

North Carolina HIV Prevention Program

# Quality Assurance Protocol for State Purchased Rapid HIV Testing Kits

Adapted from the State of Georgia



## I. PROGRAM OVERVIEW

The Rapid HIV Testing and Prevention Counseling intervention is defined as one-on-one, client-centered, risk/harm reduction counseling with persons at risk for HIV infection. The intervention is accompanied by an OraQuick Advance Rapid HIV-1/2 Antibody Test (OraQuick), Clearview Complete HIV 1/2 (Clearview), Uni-Gold Recombigen HIV (Uni-Gold), and/or Determine HIV 1/2 Ag/Ab Combo (Determine) rapid test kit that provides preliminary results in detecting HIV antibodies. OraQuick test specimens can be oral, finger-stick whole blood, or venipuncture whole blood with results interpreted between 20-40 minutes. Clearview test specimens can be finger-stick whole blood, venipuncture whole blood, serum or plasma with results interpreted between 15-20 minutes. Uni-Gold test specimens can be finger-stick whole blood or venipuncture whole blood with results interpreted between 10-12 minutes. Determine test specimens can be finger-stick whole blood, venipuncture whole blood, serum or plasma with results interpreted between 20-30 minutes. More information about each of these tests is provided in the appendix of this document.

The standards for counseling are based on the integrated CDC HIV Prevention Counseling and Rapid Testing models, which empower clients to assess their readiness for results, to identify their own risk behaviors, to develop a realistic and incremental plan for behavior change, and to begin seeking HIV primary care. More information regarding the CDC guidelines for HIV Prevention Counseling can be found in [MMWR Revised Guidelines for HIV Counseling, Testing, and Referral, 2001](#). More information on CDC guidelines for rapid HIV testing can be found in [Quality Assurance Guidelines for Testing Using Rapid HIV Antibody Tests Waived Under the Clinical Laboratory Improvement Amendments of 1988, 2007](#).

The OraQuick, Clearview, Uni-Gold, and Determine testing devices referred to in this protocol have each been classified under the Clinical Laboratory Improvement Amendments (CLIA) as “waived”. CLIA provides a “limited public health use” exception, under which a licensed laboratory can operate multiple satellite sites under the umbrella of a single CLIA certificate. Each agency is required to obtain a CLIA certificate of waiver and an HIV Testing License to conduct Rapid HIV Antibody Testing. Applications for the certificate and license can be found at:

Division of Health Service Regulation  
2713 Mail Service Center  
Raleigh, NC 27699-2713  
919-855-4620

Information can be found online at: <http://www.ncdhhs.gov/dhsr/ahc/clia/index.html>

## **II. PREREQUISITES TO IMPLEMENTING THE RAPID HIV TESTING AND PREVENTION COUNSELING INTERVENTION**

This section covers what must be done to assure the proper functioning of the HIV rapid test and to prepare an agency for rapid testing. Before the HIV counseling and testing can be performed there are prerequisites related to testing locations, policies, standing orders, certifications, supplies, quality assurance measures, and training protocol.

### **Prerequisites for Testing Locations and Policies**

Rapid HIV Testing must be conducted in locations that will assure optimal, accurate processing and reading of each test. All rapid test sites must provide adequate lighting, temperature control, testing surface, confidentiality, and counseling area(s).

Outreach locations for HIV counseling and testing are required to provide a private, confidential setting for HIV prevention counseling to occur. Crucial elements of a confidential setting include:

1. Ample space for a private conversation to occur.
2. Secluded area for counseling session.
3. Support from site staff to respect privacy of clients.

HIV testing through the North Carolina State Rapid HIV Testing Program is offered to individuals age 12 and older without parental consent, in accordance with manufacturers' instructions. Failure to comply with a manufacturer's instructions is a violation of the agency's CLIA agreement. Therefore, persons 11 and younger must be referred to a medical facility for an assessment of HIV infection. Some agencies may choose to implement financial requirements for primary care services, but a rapid HIV test must be given upon client request, regardless of income, free of charge. Agencies may not bill the client or the client's insurance for the rapid HIV test.

All agencies should develop and/or maintain written policies on confidentiality, confirmation of results, universal blood and bodily fluid precautions, and referral networks for linking positive clients to care. All agencies must develop and/or maintain standing orders from a licensed North Carolina physician that covers all counties served by the agency.

