SUNY DOWNSTATE MEDICAL CENTER
UNIVERSITY HOSPITAL OF BROOKLYN
POLICY AND PROCEDURE

No. LAB23H

Subject: **HIV COUNSELING AND TESTING IN STAR PROGRAM**

Page 1 of 16

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I. PURPOSE

To provide confidential HIV antibody testing in a manner that is sensitive to patient needs and consistent with New York State Department of Health Guidelines.

II. POLICY

The STAR Program provides confidential HIV antibody testing to the Brooklyn community through three venues: 1) Counseling and testing is available in the SHC by appointment, Monday through Friday, by calling (718) 270-3745. 2) Counseling and testing is also conducted in the community at community based organizations, businesses, schools/universities and on the mobile health unit through the Educating People at Risk (EPAR) project and, as requested, at other off-site locations by both EPAR and SHC staff. 3) Counseling and testing is provided in the Emergency Department from 11:00 a.m. to 11:00 p.m., Monday through Friday. HIV C/T is also done as part of a research called Brooklyn Minority Substance use/HIV /Hepatitis strategic prevention frame work project (SAMHSA funded) at Women's prison association and Beth Israel. The number of people tested is limited to 100 at each of these two sites.

III. DEFINITION(s)

The STAR Program comprises the STAR Health Center (SHC), an ambulatory HIV clinic at University Hospital of Brooklyn (UHB), and various other HIV-related programs including the community based Educating People at Risk (EPAR) project and the Emergency Department (ED) HIV Rapid Testing Initiative.

EIA and WB are standard tests done in the laboratory for detecting HIV-1 antibodies in blood.

Uni-Gold™ Recombigen® HIV

The Uni-Gold™ Recombigen® HIV is a single use rapid immunoassay for the qualitative detection of antibodies to Human immunodeficiency Virus Type 1 (HIV-1) in serum, plasma and whole blood (venipuncture and fingerstick). It is intended for use in point of care settings as an aid to diagnosis of infection with HIV-1

IV. RESPONSIBILITIES

The STAR Health Center Medical Director is responsible training staff on the Rapid HIV testing protocol and for directing all HIV counseling and testing activities on-site in the SHC and off-site at community based organizations and other public events. Testing conducted in the STAR Health Center is conducted by of Nursing Services. The nurse manager is responsible for overseeing the daily testing, following the regulatory procedures and QA protocol at SHC.

Testing performed in the community through Educating People at Risk (EPAR) is conducted by the Project Coordinator and Community Liaison Workers. The project coordinator is responsible for overseeing the daily testing, making sure that all the regulatory documents are complete and maintaining Quality Assurance in the community.

Testing in collaboration with the UHB Emergency Department (ED) is the responsibility of the STAR Program Director of Research, in collaboration with the ED Medical Director. The project coordinator is responsible for overseeing the daily testing, making sure that all the regulatory documents are complete and maintaining Quality Assurance in the ED. HIV counseling and rapid testing in the ED is conducted by the ED Rapid Testing Project Coordinator, the project HIV Counselor, and other ED staff.

The project Coordinator of the SAMHSA project is responsible for overseeing the daily testing, making sure that all the regulatory documents are complete and maintaining Quality Assurance..

V. PROCEDURE/GUIDELINES

A. <u>Validation of the testing kits</u>: Whenever a new shipment of Kits is received the project coordinator of the respective programs will contact the Point of Care Coordinator in the lab to validate the kits for both positive and Negative specimens of blood. No tests will be done using the new kits unless the validation process is complete and confirmation to use the kits is received from the POC coordinator.

