1. MOBILE TESTING PROGRAM

Outposted HIV Counseling, Testing, and Referral (CTR) services are available from the Adolescent AIDS Program (AAP) using the OraQuick Advance Rapid HIV 1/2 Antibody Test. The use of a non-invasive rapid HIV test enables AAP to engage more youth in HIV CTR services and to deliver test results instantly to populations that historically have had difficulty returning for their results. The AAP conducts community-based rapid HIV testing in various community locations/events often in collaboration with community partners.

HIV Testing Personnel

A. Qualifications:
   1. Attend the following trainings: AAP ACTS Rapid HIV CTR training and Montefiore Point of Care (POC) team (or its designee) Use of Rapid HIV Testing.
   2. Observe and be observed by experienced HIV CTR staff in a clinical and outposted setting

B. Competency Assessment:
   1. A competency assessment is completed for each counselor according to the following schedule:
      a. After training but before administering OraQuick Advance Rapid HIV1/2 Antibody test by AAP HIV CTR staff.
      b. One week after beginning administration by AAP HIV CTR staff.
      c. Annually at Montefiore Medical Center’s Point of Care Rapid HIV Testing In-service.

2. The competency assessment includes the following:
   a. **Pre-Test Assessment**: HIV CTR staff is observed checking and recording temperatures of testing and storage areas; setting up testing area; labeling the device and preparing control and test results log sheets; running the external controls and recording results. Following NYS DOH minimum QC requirements for controls (see control section).
   b. **Testing Assessment**: Staff is observed performing test on client or on volunteer to measure their proficiency in obtaining informed consent, performing the collecting of oral fluid (mucosal transudate) via OraQuick Advance Rapid HIV1/2 Antibody test, processing specimen in testing vial. Staff is also assessed on their interpretation of test results obtained on control samples that show a range of results.
   c. **Post-Test Assessment**: Staff is observed reporting results to a test subject; observed collecting oral fluid specimen (Orasure) and handling for confirmatory testing; reviewing test records (charts and log), and quality control results documentation (log); verifying that confidentiality is maintained, documentation signed, results filed in charts and kept in locked file cabinet, and limited access to log book.
2. ACCESSING SERVICES

HIV rapid testing is the only option available for HIV testing in community settings including on mobile units. All preliminary positive test results are confirmed using OraSure, an oral or blood specimen collected at outposted site using universal precautions and safe blood transport, or, if preferred, a blood specimen collected at the AAP clinic during regular operating hours.

Persons identified as preliminary HIV-positive will be counseled on site until they are emotionally stable and will be referred to the AAP/REP clinic the same day or within 24 hours of learning their diagnosis. The AAP testing team will always include a staff member experienced in giving results and the AAP clinical staff is on call 24/7 as back up. Field staff will attempt to collect sufficient contact information (phone numbers, email address, secondary contact) for follow-up purposes and AAP clinical staff including the Linkage to Care (LTC) Coordinator will be notified immediately of the newly identified positive client/patient so that contact can be made to further engage them in care.

3. RAPID HIV TESTING

Preparation for Meeting with the Client:

Each individual patient chart is stocked with New York State compatible consent forms (oral consent is sufficient when using rapid HIV tests), AAP Intake Form, and Montefiore Rapid HIV Antibody Test Results form. Testing area stocked with OraQuick Rapid HIV-1/2 Antibody Test Kit, timer that can be set with an alarm for 20 – 40 minutes, latex disposable gloves, clean disposable absorbent workspace cover, waste containers, and sufficient lighting to read results.

- Materials Required for Performing OraQuick Rapid HIV-1 Testing will be transported to the testing site and stored in temperature appropriate conditions by AAP staff each testing day. All unused supplies will be removed from the testing site at the end of the shift and returned to the AAP and placed in temperature appropriate storage rooms.

- The test device and developer solution vials are labeled with client’s initials.

Universal precautions must be used at all times when collecting and handling any lab specimens.

PRE-TEST COUNSELING

As mandated by the NY State Department of Health, clients who are tested via the OraQuick Rapid HIV-1 Test receive the following seven points of information about HIV testing while waiting (via brochure or wall chart) or during the standard pre-test counseling appointment. The counselor will answer any additional questions from the patient and provide additional information regarding the test.

1. HIV is the virus that causes AIDS and can be transmitted through unprotected sex (vaginal, anal, or oral sex) with someone who has HIV; contact with blood as in sharing needles (piercing, tattooing, drug equipment including needles), by HIV-infected pregnant women to their infants during pregnancy or delivery, or while breast feeding.

