of policy and procedure changes**

Notification and buy-in of staff is important for uniform and integrated implementation across all departments. RN/MD memos are provided

## **3) Arrange L&D and Nursery staff trainings with Regional Coordinator**

In-hospital training will be provided for as many L&D/nursery nursing staff as possible. Staff training power point presentation and Counseling Flip Chart, pre-test/post-test and Rapid Testing Certification are included. Remaining staff, new hires and on-going proficiency will utilize self-directed training packets with nurse manager oversight. Training of all staff must be completed by rapid testing start date. Rapid Testing Certification Sheets should be collected and filed by the Nurse Manager. Pre-test/Post-tests should be sent to the Regional Coordinators.

## **4) Initiate rapid HIV testing surveillance data collection**

Use monthly summary data collection sheet to summarize data from rapid test logs; summary data sheets will be submitted monthly to IDPH through the PRTII Regional Coordinator. Fax or email the monthly summary sheet to your Regional Coordinator. Any preliminary positive data forms should also be sent to the Regional Coordinator. A permanent mechanism for transmission of data to IDPH is pending.

## DRAFT POLICY AND PROCEDURE: Perinatal Rapid HIV Counseling/Testing Implementation Policy

### **PURPOSE:**

1. To facilitate implementation of Illinois Law, 410 ILCS 335/10 and provide guidelines in accordance with the requirements for HIV confidentiality, counseling and testing of pregnant women and infants set forth in Illinois Law, 410 ILCS 335/10.
2. To facilitate early identification of patients for rapid HIV testing across areas.
3. To facilitate documentation of HIV serostatus in the patient record and improve compliance with submission of prenatal records to labor and delivery area.
4. To provide continuity of care and compliance across obstetric areas

### **PROCEDURES:**

1. All patients presenting in labor without a documented negative or positive HIV test result during the current pregnancy are required to be offered HIV counseling and testing.

2. The OB Triage, labor & delivery, postpartum and nursery units will institute standard documentation of HIV test results (to include HIV Status: Neg \_\_\_\_ Pos \_\_\_\_ Indeterminate \_\_\_\_ Pending \_\_\_\_ Not Documented \_\_\_\_). Revisions will be made to paper/electronic forms and logs in triage, labor and delivery, postpartum and nursery areas. Forms to be revised may include:

- a. The Triage Assessment Form
- b. Labor and Delivery Admit Form
- c. Hollister
- d. Nursery admission
- e. L&D Admission log
- f. Nursery Admission log

3. All counseling and HIV testing must be performed in accordance with the standards set forth in the AIDS Confidentiality Act, with the exception of the requirement of consent for testing of newborn infants.

4. HIV counseling for all perinatal care settings must include the following information (as available in PRTII flipchart):

- a. The benefits of HIV testing for the pregnant woman, including the prevention of transmission.

- b. The benefit of HIV testing for the newborn infant, including interventions to prevent HIV transmission.
  - c. The side effects of interventions to prevent HIV transmission
  - d. The statutory confidentiality provisions that relate to HIV and acquired immune deficiency syndrome ("AIDS") testing.
  - e. The voluntary nature of the testing, including the opportunity to refuse testing of a newborn infant in writing.
- 5. Trained personnel will perform rapid HIV testing in the designated area and document HIV results in the Rapid Testing Log.
- 6. Confirmatory testing by Western Blot will be sent by usual hospital methods for all preliminary positive rapid test results.
- 7. When a patient is triaged following a delivery which occurred outside of the hospital and she does not have a documented negative HIV result, she must be offered Rapid HIV testing in accordance with Illinois law. If she refuses then her newborn should be tested for HIV unless written refusal for infant testing is given.
- 8. Upon identifying a woman or infant with a preliminary positive HIV rapid test, the nurse manager will ensure that the procedure for offering and administering ZDV is followed.
- 9. The nurse manager will ensure that an appropriate referral is made to the perinatal regional administrator for follow up HIV care of all HIV positive identified women and infants.

**SETTING SPECIFIC PROCEDURES: HIV Counseling and Testing for Women  
INTRAPARTUM**

- a. A health care professional or counselor shall provide counseling and offer HIV testing ASAP after eligibility for HIV testing has been determined.
- b. Women who accept HIV testing should be given their test results ASAP.
- c. All tests should be documented in the Rapid HIV testing log located at the testing area on the unit.
- d. All tests should be documented in the patient medical record.
- e. Women who have a positive result will be offered antiretroviral prophylaxis according to hospital policy for intrapartum medication

**POSTPARTUM-NURSERY**

- a. Women who decline or were not offered HIV testing intrapartum should be re-approached and re-counseled postpartum, prior to newborn testing.

- b. Consent for HIV testing of a newborn infant shall be presumed when a health care professional or health care facility seeks to perform a test on a newborn infant whose mother's HIV status is not known, provided that the newborn infant's parent or guardian has not indicated in writing that he or she refuses to allow the newborn infant to receive HIV testing.
- c. All infants testing HIV positive will receive antiretroviral prophylaxis according to hospital policy for newborn medication.
- d. All tests should be documented in the Rapid HIV testing log located at the testing area on the unit.
- e. All tests should be documented in the patient medical record.
- f. All patients should be informed of their rapid test results ASAP.

## MD MEMORANDUM

TO: All Obstetric Physicians

FR: Perinatal Center Administrator and OB Manager

RE: Rapid HIV Testing Pilot Training/Implementation at \_\_\_\_\_ Hospital

Date: \_\_\_\_\_

The Perinatal HIV Prevention Act is now effective under Illinois law. This Act requires that Obstetric providers counsel and test all pregnant patients for HIV infection. Infants born to women with an unknown HIV serostatus will be routinely tested unless there is written refusal for infant testing by the mother or guardian. The law also requires that HIV testing be conducted using rapid HIV tests, with results available within 1 hour, in all labor and delivery settings.

To ensure that \_\_\_\_\_ hospital is in accordance with the new Illinois statutes, we are now working in collaboration with the Perinatal Rapid Testing Initiative of Illinois (P.R.T.I.I.) Through this collaboration, hospitals in the \_\_\_\_\_ network are being offered technical assistance with implementing protocols and practices that are in accordance with this law.

P.R.T.I.I. staff will be conducting training on rapid HIV counseling and testing competencies on the unit. The dates and times of these training sessions will be posted and attendance at a session by all providers who might use rapid tests is mandatory. After training the staff in HIV rapid testing and reaching agreement on the policy and protocol, we will begin identifying patients who should be rapidly tested for several weeks. After completing this 6 week program, we will begin providing HIV RT for all women entering our unit by. We expect our start date to be \_\_\_\_\_.

Thank in advance you for your cooperation.

# RN MEMORANDUM

TO: All RN/OB staff

FR: Perinatal Center Administrator and OB Manager

RE: Rapid HIV Testing Pilot Training/Implementation at \_\_\_\_\_ Hospital

Date: \_\_\_\_\_

The Perinatal HIV Prevention Act is now effective under Illinois law. This Act requires that Obstetric health care providers ensure that Perinatal HIV counseling and testing are offered to all pregnant. Infants born to women with an unknown HIV serostatus will be routinely tested (with the exception of written refusal for infant testing by the mother or guardian). The law also requires that HIV testing be conducted using rapid HIV tests, with results available within 1 hour, in all labor and delivery settings.

To ensure that \_\_\_\_\_ hospital is in accordance with the new Illinois statutes, we are now working in collaboration with the Perinatal Rapid Testing Initiative of Illinois (P.R.T.I.I.) Through this collaboration, hospitals in the \_\_\_\_\_ network are being offered technical assistance with implementing protocols and practices that are in accordance with this law.

P.R.T.I.I. staff will be conducting training on rapid HIV counseling and testing competencies on the unit. The dates and times of these training sessions will be posted and attendance at a session by all RN staff is mandatory. After training the staff in HIV rapid testing and reaching agreement on the policy and protocol, we will begin identifying patients who should be rapidly tested for several weeks. With this 6 week program, we expect to be providing HIV RT for all women entering our unit by \_\_\_\_\_.

Thank in advance you for your cooperation.



# HIV STATUS IDENTIFICATION

("Patient name plate" or "addressograph")

Date: \_\_\_ / \_\_\_ / 20 Time: \_\_\_\_:\_\_\_\_ AM/PM

## HIV Rapid TESTING Criteria

1. Does patient have a DOCUMENTED HIV result?  YES  NO

a) If yes, results documented by:  
(VERBAL FROM PATIENT IS NOT ACCEPTABLE)

- Prenatal Record
- Other Electronic
- Other Written
- Verbal from Health Care Provider

b) If no, reason for undocumented status:

- Had NO prenatal care
  - No HIV test done during pregnancy (had prenatal care)
- Name of Clinic/MD where care was received:

\_\_\_\_\_

- Test done (per patient) but no results available
- Name of Clinic/MD where care was received:

\_\_\_\_\_

\_\_\_\_\_

# Rapid HIV Test Log/QA Data Sheet

## FOR ALL Mother/Infant Pairs WITH UNDOCUMENTED MATERNAL HIV STATUS

Patient name: \_\_\_\_\_  
 Arrival on L&D Date: \_\_\_\_\_ Time: \_\_\_\_\_  
 Delivery Date: \_\_\_\_\_ Time: \_\_\_\_\_  
 Log Completed By: \_\_\_\_\_

Reason for undocumented status:  
 Had No Prenatal Care  
 No HIV test done during pregnancy  
 (could have had prenatal care)  
 Test done (per patient) but no  
 documented results

Patient Age \_\_\_\_\_  
 Gestational Age \_\_\_\_\_  
 Race  Hispanic  
 Black  
 White  
 Other \_\_\_\_  
 Unknown

Note: All information on log must be completed for mother/infant

Patient Name	Medical Record #	HIV Testing Declined	Tester Initials	Lot # Expiration Date	Date/Time of Rapid Test	Preliminary Result from rapid test:	Date / Time Patient received result:	# of min. between rapid test and results given to patient	Western Blot Date Sent / /
		If yes check here: <input type="checkbox"/>			Date: Time:	Negative <input type="checkbox"/> Positive <input type="checkbox"/>	Date: Time:	_____ min Result Given Before delivery? Y <input type="checkbox"/> N <input type="checkbox"/>	Negative <input type="checkbox"/> Positive <input type="checkbox"/>

\* If Mother Declined HIV Testing Complete Infant Test Log Below

Infant Name	Medical Record #	Written Refusal For Infant	Tester Initials	Lot # Expiration Date	Date / Time of Rapid Test:	Preliminary Result from Rapid Test	Date / Time Patient received result:	# min between birth & rapid test performed on infant:	Western Blot Date Sent / /
		If yes check here: <input type="checkbox"/>			Date: Time:	Negative <input type="checkbox"/> Positive <input type="checkbox"/>	Date: Time:	_____ min	Negative <input type="checkbox"/> Positive <input type="checkbox"/>

