

**Protocol for Rapid HIV Testing on Labor and Delivery
San Francisco General Hospital (SFGH)**

**Department of Obstetrics, Gynecology and Reproductive Sciences; Department of Pediatrics;
Department of Laboratory Medicine; Department of Family and Community Medicine; Perinatal
Linkage Committee**

I. Intent

- A. To reduce perinatal transmission of HIV at SFGH.
- B. To provide HIV counseling and voluntary rapid antibody testing to women presenting to SFGH Labor and Delivery (L&D) if there is no documentation of prior HIV testing in the present pregnancy or if woman with prior negative prenatal HIV test has engaged in behavior putting her at risk of HIV acquisition. The intent is to provide rapid testing for women at or near term or for whom delivery is indicated. The test should also be considered earlier in gestation if the woman has had scant prenatal care, no prenatal care, or there is concern she will not follow-up.
- C. For women not in labor with positive rapid test:
 - i. To provide appropriate counseling regarding delivery options to reduce HIV transmission for women at or near term, or for whom delivery is indicated for obstetrical reasons,
 - ii. To provide opportunity for referral to HIV- specialty prenatal care to provide the best opportunity for maximal HIV viral suppression prior to delivery.
- D. For women in labor: To provide antiretroviral therapy both to the woman and her infant in a timely manner if the rapid test is positive.
- E. To delay breastfeeding among women found to be positive by rapid HIV testing until confirmatory test results are available.

II. Determining Eligibility for Testing

- A. Who is responsible:
 - i. A medical provider (family practice (FP) resident, obstetrics (OB) resident, OB attending, midwife or FP attending) will determine the HIV status of all women presenting to SFGH Labor and Delivery triage. If remote from term, and good f/u, encourage clinic HIV testing if not yet tested.
 - ii. Students who have a valid LCR username and password may obtain computerized results as well, but it is the responsibility of the medical provider to ensure proper reporting of results.
- B. Obtaining prior prenatal HIV results:
 - i. Results for HIV testing performed through SFGH Clinical Laboratory since 12/17/03 are accessible through the hospital computerized medical record (LCR). To obtain results, type "HIV" into the "SPECIFIC LAB TEST" field of the laboratory results screen or Check "HIV antibody" in "Serology" section of lab results.
 - ii. Note the date of testing and confirm that it was performed during the current pregnancy.
 - iii. Documentation: The HIV test result and date of testing must be documented on the L&D admission note. For those patients who are discharged from triage, the provider must ensure that the result is clearly documented in the prenatal chart.
 - iv. Disclosure of prior HIV test results: The medical provider must also confirm, through review of the prenatal chart and LCR or through discussion with the patient, that prior HIV test results have been disclosed. Providers disclosing test results of prior

Protocol for Rapid HIV Testing on Labor and Delivery San Francisco General Hospital (SFGH)

tests must explain the nature of the test result, the date of the testing (and any implications re: recent risk behavior) and must document this disclosure and the testing date in the prenatal record or the admission note.