B. Pretest Counseling

Pretest counseling is done in accordance with Article 27-F of the New York State Public Health Law and the NYS DOH 2005 Guidance for HIV Counseling and Testing and New Laboratory Reporting Requirements. Pre-test counseling will generally be conducted face-to-face, however, in accordance with the 2005 guidance, patients may be given the consent form to read on their own, and briefly reviewed with staff after reading. Audiovisual materials may also be used to convey pre-test counseling messages. Component of the pre-test counseling include the following:

1. the nature of HIV, HIV-related illness and AIDS;
2. explanation of the HIV test, including information about the procedure and the meaning of test results, and nature of preliminary results to client.
3. testing options, including confidential and anonymous testing
4. benefits of testing, including preventing transmission, early diagnosis and medical intervention;
5. importance of testing for pregnant women;
6. confidentiality of results and legal protections against such discrimination, including the phone number for the NYSDOH HIV Confidentiality Hotline (800-962-5065) and the New York State Division of Human Rights (800-523-2437);law requiring HIV/AIDS cases to be reported by name;
7. contact/partner notification requirements;

C. Consent to Testing

Article 27-F requires that before any HIV test is ordered or performed, the individual to be tested must sign a written consent form that specifically authorizes the HIV test. Written consent must be executed on a consent form developed by the New York City Department of Health, available in English, French and Spanish.

1. The counselor must determine that the client has the capacity to consent, by asking two questions:
   a) Is this person able to understand and appreciate the nature and consequences of undergoing an HIV test?
   b) Is (s)he able to make an informed decision about whether to be tested?

   If the answer to both of these questions is YES, then the individual has capacity to consent. If the answer to either of these questions is NO or DOUBTBUL, then the counselor must either:

   - defer or decide against testing the individual;
   - determine whether or not the person has been judicially declared incompetent and identify if another person is legally authorized to consent to health care for the individual, and contact the person for counseling and consent purposes.
2. **If, in the pre-test counseling session, a patient has expressed that he/she will commit suicide with an RHT positive result, the counselor should defer testing at that session and refer the patient to the STAR Program Mental**

Health Program for intervention. In the ED the counselor will contact the medical staff in charge that will refer the patient to the emergency psychiatric services.

3. If informed consent cannot be given, risk reduction is stressed and appropriate referrals are made for follow-up services.

4. The counselor explains why testing could not be done at the time of pretest counseling and the conditions that need to be met for testing to be provided at a follow-up appointment.

5. If the client could give informed consent at another time, a follow-up appointment will be made for that client.

6. The counselor completes data/encounter forms applicable to each specific project (as required by funders) and forwards them to STAR Program Information Services. All copies of paperwork are kept in a locked file cabinet.

D. HIV Antibody Testing

Clients may be tested in the STAR Program via venipuncture, or by finger stick using the Uni-Gold™ Recombigen® HIV test. In general, testing will be conducted as follows: For routine testing in the SHC, Uni-Gold™ Recombigen® HIV test will be used, and for reactive specimens, venipuncture will be used to collect blood for EIA and Western Blot testing. **Rapid test will not be done for clients who present with an indeterminate WB.** Whenever a new shipment arrives the lab will validate the test kits before it is used. The Project Coordinators or the Nurse Manager (in the SHC) will inform the Point of Care Coordinator when a new box arrives and the coordinator will collect the test kits and validate the kits in the main lab and inform the Coordinator about using the test kits.

1. Venipuncture

The SUNY Downstate Medical Center Virology Lab is certified by New York State to perform EIA tests and Western Blot tests for HIV on blood-drawn clients.

a. Following pre-test counseling, the counselor enters all test orders into the electronic laboratory record system, CERNER, to facilitate the tracking of orders.

b. The counselor directs the client to the Outpatient Laboratory Department for blood drawing and provides the client with barcode labels for the specimen.

2. Uni-Gold™ Recombigen® HIV Test (using fingerstick whole blood)

Prior to conducting Uni-Gold™ Recombigen® rapid testing, SHC nursing staff, ED counselor or EPAR staff will ensure that an external control has been run according to the manufacturer's instructions, and will record the results in the control log. Corrective action shall be taken, pursuant to a pre-established plan, if expected control results are not generated. If control results are not generated within two tries, Uni-Gold™ Recombigen® testing must stop. Staff will contact the Coordinator/Nurse Manager for further action and then use the venipuncture method of testing. If expected results for controls have been generated and

recorded, each staff member conducting a rapid test will follow the procedure delineated below:

a. Ensure storage temperature requirements for testing are met:

- Test devices will be stored in a locked cupboard in the Nurse Manager's Office. The test devices will be stored in the ED Coordinator's office for the tests being done in the ED. Test devices will be stored in the EPAL Coordinator's office for use off-site. A thermometer will be placed in each of these areas and on a daily basis checked (acceptable range 35.6 to 80.6° F or 2.0 -27.0° C). The temperature will be recorded on the **Uni-Gold™ Recombigen® HIV Device Storage Temperature Log** by staff each day. Corrective action will include adjustment to environmental conditions (heat/air conditioner). If storage temperature falls out of range, an external control will be performed on the supply to ensure product quality.

- Test controls will be stored in the SHC refrigerator located in locked cabinet in the Nurse Manager's Office. Test controls of for the ED will be stored in the refrigerator in the research room. Controls will be stored in the refrigerator in the EPAR Coordinator's office for use off-site. To ensure the temperature is within the limits of the acceptable range of 35.6 to 46.4° F (2-27°C), a daily reading of the thermometer inside the refrigerator will be documented in the **Uni-Gold™ Recombigen® HIV Controls Temperature Log** daily.

- The controls, device and developer solution, once removed from the refrigerator, have come to room temperature between 59 to 80.6° F (15-27°C) range before opening and using.

  Note: In the event temperatures fall outside of the specified range, testing will cease, the Nurse Manager/Coordinator will be notified and corrective action will be taken.

b. Establish test area readiness:

- To ensure lighting will be acceptable for testing, direct observation will provide information for corrective action, include providing additional lamps, and adjustment to natural light (blinds, curtains) appropriately.

- To ensure temperature ranges are maintained to meet the requirements, a thermometer will be placed in the testing room and prior to conducting testing, SHC staff will record temperatures in the **Uni-Gold™ Recombigen® HIV Testing Room Temperature Log**. If temperatures fall outside of the 59 to 80.6° F (15-27°C) range, testing will cease and adjustment to the environment (heat/air conditioning) will be made accordingly.

- Appropriate space and a flat surface will be available in exam room where testing is performed. Hand washing facilities are located in every exam room of the health center.

- Staff will utilize the **Uni-Gold™ Recombigen® HIV Testing Checklist for Clinic Room Set-Up** to ensure that all testing supplies and paperwork are available for the testing session.

- No eating or drinking will be allowed in the test area

c. Run kit controls

SHC Nursing staff will run kit controls under the following circumstances:

- Each new operator prior to performing testing on patient specimens
- Every day before a test is done
- When opening a new test kit lot;
- Whenever a new shipment of test kits is received;
- If the temperature of the test kit storage area falls outside of the acceptable range of 35.6 to 80.6° F (2.0 -27.0° C);
- If the temperature of the testing area falls outside of the 59 to 80.6° F (15-27°C) range;
- When controls are run, staff will complete the **Uni-Gold™ Recombigen® HIV Control Results Log**;
- The date when controls were first opened will be entered on the box along with the 30 day expiry date. Controls will be discarded 30 days from the date of first use.
- **Set up work space using the Rapid Testing Checklist for Clinic Room Set-Up**
  - If necessary, allow the device to come to operating temperature of 59 to 80.6° F (15-27°C), at least 20 minutes if stored in the refrigerator.
  - Once at room temperature remove the required number of Uni-Gold™ devices from their pouches. Perform no more than 10 tests at one time.
  - Cover workspace with clean, disposable, absorbent workspace cover (Chux pads may be used)
  - Set a Uni-Gold™ device and timer up on workspace cover
  - Put on disposable gloves.

d. Conduct rapid testing

- Provide the Uni-Gold™ Subject Information Leaflet to each person being tested.
- Check for the expiration date and label with appropriate client information/ID.
- Using an antiseptic wipe/alcohol pad, clean the finger of the person being tested. Allow the finger to dry thoroughly or wipe dry with a sterile gauze pad.