Agencies are responsible for obtaining the proper liability insurance coverage for testing.

Agencies must obtain a CLIA certificate independent of the public health laboratory for processing rapid HIV test specimens and a HIV Testing License to conduct Rapid HIV Antibody Testing. CLIA application fees are the responsibility of the agency. A copy of the agency's CLIA certificate and HIV License must be submitted to the North Carolina Rapid Testing Program Coordinator prior to the initiation of any rapid HIV testing activities.

## Prerequisites for Testing Supplies

Agencies contracted or approved to conduct rapid HIV testing will use OraQuick, Clearview, Uni-Gold or Determine, CLIA waived, single-use, qualitative immunoassays that detects antibodies to HIV. Determine also detects p24 HIV antigen.

- The OraQuick ADVANCE Rapid HIV-1/2 Antibody Test consists of:
  - A single-use test device and developer solution
  - A reusable test stand
  - A disposable single-use specimen collection loop
- The Clearview Complete HIV 1/2 (Clearview) Antibody Test consists of:
  - Sampler with test strip and buffer vial
  - A disposable sterile safety lancet
  - A bandage
  - Disposable test stands
- Uni-Gold Recombigen HIV (Uni-Gold) Antibody Test consists of:
  - A single-use test device and wash solution
  - A disposable single-use finger-stick sample collection pipette
- The Determine HIV 1/2 Antigen/Antibody Combo Test consists of:
  - A single-use testing device and chase buffer
  - Disposable single-use capillary tubes for finger-stick specimen collection
  - Disposable workstations
- In addition, agencies will also need:
  - Kit controls for each device used
  - Disposable absorbent workspace covers
  - Biohazard waste disposal bags
  - Latex/polyurethane/nitrile gloves
  - Sharps Container (for blood specimen testing only)
  - Disposable Lancets (for blood specimen testing only)
  - Thermometers (one for the storage area, one for the refrigerator, one for mobile sites)
  - Timers
  - 10% bleach solution or FDA approved disinfectant
  - HIV Testing Report Forms
  - Informed Consent forms
  - Other materials deemed necessary

## Quality Assurance Measures

### Test Kits and Controls

Kit Controls must be run under the following circumstances:

- Each newly trained counselor prior to performing rapid testing on client specimens
- When opening a new test kit lot (lot numbers are printed on each box and device)

- Whenever a new shipment of test kits is received
- If the temperature of the test kit storage area falls outside of the specific temperature requirements of the kits, usually 8 to 27°C (46 to 80°F)
- If the temperature of the testing area falls outside of the specific temperature requirements of the kits, usually 15 to 30°C (59 to 86°F). This may include testing at outreach locations.
- At periodic intervals as dictated by the user facility.

The kit controls verify that the rapid HIV test is working properly and that users are able to properly administer and interpret the test. If the results of any one of the control tests do not match the expected result, rerun all controls using a new testing device. The control failure should be documented on the Corrective Actions Log, as well as the actions taken to resolve the issue. If the repeated control test run produces unexpected results, do not use any tests from that entire lot number and notify the Rapid Test Coordinator immediately. All results from control tests are to be documented in appropriate logs.

Also, each rapid test device contains a built in control feature that demonstrates assay validity. A reddish-purple control line should appear in the area labeled “C”. The control line must appear in order for the respective test to be valid, whether or not the sample is reactive or non-reactive. Test results are considered “invalid” when:

- No reddish-purple line appears next to the area labeled “C” or “Control”
- A red background in the result window makes it difficult to read the result
- If any of the lines are not inside the appropriate control or test line areas.

## **Temperature Monitoring**

Test kits and controls must be monitored on a frequent basis to ensure testing supplies are maintained at an adequate temperature. Controls must be monitored in the refrigerator at least once daily on all days that the clinic or office is open. Test kits must be kept at room temperature and monitored at least once a week during the weeks that the clinic or office is open. Temperatures are to be documented in their respective temperature logs.