III. Pre-Test Counseling and Consenting Procedures

- A. Who may counsel and consent:
 - i. All licensed medical providers, including FP or OB residents, FP or OB attendings, and midwives, may perform rapid HIV test counseling on L&D.
 - ii. Students may be present during the counseling and consenting but are not authorized to perform this function independently.
- B. Confidentiality: All providers conducting the counseling and consenting must ensure confidentiality. Friends and family should be asked to leave the room during the process and may be invited to return only if specifically requested by the patient. Providers should perform the counseling and consenting in a private setting where other patients and non-staff members cannot hear.
- C. Counseling specifics:
 - i. Once a patient is deemed eligible for testing, the provider should give a copy of the Rapid HIV Testing on Labor and Delivery Information Sheet.
 - ii. The provider should review (in the patient's preferred language):
 - (a) the basics about HIV versus AIDS,
 - (b) the reason for offering a rapid HIV test and the importance of knowing a woman's HIV status in order to reduce the risk of transmission to the baby,
 - (c) the preliminary nature of the HIV test,
 - (d) the expected timing of test results,
 - (e) the management of both negative and positive test results,
 - (f) the option of deferring results disclosure while not sacrificing access to antiretroviral medication,
 - (g) the risks of a false positive test and, in turn, unnecessary medication and/or cesarean delivery,
 - (h) confidentiality, and
 - (i) the opportunity to ask further questions.
 - iii. If a woman declines testing, the medical provider should explore and address reasons for declining and make it clear that testing will be available if she changes her mind.
- D. Documentation of counseling and consent:
 - i. If a woman accepts testing, the discussion and consent should be documented in the progress note.
 - ii. If a woman declines testing, the provider should document the discussion with patient and her stated reason for declining in the hospital record.

IV. Specimen Management

- A. **Adequate specimens:**
 - i. The L&D nurse should obtain 2-5ml of whole blood using a mottled green-topped tube (preferred for fastest processing).
 - ii. Other acceptable specimens include 2-5 ml whole blood obtained in plain green, plain red, or red tiger topped tube. Test may be added on within 5 days if sufficient blood available in lab. Call 8590 to verify that this test can be added.

**Protocol for Rapid HIV Testing on Labor and Delivery
San Francisco General Hospital (SFGH)**

B. Specimen handling:

- i. **Rapid HIV test is available: 24 hours a day, 7 days/week.**
- ii. Labor and delivery blood specimens for the rapid HIV test should be considered and treated as a STAT test. Alert the lab at 206-8576 that a rapid HIV test specimen is in transport.
- iii. The specimen **should be handed to technologist in microbiology and must not be placed in bin.** The specimen may be sent using the stat lab pick-up system or may be hand-delivered by L&D staff. To use messenger service place specimen in bin and call 206-8010 requesting stat lab delivery service, keeping in mind that messenger service may take 10-20 minutes. Specimens may NOT be transported using the hospital pneumatic tube system.

C. Labor and Delivery RAPID HIV Testing Logbook:

- i. The provider will document in the Rapid HIV Testing Logbook:
 - (a) Name and medical record number (or addressograph sticker)
 - (b) Test results, including time of results.
- ii. If result is positive, enter time, date, and location for patient's follow up appointment.

V. Laboratory Management

- A. The rapid HIV test should be considered a STAT test request by the Clinical Laboratory so would be tested and reported within 60 minutes of specimen receipt during hours test is available.
- B. The SFGH Clinical Laboratory is responsible for the actual rapid testing procedure as well as the Quality Assurance associated with the test, as set by state and federal regulations.

VI. Results Management

A. Clinical Laboratory role:

- i. The lab will place results in the LCR as soon as test is completed.
- ii. The lab will call and speak with a physician if the test is positive.
- iii. For positive results, the lab will arrange confirmatory testing, including Western Blot.

B. Provider role:

- i. Results Tracking:
 - (a) Results will be available in the LCR when test is complete. To obtain results, type "HIV" into the "SPECIFIC LAB TEST" field of the laboratory results screen. Or Check "HIV antibody" in "Serology" section of lab results. Begin checking for results after 30 minutes from time lab receives specimen. If there are no results after 60 minutes, call 206-8590.
 - (b) Positive rapid HIV test results will be documented as "preliminary positive" in the LCR system.
- ii. Alerting Pediatricians:
 - (a) The managing medical provider should alert the reproductive infectious disease fellow 443-8726 and the on-call pediatrics resident of all positive rapid HIV test results to allow for preparation of infant management in a timely fashion.
 - (b) The pediatrics resident should obtain specific recommendations for nursery management by consulting directly with the reproductive infectious disease fellow (pager 443-8726).