- Using a sterile lancet capable of producing a 50µl blood let, puncture the skin just of the center of the finger pad. Hold the finger downward. Apply gentle pressure beside the point of the puncture. Avoid squeezing the finger to make it bleed. Wipe away the first drop of blood with a sterile gauze pad. Allow a new drop of blood to form. If blood flow is inadequate the subject's finger may have to be gently massaged at the finger base to produce a droplet of sufficient volume. Avoid 'milking' the finger.
- Hold the pipette bulb gently in a horizontal position to the sample to be collected. This is important, as the specimen may not be adequately drawn in the pipette if it is held in a vertical position.
- Place the tip of the pipette into the sample, taking care not to squeeze the bulb. Maintain this position until the flow of sample into the pipette has stopped. The sample should fill to the mark on the pipette. If sample is not collected to the mark, the pipette should be safely discarded and another specimen should be collected from another finger by repeating the sample collection process. The sample should be used immediately.
- Hold the pipette vertically over the sample port, squeeze the bulb until the sample is fully discharged in to the Uni-Gold™ HIV sample port. Should the sample not fully discharge, cover the small opening at the mark on the pipette with a gloved finger. Then squeeze the bulb until the sample is full discharged. Allow the sample to absorb into the paper in the sample port.
- Dispose the pipette in biohazard waste.
- If the test is being done from blood collected by venipuncture , take the transfer pipette and draw blood from the tube up to the first mark. Holding the disposable pipette vertically over the sample port, add one (1) free falling drop of sample carefully. Do not add the full volume contained within the disposable pipette.

  Allow the sample to absorb into the paper in the sample port. Ensure air bubbles are not introduced in to the sample port. Discard the disposable pipette in a biohazard waste container.
- Holding the dropper bottle of Wash Solution in a vertical position, add four (4) drops of Wash Solution to the Sample Port. Do not allow the tip of the dropper bottle to touch the blood in the port.
- Set the timer for 10 minutes and start timing the test.

e. Interpretation of Results

- Read test results after 10 minutes, but not more than 12 minutes incubation time.
  - 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

- Record results on the **Uni-Gold™ Recombigen® HIV Results Log**.

- If reactive, collect blood specimen immediately via venipuncture for confirmatory testing. If patient refuses to have a venipuncture then a confirmatory test can be done using Orasure oral swab.

E. Post-test Counseling

1. When rapid testing is done, results are given immediately after the 10 minute processing time. When the result is reactive, the client is informed of the results, post-test counseling is conducted, and blood is drawn for Western Blot confirmation. An appointment for HIV care in the STAR Health Center is given to the client, at which time the confirmatory results are first given to the client, by the counselor who tested the client, before seeing any STAR Health Center staff for intake.

2. The post-test counseling will be done by the HIV counselor who did pre-test counseling for the standard EIA/WB HIV antibody test. In the event that the pre-test counselor is out, every attempt must be made to contact the client and offer the option of either re-scheduling the appointment or receiving post-test counseling from another counselor.

3. Post-test counseling is done in accordance with the New York State Public Health Law and the New York State AIDS Institute guidelines to include:

Reactive Rapid test result or Positive HIV Antibody Test Result (WB/EIA):

1. Tell client about the reactive test result and draw blood for EIA/WB. Reinforce information given during pre-test counseling session (described above):

2. Make an appointment for SHC between 72hrs-96hrs to receive the result of the EIA/WB and to have an intake.

3. Reinforce information given during pre-test counseling session (described above):

   a. Reiterate the importance of early intervention services (EIS) including medical and psychosocial services;

   b. Help client identify EIS, according to the client's preferences, and provide referral to these services;

   c. Address that the reporting of cases of HIV infection is required by law to help monitor epidemic;

   d. Discuss prenatal transmission

   e. Discuss Contact/Partner Notification

f. Perform suicide and homicide assessment.

g. Review available support systems.

h. Conduct Domestic Violence Screening (described below)

2. A patient who does not return for his/her result, is contacted to reschedule the post-test counseling session.
3. If no phone number is available, a letter, followed by a telegram, is sent asking the person to come in for post-test counseling.
4. Contact efforts continue either until successful contact is achieved or until there is clear and convincing reason to believe that the client is unreachable.
5. Within thirty days of the initial diagnosis, the counselor must complete and mail the Department Health Medical Provider HIV/ AIDS and Partner/Contact Report Form.
6. The counselor must also complete the post-test section of the STAR Program Counseling and Testing form.