The room temperature must also be recorded at the testing location on the day of testing. If testing is performed in a temperature-controlled environment, the temperature may be recorded once at the beginning of testing. If testing is performed outdoors or in a non-controlled environment, the temperature should be recorded at frequent intervals to ensure the testing environment does not exceed the specific kit temperature requirements.

## **Proficiency Testing**

Proficiency testing is a mandatory part of the state rapid HIV testing program under state law 10A NCAC 42D .0101, *Certification for Laboratories Conducting HIV Testing*.

This is an annual occurrence that the agency is required to obtain at their expense. It ensures that testing agencies are performing the test accurately and can interpret results correctly. The Rapid Testing Coordinator may request the results of proficiency testing as a part of program evaluation. Do not specify the HIV Prevention Program as a reporting agency for proficiency testing.

For new agencies that enroll in the rapid testing program, this will be enforced the following year of enrollment. Effective December 1, 2014, all currently enrolled agencies must be enrolled in a proficiency testing program. Once registered, please send confirmation to the Rapid Testing Coordinator.

Below are descriptions of select available proficiency programs and the pertinent sections of the program catalog to help facilitate ordering:

1. Wisconsin State Laboratory of Hygiene: \$168 per year + \$55 annual registration fee + \$20 one time new account fee = \$243 new accounts, \$223 renewal accounts

The WSLH offers three samples sent twice a year. Participants should register by December 1 of the prior year for the next year's shipping cycle. Forms, catalog, and further information are available at <http://www.slh.wisc.edu/proficiency> or at 800-462-5261.

WSLH has also agreed to offer a 10% discount for our agencies. Please contact the Rapid Testing Coordinator to ensure receipt of this discount. With this discount, the cost would be \$218.70 for a new account and \$200.70 for renewal accounts.

Approximate shipment dates: Early February, Early June

**Anti-HIV - Waived Methods (HVW)**

Two shipments per year - Three samples per shipment

**Product Information:** 1mL liquid samples intended for waived rapid test kits. Compatible with rapid kits used to test for Anti-HIV-1 or Anti-HIV-1/2.

**Analyte:**  
Anti-HIV

Order Options		
Product	Item#	Price
Base product (R)	PT04040	\$168.00
Additional samples (X)	PT04050	\$42.00
Additional result reporting (Y)	PT04060	\$32.00

2. College of American Pathologists: \$218 per year + 1% fuel surcharge = \$220.18 annually

The CAP EXCEL program offers two samples sent twice a year. Participants should register by December 1 of the prior year for the next year's shipping cycle. The direct link to the catalog is located at <http://goo.gl/VaqxYv>. Forms and further information is available at [www.cap.org](http://www.cap.org), or at 800-323-4040. Agencies will need to submit a tax exemption letter with their application.

Approximate shipment dates: Mid-August, Late November

Anti-HIV-1 and Anti-HIV-1/2, Waived XB3		
Analyte/Procedure	Program Code	Challenges/Shipment
	XB3	
Anti-HIV-1 and Anti-HIV-1/2, waived methods only	I	2

**Program Information**

- Two 0.5-mL plasma specimens; report up to five different locations within your institution
- Two shipments per year: F and I

- American Proficiency Institute: \$150 per year + \$75 registration fee = \$225 annually

API-PT offers two samples sent three times a year. They also offer free continuing education credits and paperless proficiency testing. Participants should register by December 1 of the prior year for the next year’s shipping cycle. Further information is available at [www.api-pt.com/catalog.aspx](http://www.api-pt.com/catalog.aspx) or at 800-333-0958.

Approximate shipment dates: Mid-April, Mid-August, Mid-December

**433 Rapid HIV**

For laboratories using a rapid waived method to test for anti-HIV and/or HIV-1 p24 antigen. (For HIV-1/2 Ag/Ab Combo methods such as Abbott Architect and Bio-Rad, see Cat #417 - Viral Markers)  
 - 2 samples  
*Anti-HIV-1/2, p24 Antigen*

If your agency participates in a different program than the ones listed above, please check with the Rapid Testing Coordinator for compliance. Ensure that specific material for rapid HIV testing proficiency is ordered.