**Protocol for Rapid HIV Testing on Labor and Delivery
San Francisco General Hospital (SFGH)**

iii. Disclosure/Post-test counseling:

- (a) The medical provider should disclose the test results at the time specified by the patient during the consent process (i.e. in labor or post-partum)
 - 1) A negative rapid test result should be considered a final result, although there is risk of a negative antibody test in the setting of acute infection. If acute infection is being considered, consult RID Fellow (443-8726) for appropriate diagnostic tests.
 - 2) A positive test is considered a PRELIMINARY result. All positive tests will be confirmed using standard antibody testing (e.g. EIA with confirmatory IFA and/or Western Blot as indicated). Such confirmatory testing may take up to 1 week, so a positive rapid test is managed through the use of maternal and neonatal antiretrovirals and in some limited settings, a cesarean delivery. [See VII].
- (b) Documentation: The medical provider must clearly document in the hospital chart the patient's HIV test results the post-test disclosure, and the treatment/interventions provided. If the patient had previously declined learning of the test result during labor this should be clearly documented, along with the woman's expressed wish that she and her infant be given antiretroviral treatment despite her not receiving results prior to administration of medications to her or to her infant.

iv. Students:

- (a) Students with a valid username and password may obtain results through the LCR computerized system, but it is the responsibility of the medical provider to ensure that these results are correct.
- (b) Students may not disclose HIV test results.

VII. Management of Patients With Positive Results on Rapid HIV Test

(Note: positive rapid HIV test results are "preliminary positive")

- A. **POSITIVE RAPID HIV TESTING FOLDERS** will be kept in the **BAPAC bin** in the dirty utility room. Use **"Step by Step Rapid HIV Testing on Labor and Delivery"** sheet in folder **for quick reference**. Folder also contains pre-printed maternal and neonatal orders and educational material for patient to be given at results disclosure.
- B. **Delivery route:**
 - i. Indications for Cesarean delivery: Only those women with a preliminary positive rapid HIV test who are **NOT IN LABOR AND HAVE NOT RUPTURED THEIR MEMBRANES** are considered potential candidates for elective cesarean delivery to reduce perinatal HIV transmission risk.
 - ii. Women who are candidates for an elective cesarean delivery to reduce perinatal HIV transmission risk should be counseled by an OB provider that, in the event of a false positive rapid HIV test, the woman would be undergoing an unnecessary cesarean delivery.
- C. **Antiretroviral therapy:**
 - i. **Maternal:**
 - (a) Women should be started ASAP on antiretroviral medication.
 - (b) The reproductive infectious disease fellow (443-8726) should be paged immediately to assist in the selection of an optimal antiretroviral regimen.
 - (c) Providers should use the BAPAC Intrapartum HIV Order Sheet available in Rapid Positive Test packet and in provider forms bins. If not available:

**Protocol for Rapid HIV Testing on Labor and Delivery
San Francisco General Hospital (SFGH)**

- 1) Download via the CHN Intranet
 - 2) Click on “SFGHMC Forms” scroll down to “Physician Order-BAPAC/HIV+ Ante/Intra/Post Partum orders” and click to print.
 - 3) OR access the orders via the “Perinatal Site”, under “Perinatal HIV related forms.”
- (d) Women electing to NOT be informed of their test results until after delivery should be given antiretroviral medication in a discrete manner (e.g. IV Zidovudine labeled as “Z” instead of ZDV, AZT or Zidovudine; telling family members that the medication is “antibiotics” to protect the baby).
- (e) Note that all women consenting to rapid HIV testing simultaneously consent to medication for themselves and their infants regardless of their desire to obtain results.