Non-reactive rapid test result or negative HIV Antibody Test Result:

1. Reinforce information given during pre-test counseling session:
   a. HIV risk assessment and how to reduce the risk of contracting HIV;
   b. HIV test accuracy and reliability;
   c. Meaning and significance of a negative HIV test result; and
   d. Appropriateness of repeat antibody testing.
2. Every effort will be made to give the test result in person. If the test is non-reactive and the client does not return for his/her result in any of the 3 venues , the tester may contact the client by phone to give a negative result (if intake form indicates OK to contact by phone).

Invalid HIV antibody rapid test result:

1. Discuss meaning of test results; repeat the Uni-Gold™ Recombigen® HIV test and if still invalid, draw blood for standard EIA/WB; contact the supervisor for further corrective action.
2. Discuss availability of appropriate medical follow-up;
3. Reinforce personal risk reduction strategies.

F. <u>Domestic Violence Screening</u>

Screening of protected individuals (i.e., individuals who are HIV-infected) and their partners/contacts for risk of domestic violence related to HIV partner notification is a required component of posttest counseling for an HIV-infected individual and of notification of partners/contacts. This screening takes place within an overall context which recognizes the intersection between risk of domestic violence and risk of HIV/AIDS. Recognition of domestic violence concerns can inform and improve HIV prevention efforts, including strategies for HIV counseling, testing, referral and partner notification/partner assistance services. Domestic violence risk assessment is a standard of practice within counseling, testing, referral and partner notification services in New York State.

1. **Discuss domestic violence in posttest counseling before partner names are elicited.**

    a. Assure that a private, safe and confidential discussion can occur.

    b. Remain sensitive to special needs and considerations of especially vulnerable individuals (e.g., minors, pregnant women, immigrants, seniors, individuals with disabilities, individuals who are unstably housed, individuals in residential or institutional settings, substance users in and out of treatment, and persons who are gay, lesbian, transgender or bisexual).

    c. Raise the issue of domestic violence risk associated with notifying partners.

    d. Keep questions simple and specific. Avoid jargon such as "domestic violence" and "victim".

    Suggested script:

    "There are some routine questions that I ask all my patients because some of them are in relationships where they are afraid their partners may hurt them."

    Provide assurances that:

    Any information provided will be kept strictly confidential and be used only to help make decisions about whether partner notification should proceed and to offer referrals for domestic violence services.

    In no cases are names of HIV-infected individuals provided to partners, or others, by public health staff.

    a. Respond to questions about the process.

    b. Review the benefits of partner notification.

    c. Request that the individual consider partner notification.

2. **Screen for risk of domestic violence separately for each partner to be notified (i.e., on a partner-by-partner basis)**

    Assess domestic violence risk to the HIV-infected individual

    a. Screen for risk on a partner-by-partner basis for any partners voluntarily identified and for any partners who are already known to the provider (e.g., spouse). Note: The name or other information about the infected individual is never disclosed during partner notification,

    b. Use simple screening questions.

    Suggested script:

    "What response would you anticipate from this partner if he/she were notified of possible exposure to HIV?"

    Follow-up questions can be used to explore any indication of a history of domestic violence or anticipated consequences of HIV partner notification.

    "Have you ever felt afraid of your partner or ex-partner?

    "Has a partner or ex-partner currently or ever:

- Pushed, grabbed, slapped, choked or kicked you?
- Forced you to have sex or made you do sexual things you didn't want to?
- Threatened to hurt you, your children or someone close to you?
- Stalked, followed or monitored you?