2. There are treatments for HIV/AIDS that can help an individual stay healthy.
3. Individuals with HIV/AIDS can adopt safe practices to protect uninfected and infected people in their lives from becoming infected or being infected themselves with different strains of HIV.

4. Testing is voluntary and can be done anonymously at a public testing center.
   - If the client wishes to receive anonymous testing, inform the person that anonymous testing is only available at the NYC Department of Health and Mental Hygiene and where he/she can go to receive that service.

5. The law protects the confidentiality of HIV test results and other related information.

6. The law prohibits discrimination based on an individual’s HIV status and services are available to help with such consequences.

7. The law allows an individual’s informed consent for HIV related testing to be valid for such testing until such consent is revoked by the subject of the HIV test or expires by its terms.

The AAP utilizes the ACTS (Advise, Consent, Test, Support) HIV testing protocol for out-posted HIV CTR services (see page 9). The counselor can also explain the possible HIV antibody tests results (the non-reactive result interpreted as negative for HIV antibodies and a reactive result is viewed as preliminary positive) and that all preliminary positive test results need an additional standard HIV test (OraSure) to confirm the results.

The counselor must obtain and document written or verbal informed consent for rapid HIV testing from the patient. Consent will be documented on AAP Intake Form for HIV CTR Services.

DIRECTIONS ON HOW TO DO THE POST TEST COUNSELING

Delivering a NEGATIVE HIV test result:

1. Give the patient their result and allow time for them to process the information. Ask how they feel about the result and whether it is a relief or if it was the result they were expecting.

2. Inform patient that testing doesn’t guarantee they will remain HIV negative and that they need to play an active role in prevention including consistent condom use, not sharing needles, and encouraging partner testing.

3. Determine whether or not the patient needs to be tested again. The patient should get tested once a year or sooner if they have:
   a. Been diagnosed with a sexually transmitted infection (STI)
   b. Unsafe sex with a new partner or partner of unknown status
   c. Become pregnant
   d. Use injection drugs
   e. Have a flu-like illness after one of the above

4. Provide prevention strategies and referrals if needed.
Delivering a **POSITIVE HIV** test result:

**COPING**

1. Inform the patient that their rapid HIV test is preliminary positive, and that a positive rapid test result usually, but not always means that they are HIV-positive. Allow the patient time to process this information and answer any questions or concerns.

2. Advise the patient that the preliminary test will need to be confirmed with a Western Blot test, and that the result will be available in four to seven days.

3. Assure the patient that if needed, you will provide support or referrals for support while they are waiting for their confirmatory test result.

4. Discuss the meaning of an HIV-positive test result. Explain the treatment and prevention aspects of HIV infection and the differences between HIV and AIDS.

**CARE**

5. Link the patient to care. Emphasize the importance of accessing medical and psychosocial care to ensure optimum health, and immediately make an appointment or referral for follow-up visit to a medical provider and mental health provider if needed. Follow-up appointments with newly identified positives should be scheduled with 24-48 hours of receiving HIV rapid test result. Confirm best methods to contact and if possible get a friend or relatives contact information as back up.

**PREVENTION**

6. Address the importance of prevention by discussing strategies for sexual risk reduction, safe needle practices and partner disclosure and testing. For pregnant or nursing patients, inform them that their HIV can be transmitted to their babies during pregnancy, at delivery or through breastfeeding and refer them for Preventing Mother-To-Child Transmission (PMTCT) care. If they are breastfeeding, advise them to switch to formula feeding until result of Western Blot test is available.

7. Review names reporting regulations. Inform patients that in New York, all HIV+ patients’ names are reported to the DOH and held confidential.

8. Provide additional support and assess whether the patient needs to be immediately referred for psychosocial support for stabilization before allowing them to leave.
4. PROCESS CONTROL

Process Control before Testing

A. Check room temperatures of out-posted testing is used:

1. Test kits will be stored at the AAP in areas which will be monitored before each use to ensure that their temperature is between 59F – 80F, as per the manufacturer’s instructions.
2. After daily use, control kits must be refrigerated in the refrigerator on the Mobile Unit at 35F – 46F as per manufacturer’s instructions.
3. Controls will be run:
   - once a month whether or not patient testing has been performed.
   - when there is a change in lot number.
   - when there’s a receipt of a new shipment.
4. Thermometers will be available for out-posted HIV testing activities.
5. HIV CTR staff will be responsible for logging the temperature on the temperature log.
6. Corrective action: If there are doubts about whether test or control kits have stayed within the appropriate temperature range, staff will run positive and negative external control tests.
7. The AAP Director or Medical Director will be immediately informed of possible temperature control problems. If it is determined that temperatures fell below or above the required ranges, all tests since the last controls were run will be determined as invalid and new controls must be run to determine validity of Oraquick tests.