ii. **Neonatal:**

- (a) Neonates born to women with positive rapid test results should be started ASAP on antiretroviral medication.
- (b) The reproductive infectious disease fellow should be paged (443-8726) to assist in the selection of an optimal antiretroviral regimen.
- (c) The pediatrics team should use the BAPAC Neonatal HIV Order Sheet.
Download via the CHN Intranet:
Click on “SFGHMC Forms;” scroll down to “Physician Order-HIV-exposed/BAPAC Nursery Newborn orders” and click to print OR access the orders via the “Perinatal Site”, under “Perinatal HIV related forms.”
- (d) The pediatrics team should obtain a birth infant *HIV-1* DNA-PCR (purple-topped tube, 1.5 ml whole blood). Send Specimen with Chemistry requisition. To order test, write in “HIV-1 DNA-PCR” on the Chemistry requisition. Prior to specimen delivery call x8590. This specimen must be handed to a technologist. HIV Consent signed by parent should be placed in the infant’s chart. Also send CBC and ALT.
- (e) The infant should be fed with formula while the mother’s confirmatory HIV testing is pending. Inform the mother that in the case of a negative confirmatory test that she may be advised that she can breastfeed, but that she will need to pump her breasts and save or discard the milk until the results are available. If she is able to initiate breastfeeding, SFGH lactation services are available for support.

D. **Follow-up:**

i. **Maternal:**

- (a) The SFGH Clinical Laboratory will automatically perform confirmatory testing of all specimens found to have a positive rapid HIV test. The confirmatory testing (e.g. EIA, with confirmatory IFA and/or Western Blot as appropriate) will be run using the same blood specimen if there is adequate volume or a separate specimen as needed.
- (b) All women found to have a positive rapid HIV test will be scheduled by the primary medical provider on L&D for a follow-up appointment with BAPAC (at 5M Monday am) if patient is discharged undelivered. If the woman has delivered, schedule appointment with the SFGH Family HIV Clinic (located in FHC, Blue Team, Friday pm or BAPAC (5M Feakins template, Monday am), whichever can accommodate an appointment at 1 week .
 - 1) BAPAC contact: 206-8919 or Cynthia Feakins, NP: pager 443-0472
 - 2) Bay Area Family HIV Clinic contact: 206-6554

**Protocol for Rapid HIV Testing on Labor and Delivery
San Francisco General Hospital (SFGH)**

- (c) Postpartum maternal anti-retroviral therapy will be ordered as specifically directed by the RID fellow (pager 443-8726) to reduce the risk of drug resistance developing.
- (d) Women with a positive rapid HIV test who do NOT present for their follow-up confirmatory results appointment will be contacted by phone, registered mail or public health nurse. This will be coordinated by BAPAC or SFGH Family HIV Clinic, according to clinic for scheduled follow-up.
Note: Women with NEGATIVE confirmatory test should have repeat HIV test in one month.

ii. **Neonatal:**

- (a) Neonates born to women with POSITIVE confirmatory HIV testing will continue on anti-retroviral medication until deemed appropriate by, SFGH Family HIV Clinic, BAPAC, or other HIV-expert attending. Dosing of medication will be weight-adjusted at intervals decided upon by SFGH Family HIV Clinic, BAPAC or other HIV-expert attending.
- (b) Neonates born to women with NEGATIVE confirmatory testing will stop anti-retroviral therapy immediately.
- (c) Neonatal HIV testing: Neonates born to women with POSITIVE confirmatory HIV testing will undergo HIV- 1 DNA-PCR testing at birth, 2 weeks of life and/or at intervals decided upon by Bay Area Family AIDS Clinic, BAPAC or other HIV-expert attending.

VIII. Summary of Documentation

- A. Document prenatal HIV test result and date in the L&D admission note (or prenatal chart if patient not in labor.)
- B. Document offering of rapid HIV test and acceptance/declining in the L&D note of eligible women.
- C. Document results of rapid HIV test in chart and statement that results disclosed to woman, treatment/interventions offered and given.
- D. Put sticker with patient's name and MR# (addressograph) in RAPID HIV TEST LOG for ALL women undergoing rapid HIV testing on L&D. Document results and time disclosed to patient.
- E. Follow-up plan and referrals, appointment date(s)