**Prerequisites for Rapid Testing and Prevention Counseling Personnel**

*HIV Counseling, Testing, and Referral (CTR) Training*

Counselors are required to be skilled in client-centered counseling. Additionally, counselors must be knowledgeable of a wide variety of risk/harm reduction activities and be comfortable demonstrating risk/harm reduction skills such as providing condom demonstrations. CBOs supported to conduct this intervention are responsible for screening potential counselors and reinforcing skills and knowledge with internal training activities.

CTR training is not required for testing in clinical settings, i.e., substance abuse clinics, community health centers, etc. State funded agencies that receive rapid testing kits must send all non-clinical staff to Whetstone Consultations for CTR training. State

supported rapid testing agencies may attend Whetstone Consultations or conduct approved internal CTR training. Licensed practical nurses may not attend Whetstone Consultations nor give post-test counseling.

If possible, clients should only see one counselor. This includes giving test results. Consistency of the client and counselor relationship helps the client feel secure, reduces misunderstanding, and promotes the likelihood of effective risk/harm reduction. If a different counselor must provide follow-up prevention counseling sessions, careful record keeping is recommended to ensure high-quality counseling.

#### *Rapid Testing Training*

Staff and program managers that conduct or oversee rapid HIV testing must receive training by the HIV Prevention Program or attend an approved training that includes specific instruction on the rapid test s/he will be using. Proof of attendance will be required and maintained in on-site personnel records.

#### *Safe Work Habits/Universal Precautions Training*

Staff and program managers who obtain specimens from clients must be educated about universal precautions and other safe work habits. Before performing testing, all operators must read and become familiar with Universal Precautions for Prevention of Transmission of HIV, Hepatitis B Virus, and other blood-borne pathogens in healthcare settings. Online training is sufficient.

Each agency must have a designated program manager who is responsible for performing or delegating quality assurance tasks. These are included, but not limited to:

- Disseminating all updates from the HIV Prevention Program to appropriate staff
- Maintaining personnel files with updated training records
- Maintaining required internal documentation and tracking of rapid testing kits and controls
- Reviewing data submission forms for accuracy and completion
- Monitoring temperatures of the kits and controls
- Ordering proficiency testing materials and maintaining the reported results

### **III. REQUIRED ACTIVITIES WHILE CONDUCTING A RAPID TESTING AND PREVENTION COUNSELING SESSION WITH A CLIENT**

All agencies conducting the HIV Prevention Counseling and Rapid Testing intervention in North Carolina should model sessions with clients according to the format and guidelines listed below.

#### ***Before performing a rapid HIV test:***

- Introduce yourself to the client. Give the client your name and welcome them to the agency.
- Assess client's readiness to receive the results on the same day. Ask the client questions to determine their motivation for getting tested and what, if any, support system is in place.
- Offer options for testing (oral swap, finger-stick, venipuncture, etc.) that are available at the testing site. Offer clients the choice of receiving results the same day or at a later date.
- Describe the testing process, what type of specimen will be collected, how long the whole process will take, and what each of the three possible results mean. It is a part of informed consent for clients to understand what type of specimen will be taken from them, how long the rapid testing session will take, and that the three possible results are preliminary positive, negative, and invalid. Clients should also be informed what actions will take place after each of the results.
- Explain to client that if a preliminary positive result is received, a confirmatory test should be conducted.

According to the CDC, a very important part of counseling persons who have a reactive rapid HIV test result is to make sure they understand that the test result is preliminary, and further testing must be done to confirm the result. Counselors must assess if testing is beneficial at this time based on the client's response to how they would react to getting a preliminary positive result.

Persons who have identified themselves as HIV positive should not be retested with a rapid test. Individuals infected with HIV-1 and/or HIV-2 who are prescribed antiretroviral medication can produce false negative rapid test results under some circumstances. Self-identified HIV infected persons can be offered a conventional HIV test and should be referred to case management and/or medical care.

- Address Partner Services, including that if the client tests positive, a DIS will contact them to offer services. Emphasize that this is a free and confidential

service that provide clients with help in contacting partners and other referral services.