For further details, staff may refer to the CDC website [http://www.cdc.gov/hiv/pubs/rt-counseling.htm](http://www.cdc.gov/hiv/pubs/rt-counseling.htm), the Revised Guidelines for HIV Counseling, Testing, and Referral, MMWR Recommendations and Reports, and applicable New York State rules and the package (insert).

Quality Control

Internal QC: A reddish-purple line in the Control (C) zone of the result window indicates that a human specimen was added and that the fluid migrated appropriately through the device. The control line must appear on all valid tests, whether or not the sample is positive or negative for HIV-1/2 antibodies.

External QC: The kit controls are used to verify your ability to properly perform the test and interpret the results. Kit controls should be run under the following circumstances:

1. Whenever a new lot of the OraQuick Advance Rapid HIV1/2 Antibody test is used for the first time. If the control (negative or positive control) does not reflect the appropriate result, the entire lot needs to be set aside for return to vendor.
2. If the temperature of the storage areas falls outside of acceptable range, or if the temperature of the testing area falls outside of acceptable range; and
3. Once a month regardless if patient testing has not been performed.

Once control kits are opened they must be used within 8 weeks. They will be labeled with their expiration date the day they are opened and placed in the refrigerator.
Control results must be documented in the Quality Control Book, which also will be placed in a locked cabinet at the AAP clinic.

**Process Control During Testing**

**A. Safety Precautions and the Use of Gloves:**

1. Gloves should be changed after contact with each patient and disposed in the disposable bags.
2. Hands should be washed immediately after removing contaminated gloves.
3. Gloves should be worn when handling items or cleaning surfaces that are soiled.

Latex gloves are stocked in each testing station during out-posted HIV testing activities and are available to all HIV test counselors there. The Coordinator will ensure that the testing stations are adequately stocked before going out in the field. The coordinator is also responsible for informing the Administrative Site Manager when more supplies are needed.

**B. General Test Preparation:**

1. Place the Reusable Test Stand on a flat, level surface. Use only the stand provided.
2. Using the notched corners, tear the top of each end of the divided pouch containing the test device and developer solution vial.
3. To prevent contamination, leave the test device in the pouch until needed. DO NOT touch the flat pad.
4. Check to see if the absorbent packet is present. If not, discard the test device and obtain a new pouch for testing.
5. Remove the developer solution vial from the pouch.
6. Firmly holding the developer solution vial, carefully uncap the vial by gently rocking the cap back and forth.
7. Slide the uncapped developer solution vial into the top of the slot in the angled reusable test stand, making sure the vial is completely seated in the stand. Do not force the vial into the stand from the front of the slot, as splashing may occur.

**C. Specimen Collection and Testing Procedure:**

1. Have the person being tested remove the device from its pouch.
2. DO NOT allow the person to touch the flat pad.
3. Check to make sure that an absorbent packet is included with the device. If not absorbent packet is present, discard the device and obtain a new pouch for testing.
4. Direct the person to place the flat pad above the teeth against the outer gum.
5. Direct the person to gently swab completely around the outer gums, both upper and lower, one time around from molar to molar. DO NOT allow the person to swab the roof of the mouth, the inside of the cheek or the tongue. Both sides of the flat pad must be used during this procedure.
6. Instruct the person being tested to insert the flat pad of the device all the way into the vial making sure the flat pad touches the bottom of the vial.
7. The results window on the device should be facing towards you.
8. Start timing the test. DO NOT remove the device from the vial while test is running. Pink fluid will appear and travel up the result window gradually disappearing as the test develops.
9. Read the results after 20 minutes but not more than 40 minutes in a fully lighted area.

D. Test Results and Interpretation:

Refer to the result window on the test device:

1. **Non-Reactive**: A reddish-purple line appears in the result window in the area adjacent to the triangle labeled “C”, and no line appears in the area adjacent to the triangle labeled “T” (see diagram). Report test results as Negative for HIV-1/2 Antibodies. A non-reactive result does not preclude the possibility of exposure to HIV or infection with HIV. An antibody response to recent exposure may take several weeks to reach detectable levels. Individuals will be counseled about the meaning of the result.

2. **Reactive**: A reddish-purple line appears in the result window in the area adjacent to the triangle labeled “C” and “T”. One of these lines may be darker than the other. The presence of ANY reddish-purple line in the area adjacent to the “C” and “T” triangle is considered reactive (see diagram). Report test results as PRELIMINARY Positive for HIV-1 Antibodies. Patients who have a preliminary positive will be offered a choice for confirmatory testing through OraSure (done immediately onsite), a blood specimen collected at outposted site using universal precautions and safe blood transport, or, if preferred, a blood specimen collected at the AAP clinic during regular operating hours.