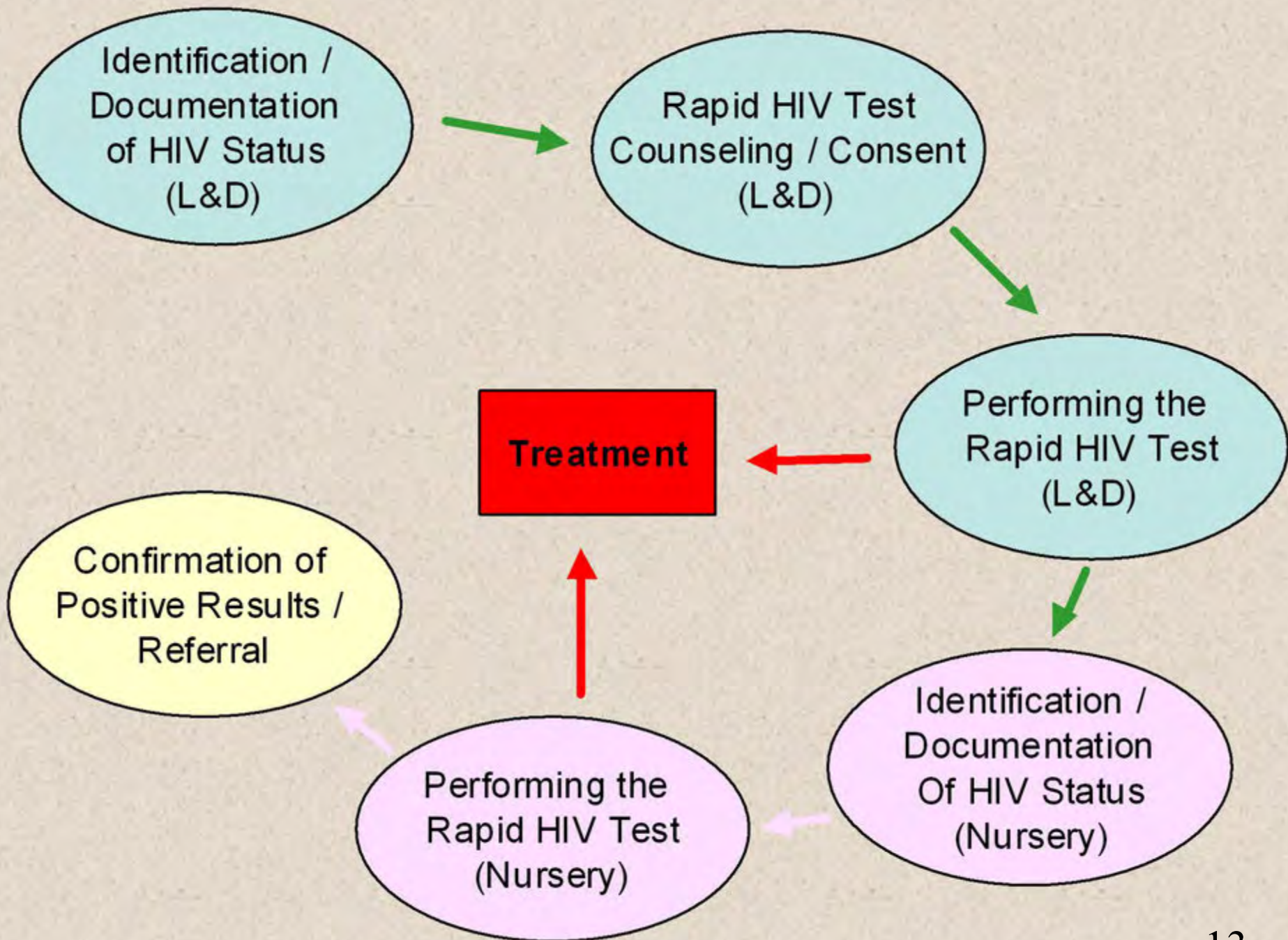
**Complete the following questions for preliminary NEGATIVE Results**

Patient was informed of negative result?  YES  NO  
 Patient results documented in chart? Date:  YES  NO

**Complete the following questions for preliminary POSITIVE Results**

Patient was informed of preliminary positive result? Date:  YES  NO  
 Patient preliminary results documented in chart?  YES  NO  
 Mother received intrapartum antiretroviral medications to reduce perinatal transmission?  
 YES  NO  
 AZT  Nevirapine  Other  
 Infant received postpartum antiretroviral medications to reduce perinatal transmission?  
 YES  NO  
 AZT  Nevirapine  Other  
 Patient referred for follow up care at:





# **Self-Directed Training Packet**

## **Steps for Completing Self-Directed Staff Training Point of Care Perinatal Rapid Testing**

**The self directed training manual is intended for all L&D staff and Newborn Nursery staff who can not attend the formal perinatal rapid testing training, new staff hires, and yearly staff competency trainings. Please copy the self-directed training packet and disseminate to the above named staff. All staff should complete perinatal rapid test training prior to the formal rapid testing start date in your hospital.**

### **Steps for completing the Self Directed Staff Training**

1. Take Perinatal Rapid Testing Training Pre-Test
2. Read and review rapid testing training documents
  - a. MATEC Rapid HIV Counseling and Testing slides
    - overview of rationale, identification of who needs rapid testing, counseling/consent, running the point of care test, documentation, and post test protocols
  - b. L&D flip chart slides
    - will be available as a sturdy flip chart on all L&D units to be used by staff during the counseling/consent process
  - c. Case Studies
    - opportunity to consider possible scenarios that may be encountered in perinatal rapid testing
  - d. Illinois Perinatal Prevention Act
  - e. Perinatal Rapid Testing Consent Templates
    - 3 templates that may be used in your hospital to facilitate the consent process. Consent is required for mothers only; no consent is required for newborn testing. Newborns without documented maternal HIV status will be tested unless there is maternal written refusal.
  - f. Rapid Testing Log/Data Sheet
    - will be located at the rapid testing station on L&D and will be completed (likely by the primary nurse) for all women on L&D without a documented HIV status
  - g. FAQ (Frequently Asked Questions) Sheet
3. Take Perinatal Rapid Testing Training Post-Test
4. Perform Rapid Testing Proficiency while observed by a previously trained user (your nurse manager/nurse educator)
  - a. Run two OraQuick Test kits on Controls, document results
  - b. Read and document results from OraQuick training card deck (25 cards), review answer key and review any cards read incorrectly.
5. Have nurse manager/nurse educator sign off on Self Directed Rapid Testing Competency Checklist and Certification of Competency to show you have completed the above steps.

## **Self-Directed Staff Training**

### **Point of Care Perinatal Rapid Testing**

#### **Rationale:**

The Illinois Perinatal HIV Prevention Act states that all pregnant women in Illinois will be counseled and offered an HIV test. HIV test results will be documented in the prenatal, L&D and newborn pediatric chart. If there is no documented maternal HIV status on arrival to L&D, the patient will be offered a Rapid HIV test. If maternal status is not known at delivery, the newborn will be given a rapid HIV test unless the mother declines and signs a written refusal for testing of her newborn.

Administrative staff in perinatal settings should use these modules to train their labor and delivery and nursery staff to perform Rapid HIV Counseling and Testing in labor and delivery. Self-directed training can be used for staff who can not attend formal perinatal rapid testing training, new staff hires and yearly staff competency training. These training modules have been designed for education in accordance with Illinois Perinatal HIV Prevention Act.

#### **Training Goals:**

1. To review the new state law regarding perinatal rapid HIV counseling and testing (Illinois Perinatal HIV Prevention Act).
2. To understand the rationale for perinatal rapid HIV counseling and testing--if maternal HIV status is known, effective treatment in labor, delivery and the newborn period can prevent perinatal transmission of HIV.
3. To competently perform rapid HIV counseling and testing in labor & delivery and newborn nursery settings in the state of Illinois.
4. To learn counseling and care of preliminary HIV positive patients and exposed newborns.



# Perinatal Rapid Testing Implementation in Illinois



Illinois Department  
Of Public Health

**PRTI<sup>2</sup>**

Perinatal Rapid Testing Implementation in Illinois





# Training Agenda

- Rapid testing rationale & law
- Protocol Implementation
- How to do Rapid HIV Counseling and Testing
- Review of hospital policy
- Review of Rapid Test log
- Post test

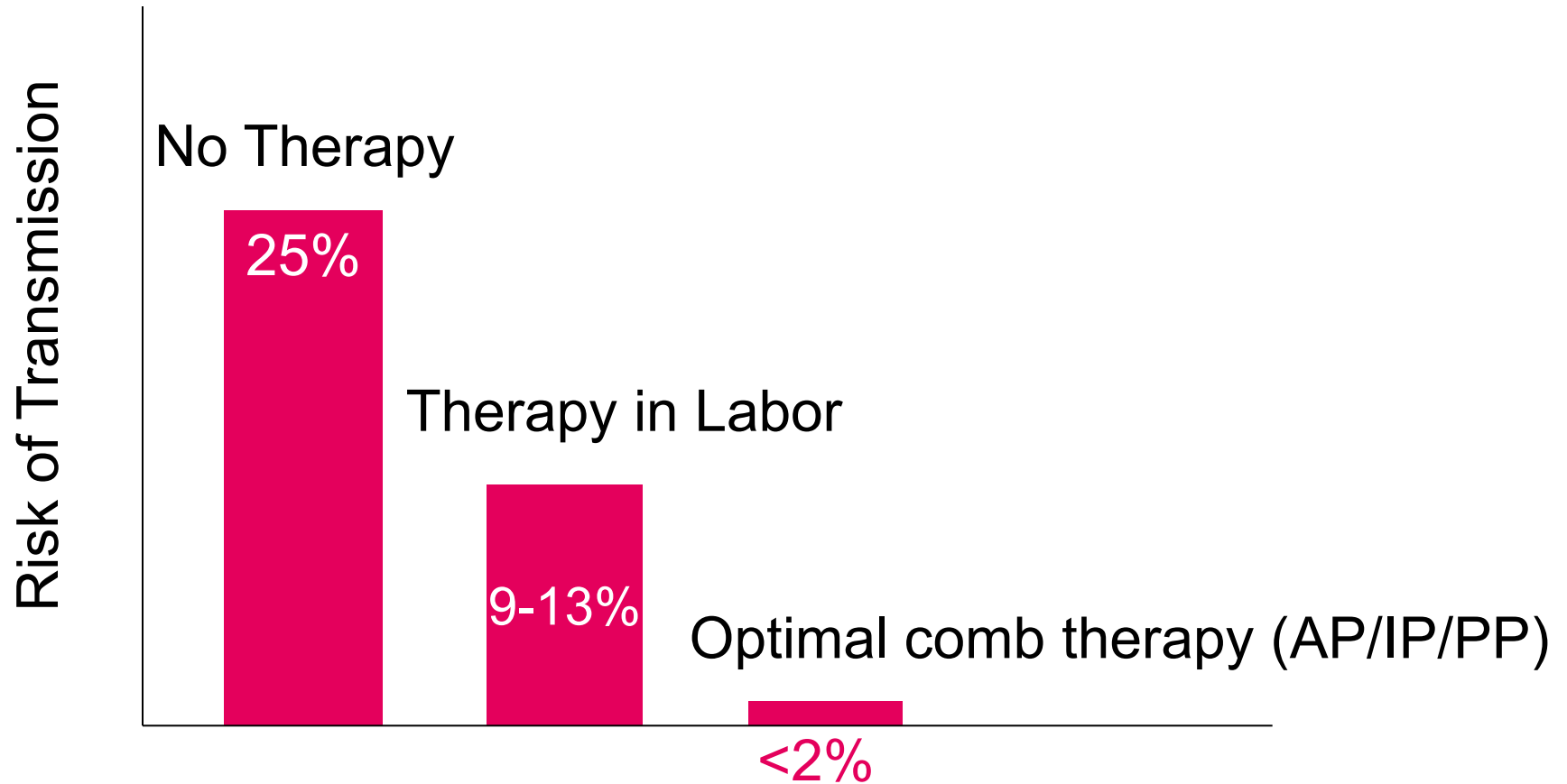


# Rationale for Rapid Testing in Labor & Delivery

- During pregnancy, women who know their HIV status and receive treatment can reduce the risk of transmission from 25% to less than 1%
- If HIV is not found until labor & delivery, transmission rates can still be reduced by as much as 50% (CDC, 2004)
- New rapid tests and law make preliminary diagnosis and treatment of HIV in labor a reality



# Rationale for Rapid Testing in Labor & Delivery



- Wade, et al. 1998 NEJM 339;1409-14
- Guay, et al. 1999 Lancet 354;795-802
- Fiscus, et al. 2002 Ped Inf Dis J 21;664-668
- Moodley, et al. 2003 JID 167;725-735

# Illinois Perinatal HIV Prevention Act

- All pregnant women in Illinois will be counseled and offered an HIV test.
- HIV test results must be documented in prenatal, L&D and newborn pediatric charts.
- If there is no documented maternal HIV status on arrival to L&D, the patient must be offered a Rapid HIV test. (Opt-In)
- If maternal status not known at delivery, newborn will be given rapid HIV test unless mother declines in writing (Opt-Out).