- Offer the client a confidential test and explain what confidential testing means. Confidential testing indicates that a client is willing to provide personal identifiers that can be used to link the individual to his/her rapid HIV test result.
- Obtain Informed Consent. Informed Consent (verbal or written) for HIV testing must be obtained prior to clients receiving any HIV testing. Clients testing confidentially must provide written consent or verbal consent must be documented in the client's records.
- Provide appropriate subject information pamphlet for the rapid test being conducted. The FDA requires that all test subjects receive the "Subject Information" pamphlet produced by the manufacturer of the rapid test device being used prior to collecting a specimen for testing. These pamphlets are included in each box of the test kits.
- Collect and run specimen. Testers must follow the manufacturer's instructions provided by the manufacturer of the rapid test device he/she will be using. In addition to manufacturer instructions, identifying stickers from the HIV Test form should be placed on the testing device (or on the developer solution vial for OraQuick tests) to insure quality control. **Not following the manufacturer's instructions may result in inaccurate test results.**

***While a rapid HIV test is processing:***

- Complete the HIV Testing Report Forms. Each rapid HIV test shall be documented on the HIV Testing Report Form. Forms must be completed in their entirety and submitted to the State Laboratory of Public Health **monthly** to be entered for analysis and CDC submission.
- Identify personal risk behavior and safer goal behaviors of the counseling process. A personalized risk assessment should explore previous risk-reduction efforts and identify successes and challenges in those efforts. Factors associated with continued risk behavior that might be important to explore include using drugs or alcohol before sexual activity, underestimating personal risk, perceiving that precautionary changes are not an accepted peer norm, perceiving limited self-efficacy for successful change efforts, receiving reinforcement for frequent unsafe practices (e.g., a negative HIV test result after risk behaviors), and perceiving that vulnerability is associated with "luck" or "fate".

When considering safer goal behaviors, counselors should focus on reducing the client's current risk and educating about HIV transmission modes. Counselors should discuss the HIV transmission risk associated with specific behaviors or activities the clients describe and then discuss lower-risk alternatives.

For example, if clients indicate that they believe oral sex with a risky sex partner poses little or no HIV risk, the counselor can clarify that, although oral sex with an infected partner might result in lower HIV transmission risk than anal sex, oral sex is not a risk-free behavior, particularly when commonly practiced. If clients indicate that they do not need to be concerned about HIV transmission among needle-sharing partners if they use clean needles, the counselor can clarify that HIV can be transmitted through the cooker, cotton, or water used by several persons sharing drugs. With newly identified or uninformed HIV-infected clients, the counselor should discuss HIV transmission risks associated with specific sexual or drug-use activities, including those in which the client might not be currently engaged.

Although the optimal goal might be to eliminate HIV risk behaviors, small behavior changes can reduce the probability of acquiring or transmitting HIV. Behavioral risk-reduction steps should be acceptable to the client and appropriate to the client's situation. For clients with several high-risk behaviors, the counselor should help clients focus on reducing the most critical risk they are willing to commit to changing.

- Continue to assess client readiness to receive result. Counselors have until the timer goes off, thus indicating the rapid test is finished processing, to assess whether the client is ready to receive same day test results. Counselors **may not** give test results before the kit is fully resolved per the manufacturer guidelines. If the counselor leaves to interpret the test result, they must provide the result upon returning to the client.

***After the rapid HIV test has developed:***

- Provide the test result to the client.
- Create a client action plan, offer referrals and provide support, summarize and close
- Set up follow-up appointment for preliminary positive clients to receive confirmatory result or, if necessary, those testing negative to get retested.
- Provide condoms, other risk/harm reduction tools and appropriate literature.
- Complete the remainder of the HIV Testing Report Form, Kit Results Log and other documentation as needed.
- Correctly dispose of used testing supplies following universal precautions and safe work practices at all times.

## ***Continue counseling session based on the results of the test:***

### **Preliminary Positive:**

- Accurately communicate results with client—the result shows signs of HIV antibodies or antigen and a confirmatory test must be done to be sure.
- Allow time for emotional response. Do not rush the client into conversation.
- Ensure the client understands what the result means and assess client concerns.
- Offer confirmatory blood or second rapid test. Clients who have a reactive/preliminary positive rapid HIV test result must be offered a confirmatory test or second rapid test and linked to early intervention after receiving their preliminary positive result. North Carolina allows for dual rapid confirmatory algorithm to increase the efficiency of linkage to care. See below for the algorithm.
- Review the client's risk assessment and risk reduction plan.
- Emphasize the importance in taking the same health precautions as a person who may have a confirmed HIV positive test result. HIV positive clients must be informed about control measures under state law 10A NCAC 41A .0202, *Control Measures—HIV*.
- Negotiate additional referrals with client, including potential medical and partner services.
- Set appointment to return for confirmatory blood draw test results.
- Provide condoms and literature as deemed appropriate.
- Document the result on the HIV Testing Report Form and Kit Results Log