"Based on what you've just told me, do you think that the notification of this partner will have a severe negative effect on your physical health and safety, or that of your children or someone close to you?" "Are you afraid of what might happen to you or someone close to you, for example your children, if this partner were notified?"

"Have you ever been afraid about harming your partner or someone close to you?"

a. Rely on the perception, if any, of the HIV-infected individual as to whether or not notification could result in domestic violence.

b. Characterize the type of domestic violence (i.e., physical, sexual, economic (e.g., withholding financial support), emotional (e.g. isolation), social and/or psychological) if any.

c. Explore severity of anticipated domestic violence to the HIV-infected individual.

Assess any domestic violence risks to each partner/contact

a. Elicit the infected individual's knowledge of the partner's current situation, if it is known, when the partner is other than the current partner.

“If you know whether our notifying a previous partner of their possible HIV exposure might put them at risk of being harmed by, or harming, someone they are currently involved with, it is important that you tell us about it."

b. Explore severity of anticipated domestic violence outcomes to the partner/contact.

3. Provide referral(s) for domestic violence services and discuss release form

For any identified risk or potential risk of domestic violence, as broadly defined:

a. Make a referral to a licensed domestic violence service provider for all cases in which a risk, threat or history of any form of domestic violence is identified. Contact the NYS Coalition Against Domestic Violence 24-hour hotlines for information on referral resources:

1-800-942-6906 (English)

1-800-942-6908 (Spanish)

b. Discuss the advantages of a release form to enable communication between the provider, the domestic violence service provider and public health staff (see "Guidelines)". A signed release will enable the provider to assist the infected individual in the future by being aware of progress on domestic violence issues. Domestic violence is a medical issue, as well.

c. Obtain a signed release of information form, if at all possible.

4. Make determination(s) regarding HIV partner notification

a. Defer partner notification any time a risk of behavior toward the HIV-infected individual may have a severe negative effect on the physical health and safety of the HIV-infected individual, his/her children, or someone who is close to them, or to a contact if identified. In all other cases partner notification should go forward. If in doubt, speak with the SHC CNAP contact

5. Discuss and implement partner notification option(s)

Move forward with action plan for HIV partner notification

a. Review options and work with the client to identify the optimal partner notification strategy for each partner, following SHC Partner Counseling and Risk Reduction Assessment Process.

b. Report status of partner notification and any identified risk of domestic violence to the State Health Department on the Medical Provider HIV/AIDS and Partner/Contact Report Form.

If HIV partner notification is deferred based on domestic violence, as outlined in step #4, above:

c. PNAP/CNAP may contact you to discuss the nature of the domestic violence risk and steps in place to deal with it.

d. Provide the HIV-infected individual for whom notification of a specific partner is deferred based on a risk of severe domestic violence with information enabling them to contact the NYS PartNer Assistance Program (PNAP) or the New York City Department of Health and Mental Hygiene (NYCDOHMH) Contact Notification Assistance Program (CNAP) at any point in the future.

e. Ask the HIV-infected individual if they are willing to sign a release form for domestic violence information to enable future follow-up to determine if the domestic violence risk has been alleviated.

f. Ask the HIV-infected individual whether or not he/she would consent to follow-up contact by public health staff for purposes of ascertaining the continued deferral of partner notification and how such contact can most safely be made.

g. Report information that the domestic violence screen indicates a risk of severe domestic violence (i.e. partner notification may have a severe negative effect on physical health and safety) to the State Health Department by checking the appropriate box indicating a risk of domestic violence on the Medical Provider HIV/AIDS and Partner/Contact Report Form.