# Rapid Testing with Oraquick

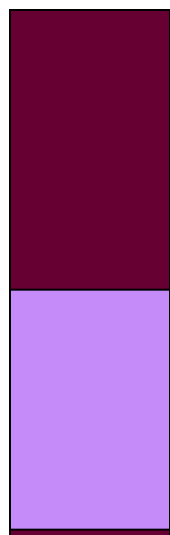


- It's quick  
→ 20 minutes
- It's easy
- It performs better  
(sensitivity and specificity are as good or better than ELISA)



# Nation-wide statistics

- 6,000 - 7,000 HIV infected women gave birth in 2000



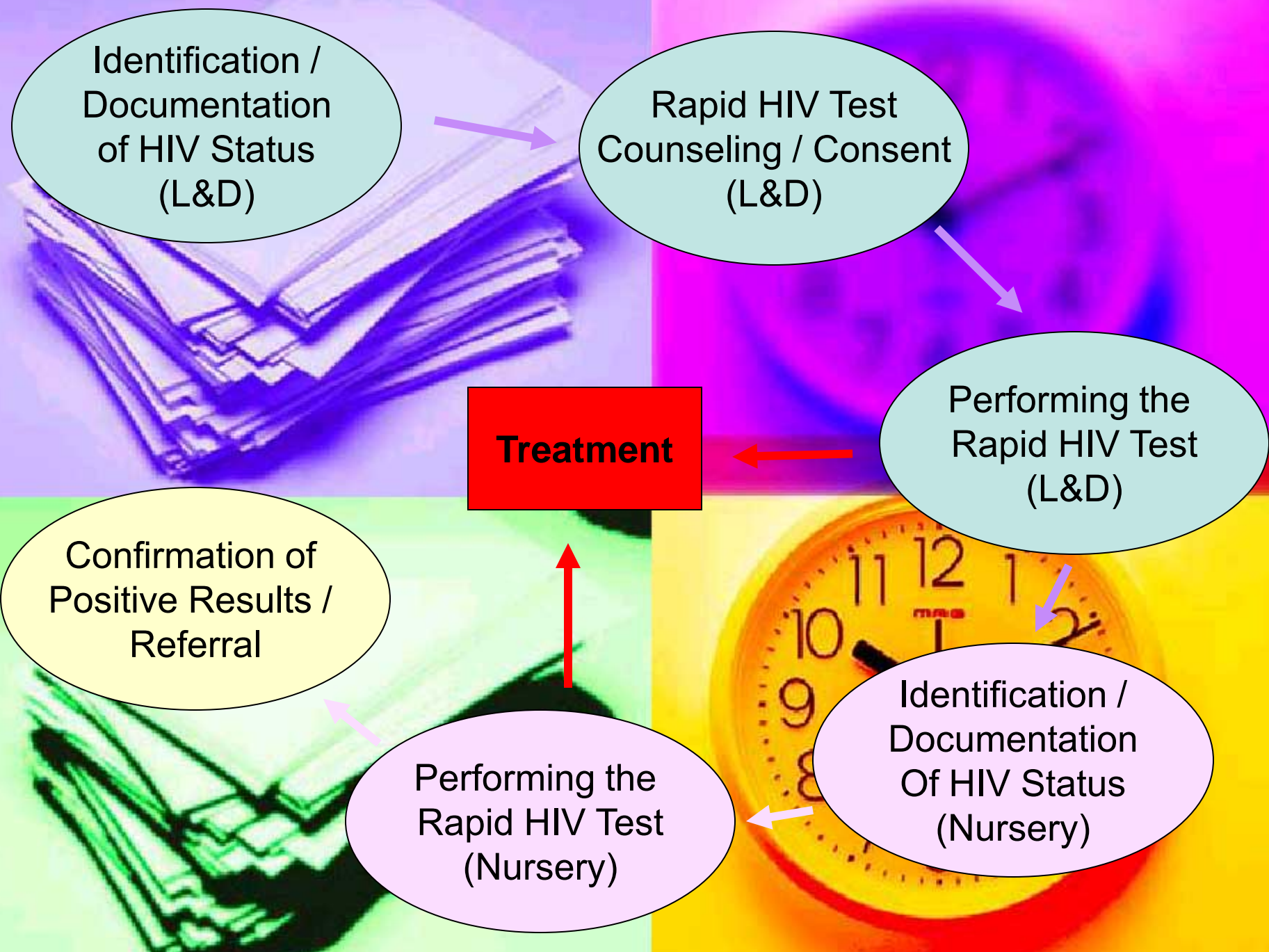
280-370 HIV infected infants

40% of infected infants born to Women who did not know their HIV status prior to delivery

# Illinois Statistics

- 150-175 HIV positive women deliver in Illinois each year
- 30-45 or 25% are not in care (unknown status)
- 0-3 women will be identified at your hospital each year





Identification /  
Documentation  
of HIV Status  
(L&D)

Rapid HIV Test  
Counseling / Consent  
(L&D)

Performing the  
Rapid HIV Test  
(L&D)

**Treatment**

Confirmation of  
Positive Results /  
Referral

Performing the  
Rapid HIV Test  
(Nursery)

Identification /  
Documentation  
Of HIV Status  
(Nursery)



# HIV Status Documentation

- Will begin process of looking for results
- Raise level of HIV consciousness on unit
- Will determine providers/clinics not sending records/testing
- Will determine baseline for HIV test ordering



HIV STATUS IDENTIFICATION

("patient name plate" or "addressograph")

Date: \_\_\_ / \_\_\_ / **2004** Time: \_\_\_\_\_ : \_\_\_\_\_ AM/PM

Empty box for patient name plate or addressograph.

**HIV Rapid TESTING Criteria**

1. Does patient have a DOCUMENTED HIV result?  YES  NO

a) If yes, results documented by:  
(VERBAL FROM PATIENT IS NOT ACCEPTABLE)

- Prenatal Record
- Other Electronic
- Other Written
- Verbal from Health Care Provider

b) If no, reason for undocumented status:

- Had NO prenatal care
- No HIV test done during pregnancy (had prenatal care)  
Name of Clinic/MD where care was received: \_\_\_\_\_
- Test done (per patient) but no results available  
Name of Clinic/MD where care was received: \_\_\_\_\_

# Rapid HIV Test Log/QA Data Sheet

## FOR ALL Mother/Infant Pairs WITH UNDOCUMENTED MATERNAL HIV STATUS

Patient name: \_\_\_\_\_  
 Arrival on L&D Date: \_\_\_\_\_ Time: \_\_\_\_\_  
 Delivery Date: \_\_\_\_\_ Time: \_\_\_\_\_  
 Log Completed By: \_\_\_\_\_

Reason for undocumented status:  
 Had No Prenatal Care  
 No HIV test done during pregnancy  
 (could have had prenatal care)  
 Test done (per patient) but no  
 documented results

Patient Age \_\_\_\_\_  
 Gestational Age \_\_\_\_\_  
 Race  Hispanic  
 Black  
 White  
 Other \_\_\_\_\_  
 Unknown

Note: All information on log must be completed for mother/infant

Patient Name	Medical Record #	HIV Testing Declined	Tester Initials	Lot # Expiration Date	Date/Time of Rapid Test	Preliminary Result from rapid test:	Date / Time Patient received result:	# of min. between rapid test and results given to patient	Western Blot Date Sent / /
		If yes check here: <input type="checkbox"/>			Date:  Time:	Negative <input type="checkbox"/> Positive <input type="checkbox"/>	Date:  Time:	_____ min Result Given Before delivery? Y <input type="checkbox"/> N <input type="checkbox"/>	Negative <input type="checkbox"/> Positive <input type="checkbox"/>

\* If Mother Declined HIV Testing Complete Infant Test Log Below

Infant Name	Medical Record #	Written Refusal For Infant	Tester Initials	Lot # Expiration Date	Date / Time of Rapid Test:	Preliminary Result from Rapid Test	Date / Time Patient received result:	# min between birth & rapid test performed on infant:	Western Blot Date Sent / /
		If yes check here: <input type="checkbox"/>			Date:  Time:	Negative <input type="checkbox"/> Positive <input type="checkbox"/>	Date:  Time:	_____ min	Negative <input type="checkbox"/> Positive <input type="checkbox"/>

<b>Complete the following questions for preliminary NEGATIVE Results</b>	
Patient was informed of negative result?	<input type="checkbox"/> YES <input type="checkbox"/> NO
Patient results documented in chart? Date: _____	<input type="checkbox"/> YES <input type="checkbox"/> NO
<b>Complete the following questions for preliminary POSITIVE Results</b>	
Patient was informed of preliminary positive result? Date: _____	<input type="checkbox"/> YES <input type="checkbox"/> NO
Patient preliminary results documented in chart?	<input type="checkbox"/> YES <input type="checkbox"/> NO
Mother received intrapartum antiretroviral medications to reduce perinatal transmission?	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> AZT <input type="checkbox"/> Nevirapine <input type="checkbox"/> Other
Infant received postpartum antiretroviral medications to reduce perinatal transmission?	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> AZT <input type="checkbox"/> Nevirapine <input type="checkbox"/> Other
Patient referred for follow up care at:	



**Illinois Department of Public Health  
Perinatal HIV Rapid Testing Surveillance  
Monthly Data Collection Form**

Hospital \_\_\_\_\_ City \_\_\_\_\_  
 Perinatal Network \_\_\_\_\_  
 Name (of person completing record summary) \_\_\_\_\_ Date \_\_\_\_\_  
 Data Collected for: Month \_\_\_\_\_ Year \_\_\_\_\_

Reason for Undocumented  
Maternal HIV Status

- A) Total # of women admitted to L&D:
- B) Total # of deliveries:
- C) # with undocumented HIV status, **no prenatal care:**
- D) # with undocumented HIV status, **no HIV test done during pregnancy** (may have had prenatal care):
- E) # with undocumented HIV status, test done (per patient) but **no documentation available:**
- F) total # with **undocumented HIV status:**  
(add C+D+E)

Maternal Rapid Test Data

- G) # counseled but **declined rapid test:**
- H) # rapidly tested on L&D with **results before delivery:**
- I) # rapidly tested with **no results until after delivery:**
- J) **Average # of minutes** between blood sample collected and Rapid test result for all women  
(add total # of minutes between test and result received, then divide by total # tested)

Maternal Preliminary  
Positive Data

- K) # tested **preliminary HIV positive** by Rapid Testing:
- L) # who received intrapartum antiretroviral **medications (before Delivery):**
- M) # of **referrals** made to a regional HIV center for follow up of HIV identified mothers and infants:

Infant Undocumented HIV status  
and Preliminary Rapid Test Data

- N) # of **infants with undocumented** maternal HIV status at delivery:
- O) # of women who **refused Rapid Testing for their infant** in writing:
- P) # of infants who had a Rapid HIV test:
- Q) # of infants who tested **HIV positive** by Rapid Test:
- R) # of infants who received antiretroviral medications:

All information on the monthly data collection form should be gathered from the "Rapid HIV Test Log/ QA Data Sheet". This form must be **faxed** monthly to the PACPI office by the **7<sup>th</sup> of each month**  
**Fax Number: 773-880-4469** ATTN: Anne Statton For ?'s: PACPI2000@aol.com, 773-880-45



# What do L & D and Nursery Staff Need to Do?

- Offer HIV counseling and testing in L&D to ALL pregnant women without a documented HIV test result
- Document HIV test log for ALL pregnant women without a documented HIV test result
- Document counseling/test offer and/or written refusal for infant test in medical record and rapid HIV test log.
- Run the test or send specimen to lab ( policy review)
- Test newborn infant if maternal HIV results are undocumented and there is no written refusal

# Which woman should be offered a test?

- Any woman presenting to L&D with undocumented HIV status (include home deliveries)



# Point of Care Hospitals Begin Rapid Testing



# *Formula* for Rapid HIV Counseling and Lab based or POC Testing

**C**<sup>3</sup> - Pretest

- **C**onfidentiality
- **C**ounseling
- **C**onsent

**R**<sup>3</sup> – Post test

- **R**un/**R**oute test to lab
- **R**etrieve/**R**ecord **R**esults
- **R**eveal **R**esults



# Confidentiality

- Offer testing, counsel and give results while the patient is alone to insure confidentiality
- HIV test results can be documented in:
  - A confidential written medical record
  - A confidential computerized medical record
  - Transmitted via secure fax

# Counseling and Consent with the Flipchart

- The Flipchart and informed consent are user-friendly and law specific
- The benefit of HIV testing for the mother
- Medication side effects
- Confidentiality
- The right to refuse testing for self and infant (in writing)





# Retrieve Results / Record Results

- Retrieve result (lab or unit test area)
- Record result in
  - HIV test log
  - the mother's chart
  - the newborn's chart
- For preliminary positives, **send blood to lab for Western Blot confirmation**



# Reveal Results - *Negative* Rapid Test Results

## *Give results simply:*

- “Your screening test came back negative
- This means that you do not have evidence of HIV at this time.”
- “Do you have any questions for me?”
- Refer for additional counseling needs, if necessary

# Reveal Results - Preliminary Positive Rapid Test Results

## *Give results simply:*

- “Your screening test came back preliminarily positive. This means that you may be infected with HIV. Remember this is only a screening test. We will need to send your blood for a confirmatory test to be absolutely sure”
- Discuss antiretroviral treatment to prevent transmission to the baby
- Refer for additional counseling needs or contact the hospital social work department



# When a result is Preliminarily Positive

- Send blood sample for Western Blot confirmation
- Inform attending physician & nurse manager
- Obtain positive packet located on your unit
- Begin ZDV(AZT) administration per hospital policy (in packet) as soon as possible
- Obtain consent for follow-up



# Hospital Specific Policy

## Who will:

- Identify HIV status on arrival to L&D?
- Counsel consent all women with undocumented HIV status for rapid HIV test?
- Obtain specimen for testing?
- Document the HIV test log?
- Perform point of care or send specimen to laboratory?