### **Negative:**

- Review with the client his/her risk assessment and risk reduction plan. Discuss plans for staying negative.
- Assess the need to retest.
- Provide condoms and other risk/harm reduction tools and appropriate literature.
- Assess the client's need for other referrals.
- Make sure client understands the window period and whether he/she needs to be retested at a later date.
- Document the result on the HIV Testing Report Form and Kit Results Log

### **Invalid:**

- Explain that there was a problem running the test, either related to the test device or the specimen collected.
- Assess client concerns and emotional response.
- Assure client that quality assurance procedures are in place. **NOTE: If you have not personally checked all storage logs that day, do so before retesting.**
- Collect new specimen and run it with new rapid test device or conduct a conventional test if the client refuses an additional rapid test.
- Provide condoms, other risk/harm reduction tools and appropriate literature.
- Review the client's risk assessment and risk reduction plan. Emphasize the need to take same risk reduction precautions as established.

- Document the invalid result on the Kit Results Logs. Document the repeated rapid test result on the HIV Testing Report Form and Kit Results Log.

## Confirmatory HIV Testing

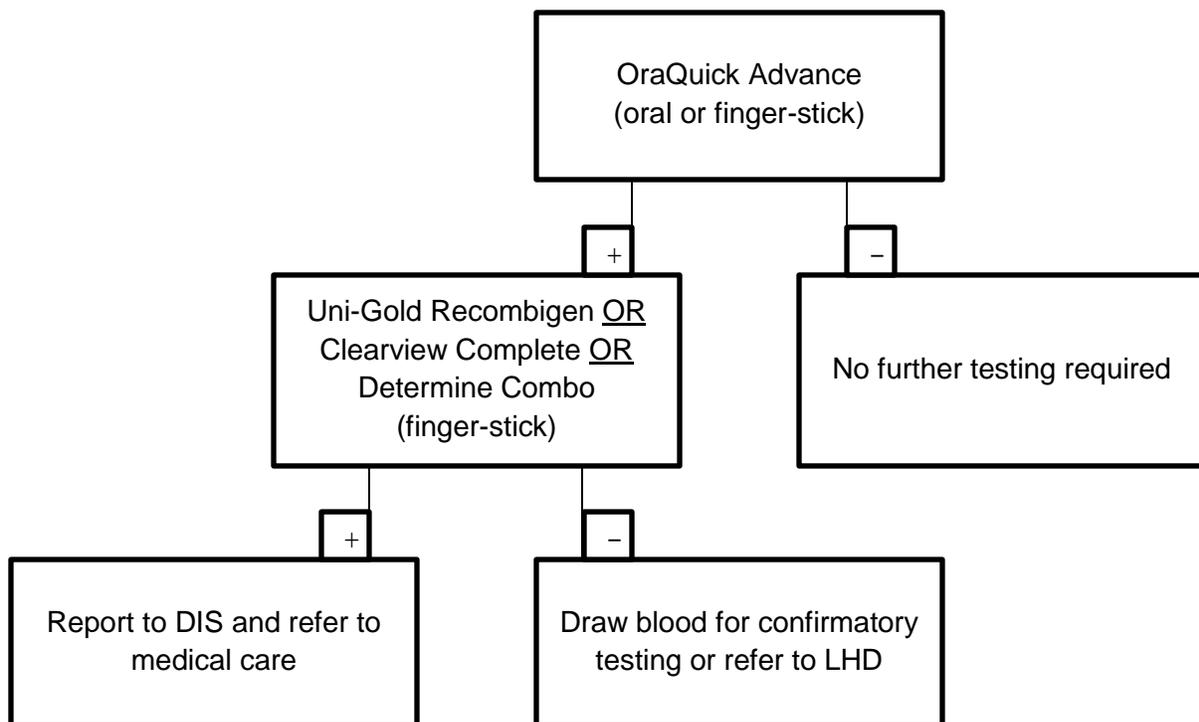
Following a preliminary positive rapid test, the client must be administered a confirmatory HIV test. This can be done with a second rapid test or a blood draw.