3. **Invalid**: A test is invalid if any of the following occurs:
   
   o No reddish-purple line is present in the area adjacent to the “C” triangle.
   o A red background in the result window makes it difficult to read the results after 20 minutes.
   o Any of the lines appear outside of the areas adjacent to the “C” or “T” triangles (see diagram 4)
   o An invalid test result means that there was a problem in running the test that was either related to the specimen, or to the test device. An invalid result cannot be interpreted or reported.
   o Repeat the test with a new test device and developer solution vial.

**Post Testing**

1. Report results to patients with a clarification that positive OraQuick Test results are preliminary and must be confirmed by a standard (OraSure) HIV test. Client will be given a result slip indicating the outcome of the test.

2. If the client chooses to have a confirmatory test done through oral specimen collection, the OraSure testing will take place right in the testing room according to the manufacturer's directions and AAP/MMC policy and procedure for oral fluid testing.

3. If available, confirmatory HIV testing can also be performed by obtaining a venous blood specimen.

4. Document Results: Detailed log results for rapid tests will be placed in the Rapid Test Results log at the time results are read. This log will include specific information on the specimen, kit and actual test, as well as confirmatory results. The general log includes demographic information, risk history, follow-up and referral information.
5. CONFIRMATORY TESTING

All OraSure specimens should be taken back to AAP immediately after testing event and sent to lab.

Heritage Labs International
560 North Rogers Road
Olathe, KS 66000
913-764-1045

Follow-up: An appointment should be scheduled within 1-2 business days after specimen collection with an AAP medical provider. For any preliminary positive test results appointments, the test counselor should offer support while client is waiting for confirmatory results.

6. RECORD KEEPING/REPORTING

CONFIDENTIALITY

1. Client charts will be kept in a locked/secured area to ensure confidentiality area when the mobile unit is in the field
2. Charts must be removed from the mobile unit at the end of the workday and stored in a locked file cabinet at AAP.
3. Program data collected from clients must be entered on a computer in the hospital’s electronic medical record.
HIV TESTING IS FOR EVERYONE

**ADVISE**
- Advise all clients to have an HIV test today
- If they decline, respond to concerns and motivate with benefits of testing
- If HIV negative, client can learn how to stay negative
- If HIV positive, client can get the care needed to stay healthy
- If HIV positive and pregnant, client can learn to prevent transmission to baby
- If HIV positive, ensure that client is in care
  Ask client about questions/concerns and if ready to get an HIV test

**CONSENT**
- Explain consent: they can only be tested for HIV if they give permission by signing the consent form
- Explain shared confidentiality: no one outside of the health team will be told about their HIV test or status without their permission
  Have client sign the consent form

**TEST**
- Explain testing procedure:
  - Finger prick to test a drop of blood for HIV
  - Results of test ready in approximately 15 minutes
- If first test is positive, explain need for confirmatory test
  Perform rapid test or take client to nurse for finger prick

**SUPPORT**

**Give test result**
- HIV negative
  - You tested HIV negative today
  - What will you do to stay negative?
    - Discuss prevention options:
      - Abstain don't have sexual intercourse
      - Be faithful to one or reduce number of partners
      - Condoms EVERY TIME you have sex
      - Encourage partner testing & counseling
      - Make sure condom is on & correct size
      - Get tested again every year or sooner
        - If you have STI, new partner, unsafe sex, or pregnant
      - Ask client if they have any questions

**Allow time to react**
- HIV positive
  - You tested HIV positive today, which means you have HIV infection
  - Coping:
    - Ask about & respond to client's concerns
    - Review client's testing status can start their life
  - Living Positively:
    - Explain importance of knowing CD4 & HIV stage
    - Stress importance of returning for CD4 results to find out if they need ARVs or other care
  - Protect Your Health & Your Partner:
    - Avoid re-infection by HIV or non-STIs
    - Use condoms EVERY TIME you have sex
    - Encourage partner testing & counseling
    - Obtain blood for CD4 test and do HIV staging
    - Assess if client needs further counselling
    - Verify the contents for results/management in case

**NURSES CAN FOLLOW THESE 4 STEPS DURING EVERY CLINICAL VISIT**

1. Determine reasons for client's visit.
2. Start ACTS if client suspects or begins the testing process.
3. Provide service per reason for visit.
4. Give HIV result & support per above.