## Who will:

- Document results in mother and newborn chart?
- Locate the HIV positive packet?
- Counsel, treat, and send confirmatory test for preliminary positive ?
- Consent patient for follow up of results/care after discharge?





# Special Considerations

- Good communication between M/B areas
- Include HIV status in shift report
- Include HIV in discharge criteria
- Exposed babies D/C w/ meds
- Identify barriers-attention to rapid testing process per hospital

*(engage follow-up with lab, phlebotomy other departments to facilitate process)*

# Eliminating Pediatric HIV Your Role

- Eliminating pediatric HIV can be accomplished by good systems and good practices.
- Complete and accurate HIV Test Logs
- Monthly data generated by HIV Test Log /preliminary positive reports.
- Consent for patient follow-up and linkage to primary care



# Reading a Result



1. Read control area  
Is it a valid test?
2. Read test area  
Is it reactive or non-reactive?

# Reading a Result



# Reading a Result



# Reading a Result

= Invalid



# Rapid testing musts!

- Label patient specimen
- Keep specimen until result is read
- Read after twenty minutes but no longer than forty minutes – use timer!
- Document Rapid test log



## Summary of Rapid Testing Procedure

Identify HIV results on patient's medical record upon admission to L&D.



If patient does not have a documented HIV result (verbal from patient not acceptable), **counsel** and **consent** the patient for Rapid HIV testing.



Counseling  
Flip Chart



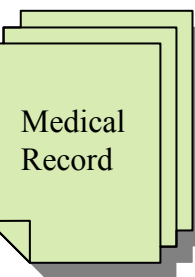
Have patient sign **consent** for Rapid HIV Testing  
*OR*  
Have patient sign **refusal** for Rapid HIV Testing.



Perform  
Rapid HIV Test



Document Rapid HIV Test Preliminary results in:  
1) Patient's L&D Admission Form  
2) Newborn's Medical Record  
3) Rapid Test Log



Explain to patient that if she refuses Rapid HIV Testing for herself, **her infant will be given a Rapid HIV Test unless she refuses in writing.** Obtain infant Refusal Form if patient refuses testing for infant.



If a patient's Rapid HIV Test is preliminarily positive, obtain a **Positive Packet** and follow the steps there-in.





# Labor and Delivery Rapid HIV Test Counseling



# Important Information about Pregnancy and HIV

Every pregnant women should know if she has HIV because she can pass HIV to her baby during . . .



pregnancy . . .



childbirth . . .



or breastfeeding

# Illinois Has an Important New Law . . .

- The Illinois Perinatal HIV Prevention Act requires that **all pregnant women** in Illinois will be counseled and offered an HIV test.



- Since there is no HIV result in your medical record, the law states that we must offer you a rapid HIV test.
- If we do not know your HIV result when your baby is born, Illinois law requires that your baby be tested.

# Benefits of Doing a Rapid HIV Test

- The sooner we know your test result, the sooner we can give you medicine to protect your baby if it's needed.



- The earlier medicine is started, the better it works to prevent HIV transmission.

# Risk of Transmitting HIV to a Newborn



1 in 4 chance without  
HIV medicine



1 in 8 chance with  
HIV medicine during labor  
and to the newborn



Less than 1 in 8 chance with  
HIV medicine for the  
mother and baby

# Rapid HIV Testing Procedures

- To do the rapid HIV test we need a small blood sample.



- You will be given the result soon as possible.

as



- Your test result will be kept in your confidential medical record.



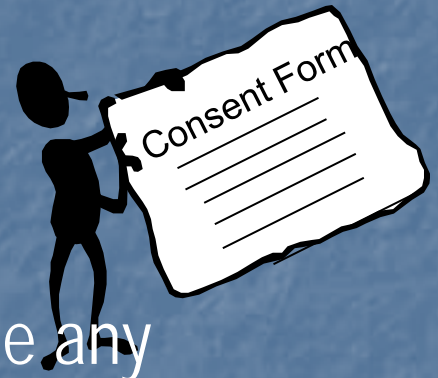
# Understanding Rapid HIV Test Results

- The rapid screening test is very reliable, but it is not perfect.
- A negative test result means that there is no sign of HIV infection at this time.
- A positive test, however, is considered a **preliminary** result
  - ▶ another test will need to be done to confirm the result before we can know for sure if it is correct.
  - ▶ just to be safe, we will give you medicine to reduce the chance of passing HIV to your baby.
  - ▶ and after delivery, we will also give your baby medicine to protect against HIV infection.



# Consent for Rapid HIV Testing

- HIV testing is completely voluntary, so we need you to sign a consent form before we run the test.
- However, if you do not have an HIV test before the delivery, your baby will be tested for HIV.
- Let's read through the form together and ask me any questions you have before you sign it.





# Your Rapid HIV Test was Negative

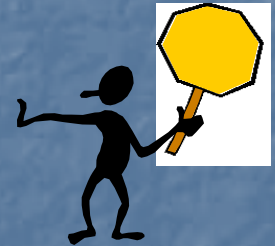
- Your HIV test came back **negative**, which means there is no sign of HIV infection at this time.



- Do you have any questions for me?

# For the Future . . .

- Would you like some information about how to prevent HIV and other STD's?

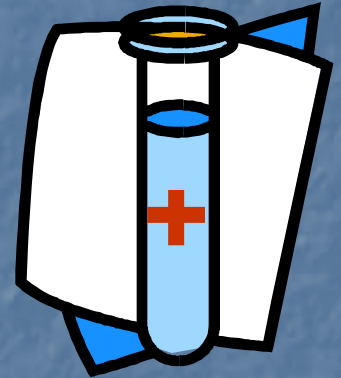


- Prenatal visits are an important part of staying healthy in pregnancy and helping you have a healthy baby.



# Your Rapid HIV Test was Preliminarily Positive

- Your HIV test was preliminarily positive, which means you **could** have HIV infection.
- Remember, this is a screening test. We need to send your blood to the lab for a **confirmatory** test before we know for sure if this preliminary result is correct.
- It will take a few days to get those results back. It is very important for you to return for care and get these results.



# Starting Medicine to Protect Your Baby

- Right now we want to make sure that you and your baby are as safe and healthy as possible.
- We would like to give you some medicine to help protect your baby from HIV.
- The sooner we start the medicine, the better it works to prevent transmission.



# Until We Have Your Confirmatory Test Result

- We recommend that you do **not** breastfeed unless the confirmatory test result comes back negative.
- You and your baby will be given HIV medicine until the confirmatory test result is back. **If that test is negative, you do not have HIV**, but you will have taken HIV medicine for a few days.
- No serious side effects have been seen in people who have taken the medicines for a short time.



# Coping with a Preliminary Test Result

- People often feel scared and overwhelmed when they hear this news.
- Can you tell me what you are feeling right now?
- What questions or concerns do you have?





# Case Studies

Revised from the The Francois Xavier Bagnoud Center New York / New Jersey AIDS Education & Training Center and The Center for Continuing and Outreach Education at the University of Medicine and Dentistry of New Jersey.

HIV Infection and Pregnancy: Prevention and Care, Faculty Training Program.



## Case Study 1: HIV counseling and testing during labor

- You Begin to explain to Ms. Q that her prenatal record does not indicate that she has had an HIV test during this pregnancy and that it is recommended for every pregnant woman. Ms. Q becomes angry and says “What kind of woman do you think I am?”







## Case Study 3: Barrier's to Rapid Testing

- Ms. G has just been admitted to L&D. No HIV test results are on her chart. Her husband and her mother are with her. She is uncomfortable. The family are recent immigrants and speak little English.
- You need to take an admission history including asking about HIV testing in labor.





## Case Study 4:

### **Patient declined HIV test in pregnancy, needs counseling for rapid testing on L&D**

John and Sally, a couple in their early 20s, arrive on labor and delivery, Sally is in early labor with her first baby. They have been married for about 18 months and have been together for 3 years.

She does not have a documented prenatal HIV test. Her nurse asks her about HIV testing during pregnancy, Sally replies that she declined testing because she doesn't think she needs an HIV test, John is the only man she has been with.



## Case Study 5: Preliminary Positive Rapid Test on L&D, not in labor

Susan L was seen on L&D for a UTI at 30 weeks gestation, her prenatal records were not available, a rapid HIV test was done on arrival after counseling and consent was obtained by her nurse. The nurse found the test to be positive after 20 minutes.

### **Counseling about a preliminary positive HIV test**

- *Susan*: Cannot believe the test. She feels it must be wrong. No risk factors. She has been faithful to her husband.



## Case Study 6: A negative test during labor

- Ms. M was not offered an HIV test during her prenatal care. She consented to have a rapid test during labor. The result of the test is negative. She asks the nurse if she can be certain that she doesn't have HIV.
- What are the key issues?





## Case Study 7: Positive Rapid Test in Labor, an HIV-exposed infant

One hour after arrival to L&D, Angela G's Rapid HIV test comes back positive. She tested negative early in her pregnancy but the test was repeated on admission to L&D because she reported that her husband was "back to using IV drugs". She is in active labor and needs an epidural.

- What are the important steps to take in labor, and postpartum to best treat this mother and infant and prevent transmission?
- What follow-up care is needed for Angela and her baby?





## Case Study 8: Known HIV +, In labor with ROM

Joan, G8P3, HIV<sup>+</sup> for 3 years, is admitted with ruptured membranes and labor. No prenatal care. Lost 2 children to HIV. Urine + for cocaine, GB strep<sup>+</sup> (urine, cervix), other STDs negative. CD4<sup>+</sup> 845.

- What are the recommendations for this mother and infant?
- What clinical and psychosocial issues does this case present?
- What should follow-up care include?

# Illinois Perinatal Rapid HIV Testing Law

In an effort to assist Managers and Educators to enhance staff understanding of the Illinois Perinatal Rapid HIV Testing law, the following scenarios are presented. Following each scenario, key learning points from the law will be noted.

## Scenario # 1

A.H is a 23yo G1P0 admitted in early labor. There is no prenatal available on the unit. The patient tells the nursing staff that she had planned on delivering at a different hospital, but had changed her mind at the last minute. The staff is able to verify that this patient did have prenatal care, and her prenatal record is available at another local hospital. In terms of her HIV status, what would be the appropriate action?

### Key Points for Learning

Because this patient is in early labor, and because the Illinois law allows for the sharing of HIV status between hospitals, the staff should attempt to obtain the prenatal record and HIV status from the other hospital. The intent of the law is not to retest patients but to verify status and to test if HIV status is unknown; there should be ample time to obtain results before this patient delivers.

## Scenario # 2

J.L is a 31yo G3P2 admitted in active labor. Her prenatal is available on the unit. She refused an HIV status prenatally. She tells the staff that she and her husband of 6 years are in a monogamous relationship. She reports that she was tested during her previous pregnancy for HIV, and she sees no reason to be retested. Her physician tells the nursing staff that retesting this patient isn't necessary. In terms of her HIV status, what would be the appropriate action?

### Key Points for Learning

Illinois law requires that all women be counseled and offered an HIV test with *each pregnancy*. This obligation under the law is not excused because of a physician's opinion that a patient doesn't need testing. The nursing staff must counsel and offer Rapid HIV testing to this patient. In addition, this patient needs to be informed that under state law, if she refuses, her infant will be tested at birth. This will lead to a delay in breastfeeding, and will cause the infant to undergo a heel stick at delivery. The purpose of testing all women is to remove the judgment of which patient is "low risk". Perceived risk should never be a factor in deciding which patient is offered counseling and testing.