## Dual Rapid Algorithm

The dual rapid algorithm allows for early referral to care for rapid positives. A repeatedly positive HIV antibody test meets the case definition for HIV infection. Clients testing positive on two different rapid testing kits may be considered for linkage to care and is reportable to DIS as case positive. Agencies should communicate with their linkage partners to ensure that the algorithm is acceptable for entrance into care.

Agencies may start with any of the four state supplied rapid testing kits. The second rapid test must be a finger-stick specimen of a different brand of test kit.

*The example below starts with OraQuick Advance:*



Due to the 4<sup>th</sup> generation technology, the dual rapid algorithm for Determine Combo has been modified. Please see the appendix for further details.

**Negative or Indeterminate (therefore Discordant Result):**

- The client should be told that their HIV status is not certain at this point and further testing is needed.
- Explain that this is a discordant result (do not use the terms false positive or false negative as these are not appropriate descriptions of this situation).
- Assess client's concerns.
- Client should be given an appointment to return for retesting in 2 weeks. It is highly recommended and compliant with CDC rapid testing protocol that follow-up confirmatory testing be conducted with a new specimen whenever possible.
- Review the client's risk assessment and risk reduction plan. Emphasize the need to take same risk reduction precautions as established during this period of uncertainty.
- Provide condoms, other risk/harm reduction tools and appropriate literature.
- Document the result on the HIV Testing Report Form and Kit Results Log and Corrective Actions Log. The Rapid Testing Coordinator should be notified as soon as possible of discordant results.

**Positive:**

- Allow time for an emotional response. Do not rush the client into a conversation.
- Ensure client understands what test result means.
- Make client aware of need for medical evaluation and the availability of treatment.
- Provide linkage to care. Linkage to care links newly identified HIV-infected persons, not currently in care, to a primary care provider. The counselor also educates basic facts about HIV and may link clients to other services when barriers are identified.
- Reassess the client's risk for transmitting HIV infection to others. Discuss partner counseling options and discuss the client's plan to inform his/her partners.
- Discuss client's plans to stay healthy, to protect self and others.
- Assist client in identifying necessary linkages. Make appropriate connections and set appointments.
- If working with a positive woman who is pregnant and not in prenatal care, link the client to prenatal care.
- Provide condoms and appropriate literature.
- Inform DIS. Clients are to be informed of the importance of contacting sex and/or needle sharing partners. Counselors should record clients' full contact information on the appropriate areas of HIV Testing Report Form facilitate referral follow up, partner services, and surveillance. Counselors must discuss the North Carolina public health policy that provides for DIS to contact all persons testing reactive to HIV to discuss and offer partner services.
- After 30 days if linkages cannot be confirmed, make appropriate documentation in client's patient information.
- Document the result on the Kit Results Logs.

## **Clean Up and Disposal of Testing Supplies**

All rapid testing devices should be disposed of in biohazard waste material bags in accordance with local regulations for infectious waste disposal. All specimens should be handled in accordance with universal precautions and the manufacturer's instructions. Proper disposal of biohazardous waste materials will be the responsibility of the agency. Shipping or transporting of processed devices/vials outside of the test area is prohibited, unless stored in a sealed and clearly marked biohazard waste container.

## IV. REQUIRED DOCUMENTATION OF HIV TESTING ACTIVITIES

The contact information for the Rapid Testing Program is:

Rapid Testing Coordinator  
1200 Front St. Suite 104  
Raleigh, NC 27609  
(919) 733-2030

HIV Testing Report Forms, Informed Consent forms, client data, temperature logs, and results logs must be maintained in accordance to your agency's internal records retention policy.

Following is a description of all documentation that must be completed and maintained and/or submitted along with the submission timeline where applicable.