6. Collaborate with public health partner notification staff

a. Provide any missing information not previously reported on the Medical Provider HIV/AIDS and Partner/Contact Report Form, specifically, whether or not a risk of domestic violence exists, to state or local health department partner notification staff when they initiate follow-up. This will ensure that public health staff do not initiate steps to notify the partner

before posttest counseling and domestic violence screening is completed.

b. If partner notification has been deferred based upon a risk of domestic violence, communicate with public health staff when they follow-up in 30-120 days to ascertain the current status of active partner notification plans, to review the status of deferrals.

c. If partner notification has been deferred based upon a risk of domestic violence, consult with the public health officer when a decision must be made whether to proceed with partner notification when partner notification has been deferred. Local health officials, including PNAP/CNAP, must make such decisions in consultation with the protected individual, his or her physician and, when a signed release is present, the domestic violence service provider. Such consultation will maximize safety of the individual(s) while assessing when, or if, concerns about the safety of the HIV-infected individual are sufficiently allayed to permit partner notification to proceed.

7. Revisit partner notification and domestic violence risk throughout the continuum of care

a. Routinely, throughout the provision of medical care and support services, remind individuals that HIV partner notification and assistance services and referrals to domestic violence service providers remain available and encourage their use throughout the continuum of care. This should be incorporated into ongoing discussion to reduce behavior that may transmit HIV to partners

b. Refer HIV-infected individuals to HIV case management services which assure ongoing discussion of HIV partner notification services, including those cases in which risk of domestic violence which may have a severe negative effect on the physical health and safety of the HIV-infected individual, his/her children, someone who is close to them, or to his or her contact(s).

c. Help ensure that HIV partner notification assistance services are accessed in the event that the previously identified domestic violence concerns are resolved.

G. Specimen Transfer

For all testing done on-campus in the SHC or ED, specimen results will be transferred to the UHB laboratory utilizing the Cerner entry process after the Eagle registration process.

H. Documentation of Test Results

1. SHC Nursing staff will document HIV test results in the HIV Counseling and Testing Log on an electronic spreadsheet maintained in the health center for 3 years. EPAR staff will document the results in the HIV C/T log and in the client file maintained in a locked file cabinet in the EPAR Coordinator's office. The counselor in the ED will document the result of the test in the medical records of the patient and will also place the signed consent form in the medical records.
2. Tests done at SHC and ED will be entered in Cerner on the same day of the test by the nursing staff and the ED counselor respectively

3. Requests for documentation of test results must be made in person, not by phone or email.
4. Clients must sign the HIPAA Compliant Authorization for Release of Medical Information and Confidential HIV Related Information

I. Minors

1. Individuals under18 years of age are generally referred to the Family Adolescent Children's Experience at SUNY (FACES) program or to Health and Education Alternatives for Teens (HEAT), located on the KCHC campus.
2. New York State Law does not require parental/guardian consent for HIV counseling and testing, provided that the youth is capable of understanding everything described in pre-test counseling and of signing consent. In some circumstances (particularly when counseling and testing is provided at community-based sites and a referral to another site would likely result in an adolescent not following through on a referral) HIV counseling and testing will be provided to youth capable of understanding and signing consent.
3. Counselors are expected to use careful judgment in providing antibody testing for minors in accordance with New York State laws.
4. Decisions regarding testing of minors are made on a case-by-case basis in consultation with the EPAR Coordinator, the ED Medical Director or the STAR Health Center Medical Director.

J. Intra-Institutional Referral

1. STAR Health Center HIV counselors counsel and test outpatients referred from other University Hospital Brooklyn departments.
2. STAR Health Center coordinates services with SUNY UHB's Department of Epidemiology/Infection Control, which provides inpatient counseling and testing, on-site testing in other UHB Ambulatory Care areas, and testing of employees involved in a work related incident where there is possible exposure to bodily fluids.

K. Resources and Referrals

1. The HIV counselor assess each client's medical and psychosocial needs and make referrals, as indicated, to a variety of services such as primary care, drug treatment, support groups, long term counseling, adolescent programs, prenatal and family planning services.

L. Emergency Procedures

1. If a client exhibits suicidal, homicidal or threatening behavior, the counselor immediately implements the emergency protocol delineated under **Assessment of Patients/High Risk Psychiatric Emergencies**.
2. If the client is being tested in the ED, the counselor will contact the ED Nurse Manager who will contact the UHB psychiatrist on-call as per the ED policies and procedures.
3. If the client is being tested at a community based organization, the counselor will follow the emergency procedures prescribed by the host agency, which may include immediate referral to an on-site mental health worker or call to 911 for transport to the nearest mental health facility for evaluation.