## Scenario # 3

K.T. is a 30yo G4P2 admitted for a scheduled C/S. She is a known HIV positive patient, and orders for medications and treatment are available with the prenatal. In the case of a known HIV positive patient, who should receive a Rapid Test upon delivery; the mom or the infant?

### **Key Points for Learning**

The correct answer is neither. The mother doesn't need to be tested; she is a known positive. Rapid HIV tests are testing for antibodies. There are only one set of antibodies available per couplet at delivery, and those are the mother's. When we test infants, we are actually testing for maternal antibodies. We already know that this mother is HIV positive. Since the infant will still have mother's antibodies, then the only thing that testing the infant will tell us is that mom is positive. Rapid HIV testing is not appropriate for a known HIV positive mom or an HIV exposed infant.

### **Scenario # 4**

In the above scenario, would the appropriate action be to order a confirmatory Western Blot on the infant to determine if the infant was infected with HIV?

### **Key Points for Learning**

No, a Western Blot should *not* be ordered on the infant. It is important to understand that a Western Blot is also an antibody test, just as a Rapid test is an antibody test. The Western Blot simply confirms the presence of antibodies that were found by the Rapid Test. Again, the infant is going to have the same antibodies at birth as the mom. A Western blot on the infant will simply confirm that the *mother* has antibodies for HIV. It tells nothing about the infant's HIV status. The recommendation, as per hospital policy, is that a DNA-PCR test be drawn on the infant. This is a test that actually looks for the DNA of the virus, not the antibodies. If an infant has a negative DNA-PCR at birth, then that means that the infant *was not* infected during pregnancy. This test is repeated at intervals to determine if the infant was infected during the labor and delivery process.

### **Situation # 5**

D. N. is a 25yo G2P2 who delivered yesterday. She received no prenatal care, and a Rapid HIV test was preliminary positive. The results of a Western Blot are still pending. D.N. had planned on breastfeeding. The staff assisted her in pumping her milk until the results of the Western Blot are returned. The patient turned on her call light and asked the staff to bring her the milk that she had pumped, so that she could feed her baby with a bottle. Based on this patient's question, what immediate teaching needs are evident?

### **Key Points for Learning**

This patient probably assumes that the risk of infection to her baby comes from the physical contact with the breast, and doesn't understand that the risk comes from the milk itself. She needed to be educated on the fact that her milk carries the HIV virus, and if she is indeed HIV positive, this will put her baby at further risk of infection. It should be explained that the purpose of pumping and DUMPING is to maintain her milk supply, should she actually be HIV negative and still desire to breastfeed.



## HIV Rapid Testing Law in L&D Staff Competency Template

**Goals and Objective:** To make sure every pregnant woman in Illinois has a documented HIV status at the time of delivery and to identify HIV positive women in order to reduce the risk of HIV transmission during labor & delivery.

1. Any woman who presents to L&D without a documented HIV result must be counseled and offered a rapid HIV test T F
2. When a patient presents and states she is HIV positive, L&D staff should try to obtain her HIV results from the physician/clinic she receives treatment from and/or verify the HIV medications she is taking T F
3. If a rapid HIV test result is preliminary positive, the unit specific policy should be immediately referenced for next steps T F
4. In the event of a preliminary positive rapid HIV test result, consult with an infectious disease attending or the perinatal hotline for current treatment guidelines T F
5. Confirmatory Western Blot must immediately follow preliminary positive rapid HIV result T F
6. Illinois law requires that a preliminary HIV positive test result be called into the 24/7 perinatal hotline within 24 hours T F
7. An enhanced case manager may be assigned to the patient without the patient's written consent T F
8. Hospitals may release a patients HIV status to another hospital T F
9. It is legal to fax an HIV result T F
10. When a preliminarily positive woman delivers, the infant should be rapid tested at birth T F
11. HIV positive women may breastfeed if they pump and give it to their baby in a bottle. T F
12. Where is the Hotline number located on your unit \_\_\_\_\_
13. HIV test results must, by law, be documented in the
  - a. prenatal record
  - b. maternal chart
  - c. newborn chart

**All of the above**      a and c      b and c
14. Who can call the Perinatal HIV Hotline
  - a. Physicians
  - b. Nurses
  - c. Unit secretaries
  - d. **All of the above**
15. If a woman is HIV positive or has a preliminary positive diagnosis should she be encouraged to breastfeed Yes No
16. Can a woman refuse HIV testing for herself Yes No
17. Can a woman refuse HIV testing for her infant Yes No
18. If a woman arrives at L&D and had an indeterminate result in her chart do you offer her a rapid test Yes No
19. If the same woman refused the test do you test the infant Yes No
20. Do you follow through on an indeterminate result until it is conclusive Yes No

**Perinatal Rapid HIV Implementation Training**  
**Competency Checklist**

COMPETENCY	CHECK IF COMPLETE
Complete Perinatal Rapid HIV Implementation Training Pre-test	
Participate in rapid testing training session OR complete self-Directed training packet	
Run a positive and negative control and interpret 25 OraQuick test results using the OraQuick Training Card Deck with Nurse Manager/Nurse Educator present	
Complete Perinatal Rapid HIV Implementation Training Post-test	

*Participant:*

Name (Please Print): \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

*Nurse Manager / Nurse Educator:*

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

## Rapid Test Certification for Ora-Quick HIV

Name & Title: \_\_\_\_\_ Date: \_\_\_\_\_

Learner to Be Observed by Rapid Testing Trained User to:

1. Demonstrate proficiency in correctly following the test performance criteria outlined below in the checklist.
2. Demonstrate proficiency in correctly interpreting/documenting results from a negative and positive control sample for OraQuick HIV.
3. Demonstrate proficiency in correctly interpreting OraQuick training cards with negative/positive/invalid test results.

Rapid Test Lot number and expiration date: \_\_\_\_\_

Control Lot number and expiration date: \_\_\_\_\_

Directions: Indicate whether performance criteria were met or not met by placing a check in appropriate column.

PERFORMANCE CRITERIA	MET	NOT MET	COMMENTS
1. Perform test in a well-lit area.			
2. Place the stand on a flat surface. Use only the stand provided.			
3. Using the notched corner, tear the top of the divided pouch containing the testing device and vial of developer solution.			
4. To prevent contamination, leave testing device in its pouch.			
5. Put on gloves.			
6. Remove the vial of developer solution.			
7. Label vials with a pen.			
8. Place in stand. Firmly holding the vial, carefully uncap the vial by gently rocking the cap back and forth.			
9. Touch the collection loop to the control sample one. Visually inspect the loop to make sure that it is filled with a sample.			
10. Transfer the sample-filled loop to the vial. Use the loop to stir the plasma/serum sample in the vial of developer solution. Remove loop and discard as biohazardous waste.			
11. Repeat for control sample 2.			
12. Remove the testing device from its pouch and insert it into the vial of developer solution and serum/plasma mixture. Be sure the results window faces forward and flat pad touches the bottom of the vial.			
13. Start timing the test. Read the results after 20 minutes. Do not exceed 40 minutes.			
14. Dispose of used testing materials in accordance with local regulations for biohazardous materials.			
15. Wash hands thoroughly.			

### Conduct 2 Ora-Quick Tests with Controls

Panel	Positive/Negative/Invalid	Comment
Proficiency #1		
Proficiency #2		

Interpret 25 Ora-Quick Test Cards

	<b>Result 1</b>	
أNegative	أPositive	فInvalid
	<b>Result 2</b>	
أNegative	أPositive	فInvalid
	<b>Result 3</b>	
أNegative	أPositive	فInvalid
	<b>Result 4</b>	
أNegative	أPositive	فInvalid
	<b>Result 5</b>	
أNegative	أPositive	فInvalid
	<b>Result 6</b>	
أNegative	أPositive	فInvalid
	<b>Result 7</b>	
أNegative	أPositive	فInvalid
	<b>Result 8</b>	
أNegative	أPositive	فInvalid
	<b>Result 9</b>	
أNegative	أPositive	فInvalid
	<b>Result 10</b>	
أNegative	أPositive	فInvalid
	<b>Result 11</b>	
أNegative	أPositive	فInvalid
	<b>Result 12</b>	
أNegative	أPositive	فInvalid
	<b>Result 13</b>	
أNegative	أPositive	فInvalid
	<b>Result 14</b>	
أNegative	أPositive	فInvalid
	<b>Result 15</b>	
أNegative	أPositive	فInvalid
	<b>Result 16</b>	
أNegative	أPositive	فInvalid
	<b>Result 17</b>	
أNegative	أPositive	فInvalid
	<b>Result 18</b>	
أNegative	أPositive	فInvalid
	<b>Result 19</b>	
أNegative	أPositive	فInvalid
	<b>Result 20</b>	
أNegative	أPositive	فInvalid
	<b>Result 21</b>	
أNegative	أPositive	فInvalid
	<b>Result 22</b>	
أNegative	أPositive	فInvalid
	<b>Result 23</b>	
أNegative	أPositive	فInvalid
	<b>Result 24</b>	
أNegative	أPositive	فInvalid
	<b>Result 25</b>	
أNegative	أPositive	فInvalid

Certification of Competency:

To Be Signed by Staff Administration and learner

1. The learner has demonstrated proficiency in correctly following the test performance criteria outlined in the checklist.
2. The learner has demonstrated proficiency in correctly reading/interpreting and documenting results from a negative/positive/invalid control sample for OraQuick HIV.
3. The learner has demonstrated proficiency in correctly reading/interpreting and documenting a set of 25 OraQuick negative/positive/invalid test results.

Learner Signature \_\_\_\_\_ Date \_\_\_\_\_

Administrator/Observer Signature \_\_\_\_\_ Date \_\_\_\_\_

## **Frequently Asked Questions**

### **1. What is the OraQuick Rapid HIV-1 Antibody Test, and how is it performed?**

The OraQuick Rapid HIV-1 Antibody Test checks for antibodies to HIV-1, the virus that causes HIV/AIDS. The test detects antibodies to HIV-1 found in blood specimens obtained by fingerstick or venipuncture. As is true of all HIV screening tests, a reactive test result needs to be confirmed by an additional, more specific test.

When testing a fingerstick specimen, the fingertip is cleaned with alcohol and pricked with a lancet (needle) to get a small drop of blood. The blood is collected with a specimen loop and transferred to a small plastic vial containing a premeasured volume of developing solution, into which the sample is mixed. The testing process is the same for whole blood specimen obtained by venipuncture. The specimen loop is inserted into the tube of blood after the tube has been inverted to ensure the blood is well mixed. The loop is then inserted into the test vial. Results of the test can be read in as little as 20 minutes but no longer than 40 minutes. The OraQuick HIV-1 test can also be used with oral fluids; however at this time in the perinatal setting we believe there is a slightly higher false-positive rate with the use oral fluids over a blood specimen. More data may become available.

### **2. How accurate is OraQuick?**

According to data provided by the manufacturer in support of the approval of the OraQuick<sup>®</sup> Rapid HIV-1 Antibody Test, the test is able to correctly identify at least 99.6% of specimens from HIV-infected persons and to correctly indicate that 100% of specimens from uninfected individuals are negative.

The OraQuick rapid test provides reliable negative test results (no further testing will be needed to confirm this). This negative result should be shared with the patient in the context of post-test counseling and appropriately documented.

The OraQuick test may, in rare cases, provide false positives. Patients who are preliminarily positive (test positive using OraQuick) must have another blood sample collected to be sent for confirmatory testing (EIA and Western Blot). Preliminary positive results should be given in the context of post-test counseling, and the woman should be referred to follow-up care.

### **3. What are the side-effects of the AZT treatment on the mother and baby?**

Short term use has minimal side effects, but might include dizziness and nausea. Longer term use may cause anemia, raised blood levels of liver enzymes and bilirubin, myalgia, and malaise. Less common side effects include thrombocytopenia and pancytopenia with marrow hypoplasia, dyspnea, and myopathy. More serious reactions include neutropenia and leukopenia but are very rare.

**4. If a woman tests positive, should a nurse (or healthcare professional) inform her partner?**

Under no circumstances should a nurse inform a woman's partner of her test results. Any preliminary positive result will require a confirmatory test, and the role of a health provider is to help facilitate opportunities for the woman to inform her partner. The woman should be informed of safer sex practices.