1. Monthly Submission:
  - a. **HIV Testing Report Form.** This form must be completed and submitted to the State Laboratory of Public Health for each rapid HIV test conducted. Follow completion instructions for the form for submission details. Submitted forms must be printed from the original PDF file, but a copy of the completed form may be kept in the client file. Agencies that submit data through the Expanded Testing Program are not required to fill out an HIV Testing Report Form.
2. Quarterly Submission:
  - a. **Agency Progress Reports.** This spreadsheet must be completed and submitted to the Rapid Testing Coordinator one month after the end of the calendar quarter. This is a detailed account of rapid testing sites and kit usage at those sites.
  - b. **Expanded Testing Data.** Community health centers that submit testing data to the University of North Carolina Chapel Hill must submit data on a quarterly basis to the designated contact. Agencies that submit data through the Expanded Testing Program are not required to fill out an HIV Testing Report Form or Agency Progress Report.
3. As needed:
  - a. **Rapid Testing Request Form.** This form should be completed when supplies are needed. Please allow at least two weeks for processing. The form can be accessed [here](#).
4. Maintain on site:
  - a. **CLIA Certificate of Waiver.** Each testing agency must obtain a CLIA Certificate of Waiver or have a CLIA Certification Laboratory Number from the Division of Health Service Regulation prior to requesting approval for any

- rapid testing activities. The CLIA Certificate must be current and a copy must be provided.
- b. **HIV Testing License.** Each testing agency must obtain an HIV Testing License prior to requesting approval for any rapid testing activities. Licenses must be current and a copy must be provided.
  - c. **Kit Results Log.** Documentation of all test results including invalid and reactive.
  - d. **Kit Temperature Log.** Documentation of temperatures in the storage room must be recorded weekly for test kits. These logs are kept in agency files and may be requested by the Rapid Testing Coordinator at any time.
  - e. **Control Results Log.** All control tests run at the testing site must be logged on the Control Kit Log.
  - f. **Control Temperature Log.** Documentation of temperatures in the control storage area must be recorded daily for test kits. These logs are kept in agency files and may be requested by the Rapid Testing Coordinator at any time.
  - g. **Confidentiality Agreements.** All agency staff and volunteers must have a confidentiality agreement signed and on file at the testing agency.
  - h. **Standing Orders.** A licensed North Carolina physician must oversee all testing activities in the counties served by the agency. The standing orders must be current, valid, and reviewed on a regular basis to ensure accuracy.
  - i. **Training Records Form.** Counselors must attend approved CTR, rapid testing, and blood borne pathogens/universal precautions training. Staff and volunteers conducting rapid testing and prevention counseling activities are required to be skilled in client-centered counseling, safe work habits, collecting and processing rapid HIV test specimens accurately, and completing forms correctly. Skills and knowledge must be reinforced with participation in ongoing training and evaluation activities. Certificates must be stored in agency files and may be requested by the Rapid Testing Coordinator.
  - j. **Other Testing Policies.** Agencies may have additional quality assurance measures in place with required staff compliance. Policies may be more specific than the state quality assurance plan, but must meet the minimum requirements as described.

## V. CONSEQUENCES OF PROTOCOL VIOLATIONS

Failure to follow North Carolina's rapid testing and prevention counseling protocol may result in a cease of rapid testing activities until protocol issues are resolved or indefinitely. Protocol violations witnessed by or reported to the Rapid Testing Coordinator will be discussed with the testing site as soon as possible. Corrective action, if any, will be documented and submitted to the testing site and the HIV Prevention Program

An immediate halt of testing activities can occur when:

- Confidentiality is compromised in the test processing area or through handling of documentation.
- Quality assurance records/documents are not maintained as specified in this protocol.
- The agency fails proficiency testing.
- Informed consent is not obtained from clients prior to specimen collection.
- Completed HIV Test forms are not stored in a confidential manner and the specified copies are not submitted at frequent intervals
- Rapid test kits or other testing supplies are distributed to and/or used by unauthorized entities or are unaccounted for.
- The agency's CLIA waiver or HIV license expires without renewal.
- Confirmatory testing is not offered to a client who has a preliminary positive rapid test result.
- Documentation for clients who test positive for HIV is not filled out completely and accurately and/or submitted to the State Laboratory of Public Health at least monthly.
- Clients who test positive for HIV are not linked to appropriate HIV medical treatment services and/or follow-up on HIV medical care linkages are not made and/or documented.
- Test kits are used to test low risk populations.