M. Quality Assurance

HIV Counseling and Testing activities will be integrated into the SHC Quality Assurance Plan. Specific HIV C/T indicators will be identified and reviewed monthly as per established SHC QA Procedures. The SHC will follow the **Quality Assurance Guidelines for Testing Using the UNIGOLD Rapid Antibody Test** produced by the CDC. Any problems noted related to test kits or controls will be documented in the logs and reported to the Nurse Manager, the EPAR Coordinator, or the ED Rapid Testing Coordinator, as appropriate All Uni-Gold™ Logs will be reviewed by weekly by the SHC Nurse Manager, the ED Rapid Testing Coordinator and the EPAR Coordinator. Necessary corrective action documented on the logs and discussed monthly with senior staff, including the SHC and ED Medical Directors, at the SHC Operations meeting and in the monthly QA meeting.

N. Staff Training and Competency Assessment

Training is crucial to ensuring quality HIV testing. Key components to include in training associated with HIV counseling and testing are:

- HIV counseling and testing skills (all staff performing testing must complete NYS or NYC HIV Counseling training)
- NYS Public Health Law - confidentiality, HIV reporting and partner notification
- Laboratory regulations, Part 58-8
- How to perform the test (including procedures performed before, during and after testing)
- How testing is integrated into the overall counseling and testing program
- QA program elements and documentation
- OSHA guidelines (i.e., exposure control plan of universal precautions, bio-hazard safety)
- Before an employee is permitted to perform counseling and testing on his own, his/her ability to conduct the test will be demonstrated via direct observation of the supervisor. This assessment will also be carried out at periodic intervals after training and documented through the UHB Assessment and Performance Evaluation. The **Employee Competency Checklist for the Uni-Gold™ Recombigen® HIV test** will be completed by the supervisor for any staff member conducting rapid HIV testing every 6 months. Testers will participate in the proficiency testing twice a year given by CAP

VI. ATTACHMENTS

- STAR Program Counseling and Testing Form
- NYS Department of Health Informed Consent to Perform HIV Testing
- NYS Department of Health Medical Provider HIV/AIDS and Partner/Contact Report Form

- HIPAA Compliant Authorization for Release of Medical Information and Confidential HIV Related Information
- Uni-Gold™ Recombigen® HIV Controls Temperature Log
- Uni-Gold™ Recombigen® HIV Kits Storage Temperature Log
- Uni-Gold™ Recombigen® HIV Testing Room Temperature Log
- Uni-Gold™ Recombigen® HIV Testing Checklist for Clinic Room Set Up
- Uni-Gold™ Recombigen® HIV Control Results Log
- Uni-Gold™ Recombigen® HIV Rapid Test Results Log
- Transfer Results Log
- Cerner Entry Process
- Employee Competency Checklist for the Uni-Gold™ Recombigen® HIV Rapid Test

VII. REFERENCES

- Article 27-F of the New York Public Health Law
- Emergency Amendments to Part 63 Regulations
- NYS Department of Health AIDS Institute Guide to HIV Pre-test and Post-test Counseling
- 2005 Guidance for HIV Counseling and Testing and New Laboratory Reporting Requirements
- Workbook and Implementation Guidelines for Limited Testing Sites in New York State Using the Uni-Gold™ Recombigen® HIV antibody test
- NYSDOH Protocol - Domestic Violence Screening in Relation to HIV Counseling, Testing, Referral & Partner Notification
- Quality Assurance Guidelines for Testing Using the Uni-Gold™ Recombigen® Test – Center for Disease Control
- UHB policy EPI-11 –HIV antibody testing and counseling.
- UHB policy Lab 23—Point of care testing

Date Reviewed	Revision Required (Circle One)		Responsible Staff Name and Title
	Yes	**No**	
	Yes	**No**	
10/07	**Yes**	**No**	
	Yes	**No**	