**5. Once the OraQuick testing device paddle is placed in the solution, should the vial be recapped?**

No. Once the test device paddle has been inserted in the solution, the vial should be placed on a level surface and left uncapped and undisturbed for the entire reaction period. The testing device should stay in the solution during this period. After drawing the initial specimen it is ok to insert the blood specimen loop, recap the vial and take the vial back to a point-of-care work site. Make sure the vial is labeled with the patient's identification. The timer (20 – 40 minutes) does not start until the test device paddle is inserted into the solution.

**6. What does the test actually test for? Antibody presence?**

Yes, the OraQuick<sup>®</sup> Rapid HIV-1 Antibody Test detects antibodies to HIV-1, the virus that causes AIDS, in the blood of an HIV-infected individual.

**7. If the baby tests positive is the baby necessarily infected with HIV?**

If the newborn tests positive for HIV, then the mother can be assumed to be HIV positive (since the baby receives the mother's antibodies *in utero*). The baby may not be infected even though he/she does have the mother's antibodies to HIV at birth. It will take several repeat tests during the next three months to determine whether the baby is infected. A preliminary positive rapid HIV test for a baby tells you that the baby has been "preliminarily" exposed to HIV...

**8. Clarification of "documented" HIV status--does this include documented tests prior to pregnancy?**

According to the Perinatal HIV Prevention Act, every health care professional should provide the woman with HIV counseling and offer HIV testing, unless she has already received an HIV test during her *current* pregnancy. The same standard for Hepatitis (HepBsAg) and syphilis (RPR) apply to pregnancy.

**9. Can a physician override a mother's decision not to be tested, or not to have her newborn tested?**

Not according to the Perinatal HIV Prevention Act. However, there is an Illinois law stating that a physician can test for HIV if they determine it to be "medically necessary".

**10. If the test is preliminary positive, what confirmatory blood test should be sent?**

Send a Western Blot blood test for confirmation of all rapid HIV preliminary positive results. Laboratories doing routine (non-rapid) HIV tests usually perform an EIA on all specimens submitted and will follow-up with Western Blot on all

EIA reactivities. However, if the laboratory receives information that this is a rapid test preliminary positive, the laboratory should perform a Western Blot for confirmatory testing, regardless of any EIA result.

**11. What blood tube is used for Western Blot test?**

Blood tubes that have a red cap (indicating whole blood specimens) and no additives can be used for the Western Blot confirmatory test.

**12. Will the patient have to pay for the test if they are self-pay?**

Because pregnant women qualify for Medicaid coverage in Illinois, hospitals should be reimbursed for testing expenses, if no other HIV test has been done.

**13. Will insurance pay for the test?**

Each HMO and private insurance company will determine whether they will extend benefits for rapid HIV testing and for whom.

Effective May 1, 2003, health facilities enrolled in the HIV Primary Care Medicaid Program (HIV EFP) may bill an HIV pre-test counseling visit on the same day as an HIV post-test counseling visit when rapid testing technology is used.

**14. Will you offer patients a test with every admission to L&D?**

If the woman presents to L&D with an undocumented HIV status, then a rapid HIV test will be offered. This standard applies regardless of the frequency of a patient's visits, so long as their HIV status remains undocumented, even after several visits.

**15. Will you test the baby if the mother's test is negative?**

No. A negative result indicates that the mother does not have HIV (is not expressing antibodies for the virus at this time) and therefore requires no further testing to confirm this. Thus, if the mother is confirmed to be HIV-negative by this test, the newborn will not need to be tested.

**16. What is considered a secured fax?**

A secure fax is one that is not located in a public area and is accessible only to health care professionals.

**17. If the mother is HIV preliminary +, will the infant receive an OraQuick test also? Or will the infant just get a PCR-DNA test instead?**

No. Once the mother tests positive, she should receive immediate treatment in labor and the baby should be started on AZT syrup as soon after birth as possible. The infant may have blood drawn for an HIV-1 DNA PCR test (a blood test that looks for the virus itself, not antibodies). The mother will have a confirmatory Western Blot test done. If that test is negative, the infant's AZT can be stopped.



# **Preliminary Positive Patient Packet**

### **Post-Test Counseling: Providing POSITIVE Rapid HIV Test Results**

If the rapid HIV test result is positive, the clinician should tell the woman that she is likely to have HIV infection and that the baby may be exposed to HIV. She should be assured that a second test is being done right away to confirm the rapid test result but that the results will not likely be available before delivery. The clinician should explain that the rapid test result is preliminary and that false positive results are possible but that it would be best to start ARV prophylaxis as soon as possible to reduce the risk of HIV transmission to the baby. The medication regimen that will be offered to the woman and her baby should be explained, including the known effects and possible adverse effects, and she should be given the opportunity to ask questions before accepting it. She should also be told to postpone breastfeeding until the confirmatory results are available because she should not breastfeed if she is HIV infected. The clinician should explain that all ARV prophylaxis will be stopped if the confirmatory test result is negative.

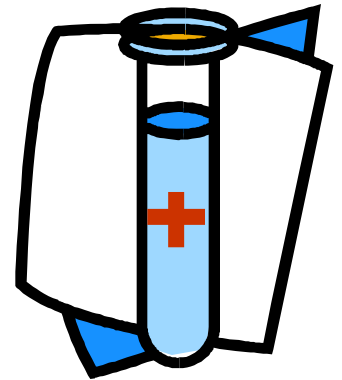
Preliminary results may not be available before delivery if labor is rapid or the woman is admitted to the unit late in labor. If the preliminary HIV test result is positive, ARV prophylaxis for the neonate should be initiated as soon as possible. (See Section G, for information on peripartum clinical management, scenario 4.) If the confirmatory HIV test result is positive, antiretroviral prophylaxis for the infant, to help prevent perinatal transmission, will be continued.

If the rapid HIV test result is positive, complicated and sensitive information needs to be explained privately to the woman during labor, a very vulnerable time. The clinician should allow time for questions and assure her that with her permission, every measure will be taken to reduce the infant's risk of acquiring HIV. She should also be reassured that effective treatment is available to help keep her healthy while she is raising her child.

In some settings, the results of the confirmatory Western blot or IFA will be available after the mother and her infant are discharged from the hospital. As part of discharge planning, the woman should be informed of the importance of returning to discuss her confirmatory test result so that both she and her infant can receive appropriate medical care. A system for contacting women who miss appointments to receive their confirmatory test results is important, especially for women who did not receive prenatal care. Involving family members or other support persons in discharge planning can be helpful if the woman agrees to their participation and has disclosed her rapid HIV test results to them.

# Your Rapid HIV Test was Preliminarily Positive

- Your HIV test was preliminarily positive, which means you **could** have HIV infection.
- Remember, this is a screening test. We need to send your blood to the lab for a **confirmatory** test before we know for sure if this preliminary result is correct.
- It will take a few days to get those results back. It is very important for you to return for care and get these results.



# Starting Medicine to Protect Your Baby

- Right now we want to make sure that you and your baby are as safe and healthy as possible.
- We would like to give you some medicine to help protect your baby from HIV.
- The sooner we start the medicine, the better it works to prevent transmission.



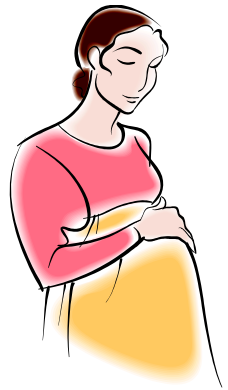
# Until We Have Your Confirmatory Test Result

- We recommend that you do **not** breastfeed unless the confirmatory test result comes back negative.
- You and your baby will be given HIV medicine until the confirmatory test result is back. **If that test is negative, you do not have HIV**, but you will have taken HIV medicine for a few days.
- No serious side effects have been seen in people who have taken the medicines for a short time.



# Coping with a Preliminary Test Result

- People often feel scared and overwhelmed when they hear this news.
- Can you tell me what you are feeling right now?
- What questions or concerns do you have?



# Your Rapid HIV Test was Negative

- Your HIV test came back **negative**, which means there is no sign of HIV infection at this time.



- Do you have any questions for me?

# For the Future . . .

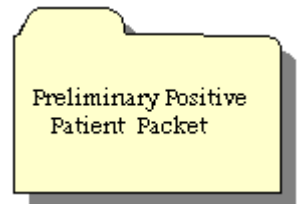
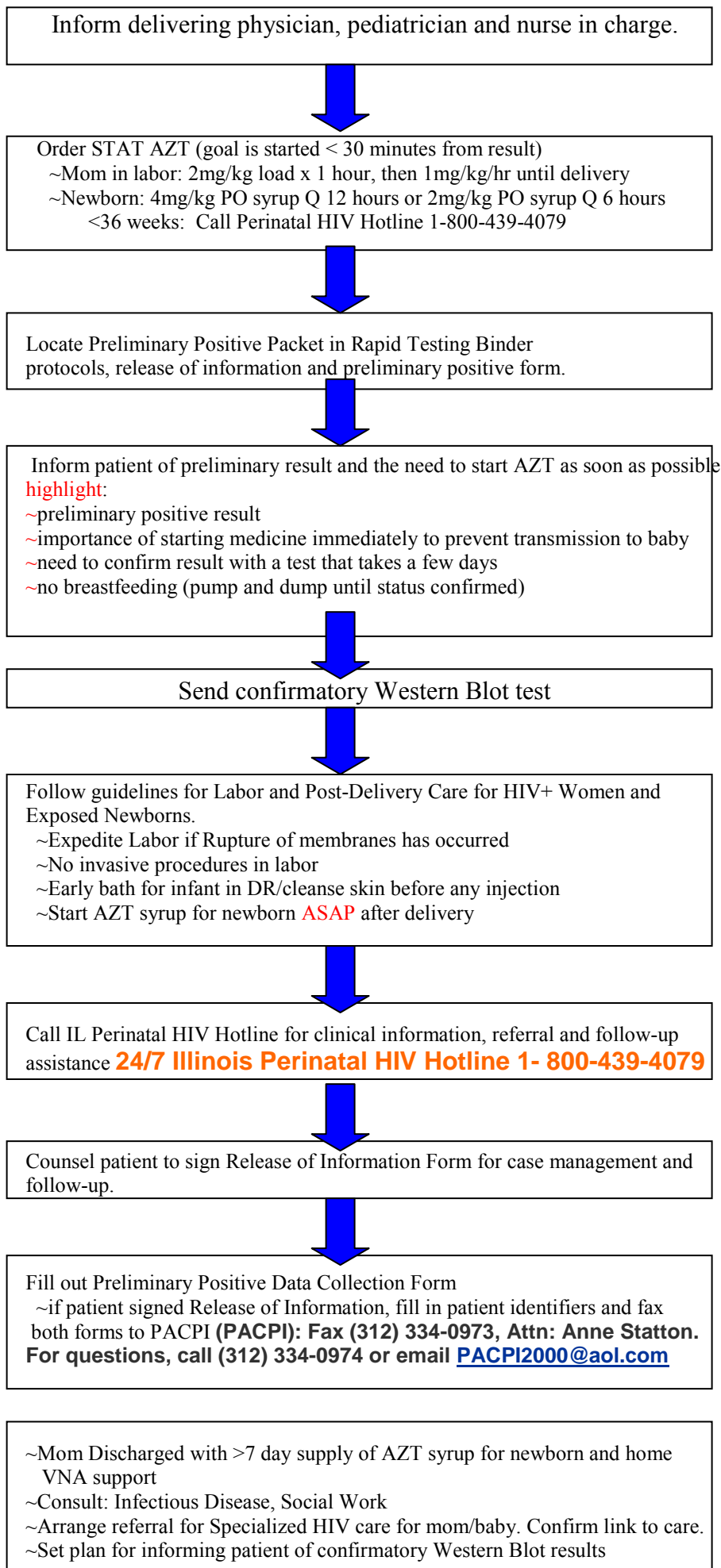
- Would you like some information about how to prevent HIV and other STD's?
- Prenatal visits are an important part of staying healthy in pregnancy and helping you have a healthy baby.





# Preliminary Positive Flow Sheet

24/7 IL Perinatal HIV Hotline 1- 800-439-4079



\*\*\* It is the attending physician's responsibility to ensure patient is informed of confirmatory test results, link to care takes place and infant has appropriate AZT. Local Dept. of Public Health/PACPI can be called to assist with follow-up\*\*\*

# ILLINOIS PERINATAL HIV HOTLINE BEST PRACTICES

## LABOR & DELIVERY AND POSTPARTUM CARE FOR HIV INFECTED MOTHERS, MOTHERS WITH A POSITIVE RAPID HIV TEST, AND HIV-EXPOSED NEWBORNS

### I. PURPOSE

To establish guidelines for the nursing care of women infected with HIV (including those with a positive rapid HIV test) and HIV-exposed Newborns.

### II. Considerations for LABOR and DELIVERY

- A. Notify a Maternal-Fetal Medicine or Infectious Disease specialist when patient **arrives** in L&D (or at the time of a positive rapid test result). The Illinois Perinatal HIV Hotline (**800-439-4079**) is available to provide consultation if no hospital-based specialist experienced in perinatal HIV is available. **Per Illinois law, the Illinois Perinatal HIV Hotline must be called within 24 hours for all pregnant patients found to be preliminarily positive with Rapid HIV testing.**
- B. Intravenous AZT should be started as soon as possible after the patient presents in labor. AZT dosage is based on the patient's weight. Patients admitted in preterm labor with a significant chance of delivery should be started on IV AZT as well as a tocolytic agent.
- C. IV AZT dosing is as follows: 2 mg/kg loading dose over 1 hour followed by 1 mg/kg/hour maintenance infusion until the cord is clamped. See Perinatal Guidelines regarding IV AZT at <http://aidsinfo.nih.gov/guidelines/html/3/perinatal-guidelines/0/>  
**AZT is not compatible with all medications. Please check with pharmacy before running AZT in the same line with other medications.**
- D. In situations where IV AZT is not available, oral AZT should be administered to the mother as soon as possible (600mg loading dose and then 300mg PO q3 hrs). The Illinois Perinatal HIV Hotline should be consulted.
- E. Invasive procedures should be avoided if possible (fetal scalp electrodes, fetal scalp sampling, artificial rupture of membranes (AROM) and operative vaginal delivery).
- F. Route of delivery for a previously diagnosed woman is determined by the patient's HIV status (viral load). Cesarean delivery should be offered to women with clinically significant viral loads (>1000 copies/ml). Women who are scheduled for Cesarean section should receive IV AZT for 3 hours prior to surgery. **Cesarean delivery is associated with a reduced risk of transmission when performed prior to active labor and rupture of membranes.** For women with undetectable or low viral loads (<1000 copies/ml) and receiving antiretroviral therapy, the risks of Cesarean Section may not outweigh any theoretical benefit of reduced transmission.
- G. Route of delivery for women newly diagnosed in labor by a rapid HIV test and who are not confirmed to be HIV-positive should be carefully considered. If the woman is truly positive and has not received antiretroviral therapy, Cesarean delivery performed early in labor with intact membranes may still be beneficial. However, in the only randomized study of route of delivery, Cesarean section performed after rupture of membranes and during active labor was not associated with a reduction in

transmission as compared with vaginal delivery. Consultation should be sought with a Maternal-Fetal Medicine or Infectious Disease Specialist experienced in perinatal HIV. The Illinois Perinatal HIV Hotline is available for this consultation.

### III. Considerations for MOTHER-BABY RECOVERY

- A. Infants should be suctioned and bathed as soon as possible to remove maternal blood contamination **before** vitamin K and eye prophylaxis (Erythromycin) administration. This early infant bath should occur in the delivery room if possible. If Narcan or other medications need to be given urgently, cleanse the site with alcohol followed by Betadine prior to injection.
- B. Infant AZT syrup should be given **as soon as possible after birth, but within 12 hours at the latest**. AZT dosage is based on the infant's weight. The Department of Health and Human Services Perinatal Guidelines recommend 4 mg/kg PO syrup every 12 hours for six weeks <http://aidsinfo.nih.gov/guidelines/html/3/perinatal-guidelines/0/> The Illinois Perinatal HIV Hotline also recommends 4 mg/kg PO syrup every 12 hours for six weeks. In some cases, 4 weeks of infant AZT may be indicated. Call the Hotline at 800-439-4079 for more information. In order to expedite the process, the pharmacy should be notified of the imminent need for a stat AZT syrup order when the patient is admitted to Labor and Delivery. **Have AZT syrup available at delivery.**
- C. An infant unable to tolerate oral feedings may be given the oral dose via a feeding tube or intravenous preparation. The recommended dose for infants  $\geq 35$  weeks is 3mg/kg Q 12 hours if given intravenously. Preterm infants will require a dose reduction and the Hotline should be consulted.
- D. Some exposed infants at especially high-risk may require additional post-exposure prophylaxis with nevirapine (i.e., infants born to mothers with high viral loads and/or no antiretroviral therapy). The Illinois Perinatal HIV Hotline or a pediatric infectious disease specialist should be consulted.

### IV. Considerations for POSTPARTUM UNITS

- A. **Breastfeeding is contraindicated for HIV positive women** given the continued risk to the neonate from virus excretion in breast milk. Women should be instructed in measures to suppress lactation such as supportive/tight bra, ice or cold compresses and ibuprofen to reduce discomfort. If the patient is a **preliminary HIV positive from a rapid HIV test** and **desires to breastfeed if her confirmatory HIV test is negative** she can be instructed to pump and dump (throw away) her breast milk until the confirmatory Western blot test result is back. This can be done to ensure a milk supply for a patient that desires to breastfeed if her confirmatory HIV test comes back as negative. The patient needs clear counseling regarding the **importance of not using her breast milk to feed the baby unless the confirmatory test result is negative.**
- B. Universal precautions should be reviewed prior to discharge with particular attention to vaginal bleeding and disposal of sanitary pads.

- C. Contraceptive and STD counseling should be performed prior to the patient's discharge.
- D. Follow-up appointments for the mother and baby must be scheduled prior to discharge. For women or newborns with a positive rapid HIV test, a confirmatory test (Western blot) must be sent prior to discharge. **The positive rapid test result must be reported to the Illinois Perinatal HIV Hotline (800-439-4079).** Follow-up for this confirmatory test is essential. The Illinois Perinatal HIV Hotline is available to provide a list of resources in the area for referral as well as case management for women at risk of loss to follow-up.

## V. Considerations for HIV-EXPOSED NEWBORNS

- A. The Department of Health and Human Services Perinatal Guidelines recommend all HIV-exposed infants have an HIV DNA PCR test performed on peripheral blood at age 14-21 days <http://aidsinfo.nih.gov/guidelines/html/3/perinatal-guidelines/0/>  
**Only do a Rapid HIV test on babies born to mothers with an undocumented HIV status.** Do not do a Rapid HIV test on a baby born to a known HIV infected mother or a mother that had a positive Rapid HIV test. Those infants require the HIV DNA PCR test beginning at age 14-21 days.
- B. Instruct mothers on how to draw up and administer AZT syrup to HIV-exposed infants. **Nurses should observe and document that the mother can draw the correct dosage and administer the syrup to the infant successfully prior to discharge. See Section III for dosage information. Newborns will be discharged with a 4 week supply of AZT syrup** because many times patients have difficulty obtaining the syrup from community pharmacies. It is critical that AZT doses are administered at **scheduled times**.
- C. Newborns who are unable to tolerate PO fluids should receive IV AZT. The recommended dose for infants  $\geq$  35 weeks is 3mg/kg Q 12 hours if given intravenously. Preterm infants will require a dose reduction and the Hotline should be consulted.
- D. A physician experienced in pediatric HIV should evaluate all HIV-exposed infants within 7-10 days of discharge. Referral resources as well as case-management resources are available through the Illinois Perinatal HIV Hotline.

## GIVING YOUR NEWBORN MEDICINE

Your baby is being sent home on AZT syrup (also called Zidovudine). This is a medication that stops the HIV virus from growing. Giving you baby this medication may help him or her to not become HIV positive. You should give your baby this medicine for \_\_\_\_\_ weeks after you leave the hospital.

Your baby's dose is \_\_\_\_\_ ml (\_\_\_\_\_ mg) to be given every \_\_\_\_\_ hours.

## HOW TO GIVE THIS DRUG

Use the syringe that the nurses gave you to draw up the medication dose. You may pour a small amount of medication into the medication cup if it is easier for you. The nurses will show you how to give the medication to you baby while you are still in the hospital and make sure that you can give it properly.

You can slowly squirt the medicine from the syringe directly into your baby's mouth or you can slowly squirt the medicine into a clean bottle nipple. You may add a teaspoon of formula to the nipple if your baby takes it better that way.

Have your baby suck on the nipple until all of the medicine is gone.

Give your baby the medicine every \_\_\_\_\_ hours for \_\_\_\_\_ weeks. It is very important to stay on schedule.

Take the syringe apart and clean it with water after each dose.

## IF YOU FORGET A DOSE

If you remember it less than 2 hours after the time you were supposed to give it, GIVE IT, AND give the next dose on time.

If you remember it more than 2 hours later than the time you were supposed to give it, DO NOT GIVE THE DOSE. Just give the next dose on time.

If you forget 2 or more doses, give a dose right away, and call your doctor or nurse.

## IF YOUR BABY SPITS UP

If your baby spits up a little, do not worry.

If your baby throws up a lot, check to see when you last gave the medicine.

- If it was less than 1 hour ago, GIVE another dose of the medicine right away.
- If it was more than 2 hours ago, DO NOT GIVE an extra dose of the medicine. Just give the next dose on schedule.

## OTHER INFORMATION

Keep this medication in the refrigerator.

Do not mix the medicine with the baby's bottle of formula. The baby may not receive all of the medicine

Do not change the dose of the medicine unless you have been told to do so by your doctor or nurse.

Do not give your baby any other medicine without talking to your doctor or nurse first.

Watch your baby for side effects of the medication. Call your doctor or nurse if your baby has diarrhea, vomiting, a fever, or unusual bleeding or bruising.

REMEMBER, YOUR BABY HAS THE BEST CHANCE OF NOT BECOMING HIV POSITIVE IF YOU GIVE EVERY DOSE FOR THE TOTAL NUMBER OF WEEKS.

### SAMPLE DOSING SCHEDULES

The medicine should be given every \_\_\_ hours for \_\_\_ weeks. The nurses will help you decide on a schedule for your baby. Circle the times so that you won't forget!

1am	7am	1pm	7pm
2am	8am	2pm	8pm
3am	9am	3pm	9pm
4am	10am	4pm	10pm
5am	11am	5pm	11pm
6am	12pm	6pm	12am

# HIV Positive Women and Their Babies

## After Birth

### I am an HIV positive pregnant woman and I am currently on an anti-HIV drug regimen. Will my regimen change after I give birth?

Many women who are on an anti-HIV drug regimen during pregnancy decide to stop or change their regimens after they give birth. You and your doctor should discuss your **postpartum** treatment options during your pregnancy or shortly after delivery. Don't stop taking any of your drugs without consulting your doctor first. Stopping drug treatment could lead to problems.

### How will I know if my baby is infected with HIV?

Babies born to HIV infected mothers are tested for HIV differently than adults. Adults are tested by looking for antibodies to HIV in their blood. A baby keeps antibodies from its mother, including antibodies to HIV, for many months after birth. Therefore, an antibody test given before the baby is 1 year old may be positive even if the baby does NOT have HIV infection. For the first year, babies are tested for HIV directly, and not by looking for antibodies to HIV. When babies are more than 1 year old, they no longer have their mother's antibodies and can be tested for HIV using the antibody test.

Preliminary HIV tests for babies are usually performed at three time points:

- within 48 hours of birth
- at 1 to 2 months of age
- at 3 to 6 months of age

Babies are considered HIV infected if they test positive on two of these preliminary HIV tests.

At 12 months, babies who test positive in the preliminary tests should have an HIV antibody test to confirm infection. Babies who test negative for HIV antibodies at this time are not HIV infected. Babies who test positive for HIV antibodies will need to be retested at 15 to 18

#### Terms Used in This Fact Sheet:

**Adherence:** how closely you follow, or adhere to, your treatment regimen. This includes taking the correct dose at the correct time as prescribed by your doctor.

**Anemia:** a condition in which there are too few red blood cells in the blood. Without enough red blood cells, not enough oxygen gets to tissues and organs. Symptoms of anemia include fatigue, chest pain, and shortness of breath.

**CDC (Centers for Disease Control and Prevention):** an agency of the U.S. Federal government that focuses on disease prevention and control, environmental health, and health promotion and education. [www.cdc.gov](http://www.cdc.gov).

**Complete blood count (CBC):** a routine blood test that measures white and red blood cell counts, platelets (cells involved in blood clotting), hematocrit (amount of iron in the blood), and hemoglobin (an iron-containing substance in red blood cells). Changes in the amounts of each of these may indicate infection, anemia, or other problems.

**Mother-to-child transmission:** the passage of HIV from an HIV positive mother to her infant. The infant may become infected while in the womb, during labor and delivery, or through breastfeeding. Also known as perinatal transmission.

**Oral:** to be taken by mouth.

**P. carinii/jiroveci pneumonia (PCP):** a common opportunistic infection in which fluid develops in the lungs. It is caused by the fungus *Pneumocystis carinii/jiroveci*. PCP is considered an AIDS-defining illness by the CDC.

**Postpartum:** the time after giving birth.

months. A positive HIV antibody test given after 18 months of age confirms HIV infection in children.

### Are there any other tests my baby will receive after birth?

Babies born to HIV positive mothers should have a **complete blood count (CBC)** after birth. They should also be monitored for signs of **anemia**, which is the main negative side effect caused by the 6-week zidovudine (ZDV or AZT) regimen infants should take to reduce the risk of HIV infection. They may also undergo other routine blood tests and vaccinations for babies.



## HIV Positive Women and Their Babies After Birth (continued)

### Will my baby receive anti-HIV treatment?

It is recommended that all babies born to HIV positive mothers receive a 6-week course of **oral** ZDV to help prevent **mother-to-child transmission** of HIV. This oral ZDV regimen should begin within 6 to 12 hours after your baby is born. Some doctors may recommend that ZDV be given in combination with other anti-HIV drugs. You and your doctor should discuss the options to decide which treatment is best for your baby.

In addition to anti-HIV treatment, your baby should also receive treatment to prevent **P. carinii/jiroveci pneumonia (PCP)**. The recommended treatment is a combination of the drugs sulfamethoxazole and trimethoprim. This treatment should be started when your baby is 4 to 6 weeks old and should continue until your baby is confirmed to be HIV negative. If your baby is HIV positive, he or she will need to take this treatment indefinitely.

### What type of medical follow-up should I consider for my baby and me after I give birth?

Seeking the right medical and supportive care services is important for your and your baby's health. These services may include:

- routine medical care
- HIV specialty care
- family planning services
- mental health services
- substance abuse treatment
- case management

Talk to your doctor about these services and any others you may need. He or she should be able to help you locate appropriate resources.

### What else should I think about after I give birth?

The CDC recommends that in areas where safe drinking water and infant formula are available (such as the United States), women should not breastfeed in order to avoid transmission of HIV to their infants through breast milk.

Physical and emotional changes during the postpartum period, along with the stresses and demands of caring for a new baby, can make it difficult to follow your anti-HIV drug regimen. **Adherence** to your regimen is important for you to stay healthy (see [What is Treatment Adherence Fact Sheet](#)). Other issues you may want to discuss with your doctor include:

- concerns you may have about your regimen and treatment adherence
- feelings of depression (many women have these feelings after giving birth)
- long-term plans for continuing medical care and anti-HIV drug treatment for you and your baby

For more information about HIV and pregnancy, your doctor can contact the National HIV Telephone Consultation Service (Warmline), a service that provides health care professionals with HIV information. The number is 1-800-933-3413.

If you are interested in joining a pregnancy registry that monitors HIV positive women during their pregnancies and after giving birth, please visit the Food and Drug Administration's Guide to Pregnancy Registries at [www.fda.gov/womens/registries](http://www.fda.gov/womens/registries). Researchers are especially interested in learning more about the effects of anti-HIV drugs during pregnancy. HIV positive pregnant women are therefore encouraged to register with the Antiretroviral Pregnancy Registry at 1-800-258-4263 or [www.APRegistry.com](http://www.APRegistry.com).

### For more information:

Contact your doctor or an *AIDSinfo* Health Information Specialist at 1-800-448-0440 or <http://aidsinfo.nih.gov>.

## PRTII Preliminary Positive Data Collection Form

1. **Immediately call** the 24-hour IL Perinatal HIV Hotline at (800) 439-4079 **to report all** preliminary positive rapid test results.
2. Complete reporting institution information box **for all calls**.
3. Complete the delivery and treatment information box for **all** positive rapid test results.
4. Complete the patient information box **only** if a release of information is signed by the patient. If release is signed, PACPI will assist with case management and follow-up at your request.

Staff filling out form: _____	Staff phone number _____
Delivery Hospital/City: _____	Date of Delivery: ____/____/____
Maternal age: _____	Time of Delivery ____:____
Maternal race _____	G ____ P _____
Prenatal Care: <input type="checkbox"/> None <input type="checkbox"/> Sporadic <input type="checkbox"/> Routine	
Type: <input type="checkbox"/> Hospital Clinic <input type="checkbox"/> Private Office <input type="checkbox"/> Health Dept Clinic	
In the opinion of the staff, did the patient know her HIV positive status (even before the rapid test was performed) <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	
Was a DCFS referral made for this family? <input type="checkbox"/> Yes <input type="checkbox"/> No	

**Complete the following (including dates and times) for all patients with a preliminary positive rapid test.**

	Date (MM/DD/YYYY)	Time (24 hour clock)
1. Presentation at L & D	/ /	:
2. Reason for undocumented HIV status <input type="checkbox"/> No PNC <input type="checkbox"/> No PNC record available <input type="checkbox"/> Not tested antenatally (not offered / declined)		
3. Date/Time <b>maternal</b> sample obtained for rapid test	/ /	:
Test Brand used: <input type="checkbox"/> Oraquick <input type="checkbox"/> Unigold <input type="checkbox"/> Reveal <input type="checkbox"/> Multispot <input type="checkbox"/> Other		
Rapid Test performed at: <input type="checkbox"/> POC/L&D <input type="checkbox"/> Lab		
4. Date/Time <b>Maternal</b> rapid test result available	/ /	:
5. Date/Time <b>Baby</b> sample for rapid test obtained (if applicable)	/ /	:
6. Date/Time <b>Baby</b> rapid test result available (if applicable)	/ /	:
7. Reason mom not rapid tested: <input type="checkbox"/> offered, declined <input type="checkbox"/> not offered, not tested <input type="checkbox"/> offered, accepted but delivered before test could be done <input type="checkbox"/> other		
8. <b>Maternal</b> Treatment <b>before</b> Delivery: <input type="checkbox"/> Yes <input type="checkbox"/> No		
Date/Time AZT IV started	/ /	:
Date/Time AZT PO started	/ /	:
Other medication started (specify: _____)	/ /	:
9. Route of Delivery		
<input type="checkbox"/> Vaginal Delivery <input type="checkbox"/> Non-Emergent / Scheduled Cesarean <input type="checkbox"/> Emergent Cesarean <input type="checkbox"/> Unknown		
10. <b>Newborn</b> Treatment:		
Date/Time AZT syrup started (Was it within 12 hours of birth? <input type="checkbox"/> Yes <input type="checkbox"/> No)	/ /	:
Date/Time Nevirapine PO started	/ /	:
Other (specify: _____)	/ /	:
<b>Pediatrician/Obstetrician of record is responsible for the following six items:</b>		
11. Date/Time patient informed of rapid test results	/ /	:
12. Infant d/c with $\geq 7$ days AZT syrup <input type="checkbox"/> Yes <input type="checkbox"/> No	/ /	:
13. Newborn HIV care referral made to (place): _____	/ /	:
14. Mother HIV care referral made to (place): _____	/ /	:
15. IL Perinatal HIV Hotline called: (800) 439-4079 (required by IDPH rules)	/ /	:
16. Local Dept Public Health called (if applicable)	/ /	:
<b>Follow up: Please complete and re-fax form to PACPI when follow up information is available.</b>		
17. Confirmatory Western Blot test sent:		
Result: <input type="checkbox"/> positive <input type="checkbox"/> negative <input type="checkbox"/> indeterminate	/ /	:
18. Patient informed of Western Blot result <input type="checkbox"/> Yes <input type="checkbox"/> No	/ /	:
19. Infant HIV-DNA PCR sent: <input type="checkbox"/> Yes <input type="checkbox"/> No Result: <input type="checkbox"/> positive <input type="checkbox"/> negative	/ /	:

Patient's name: \_\_\_\_\_

Medical record #: \_\_\_\_\_

Address: \_\_\_\_\_

Home Telephone #: ( ) \_\_\_\_\_ - \_\_\_\_\_

Patient's date of birth \_\_\_/\_\_\_/\_\_\_

Emergency Contact info: \_\_\_\_\_

Please send this form to (PACPI): Fax (312) 334-0973. For questions, call (312) 334-0974 or email [PACPI2000@aol.com](mailto:PACPI2000@aol.com)

## Birthing Hospital Perinatal Rapid HIV Testing Monthly Report

**Hospital:** \_\_\_\_\_ **City:** \_\_\_\_\_

**Month:** \_\_\_\_\_ **20** \_\_\_\_\_

### 1) Of all women delivering in the hospital, please provide the totals as follows:

- |  |  |
|--|--|
| <p><b>A. Total # of women who delivered</b><br/>The total number of women who delivered in the calendar month.</p>   |  |
| <p><b>B. Total # <i>known</i> HIV positive women delivered, <i>prior to rapid testing</i></b><br/>The number of women who were delivered, who were diagnosed as being HIV positive prior to delivery, and their status is documented in the medical chart, <i>prior to rapid testing</i>. (If a woman presents with undocumented status but announces she is positive and a rapid test is performed, she should be counted below in C.3.b)</p> |  |
| <p><b>C. Total # delivered women who presented without documented HIV test</b><br/>The number of women who delivered, who presented to L&amp;D without documentation of HIV status in their chart <b>prior to delivery</b>.</p>  |  |
| <p><b>1. Total # women missed, not rapid tested</b><br/>Of the total undocumented women, total women not declined and not rapid tested.</p>  |  |
| <p><b>2. Total # declined rapid HIV testing</b><br/>Of the total undocumented women, total women who declined rapid testing</p>  |  |
| <p><b>3. Total # rapid HIV tested</b><br/>Total number of women who were rapidly tested for HIV</p>  |  |
| <p><b>a. # negative women</b><br/>Total number of women who were rapidly tested with negative results</p>  |  |
| <p><b>b. # positive women</b><br/>Total number of women who were rapidly tested with a preliminary positive result</p>   |  |
| <p><b>4. Total # women with late prenatal documentation of HIV test</b><br/>Prenatal HIV results not available at presentation, but available prior to delivery.</p>   |  |
| <p><b>5. Total fetal deaths</b><br/>From <b>declined women only</b>, total number of fetal deaths, stillbirths, IUFDs.</p>   |  |
| <p><b>6. Total multiple births and infants received through transports</b><br/>From <b>declined women only</b>, total number of the number of multiple births. Also add the number of infants received through transports.</p>   |  |

### 2) Of all *newborns* presenting to the nursery, please provide totals as follows:

- |  |  |
|--|--|
| <p><b>A. # of newborns without documented maternal HIV test</b><br/>Number of newborns without documentation of HIV status at time of presentation to the nursery. This does not include a newborn whose mother's <i>test is in process</i>, only a newborn whose mother declined testing, or whose mother was missed or not tested.</p> |  |
| <p><b>B. # of newborns rapid HIV tested</b><br/>Total number of newborns who were rapidly tested for HIV</p>   |  |
| <p><b>1. # negative newborns</b><br/>Total number of newborns who were rapidly tested with negative results</p>  |  |
| <p><b>2. # positive newborns</b><br/>Total number of newborns who were rapidly tested with a preliminary positive result</p>   |  |
| <p><b>C. # of newborns not rapid test</b><br/>Number of newborns who remain untested <i>at time of discharge</i>.</p>  |  |

**Prepared by:** \_\_\_\_\_ **Phone #:** (\_\_\_\_) \_\_\_\_-\_\_\_\_ **Date:** \_\_\_\_/\_\_\_\_/\_\_\_\_

This form must be submitted by the 10<sup>th</sup> of each month to: PACPI/PRTII Attention: Anne Statton  
 Questions? (312) 334-0974 (Anne Statton)  
 Email to [pacpi2000@aol.com](mailto:pacpi2000@aol.com) or fax to 312-334-0973.