



COMMONWEALTH of VIRGINIA

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To: Community-Based Organization Test Sites

Enclosed please find the Virginia Department of Health's *Quality Assurance Manual for Community-Based HIV Rapid Testing*. This quality assurance (QA) manual will be the benchmark by which all Division of Disease Prevention-funded HIV testing programs are evaluated and will be used in conjunction with the *Virginia Facts and Fundamentals* training required of all testing staff.

All testing staff are required to familiarize themselves with this manual. In addition, the "Personnel Responsibilities" section must be completed for each agency and must be filed in the enclosed binder, along with all other required documentation as set forth in the manual. The "Personnel Responsibilities" section, which addresses the agency protocols necessary to ensure a successful testing program, will be reviewed at each site visit. Agencies are expected to keep this document current.

Please note that this document is effective immediately and standards laid out herein must be followed **even where they are more extensive than the law and/or the Centers for Disease Control and Prevention's requirements**. Agencies whose policies and procedures meet and go beyond those laid out in this manual may choose to continue with their current policies if desired. However, all agencies must have the completed the "Personnel Responsibilities" section on file as described above.

An electronic copy of this document is also being provided to you so that you may make additional copies and supplement your current QA materials as needed. Future modifications to this document will be issued electronically as addenda and/or with notations on the sections and pages modified.

I hope this manual will provide you with a strong foundation on which to monitor the quality of your testing program and procedures.

A handwritten signature in blue ink, appearing to read "Elaine Martin".

Elaine G. Martin, Director
HIV Prevention Services
Division of Disease Prevention

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Introduction

Quality Assurance (QA) guidelines contained in this document focus on Waived Rapid HIV Testing. This document provides procedures for the Federal Drug Administration (FDA) Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waived Rapid HIV Test: OraQuick® ADVANCE Rapid HIV-1/2 Antibody Test.

The OraQuick® ADVANCE Rapid HIV-1/2 Antibody Test is manufactured by OraSure Technologies, Inc. It is a single-use, qualitative, immunoassay used to detect antibodies to Human Immunodeficiency Virus Type 1 (HIV-1) and Type 2 (HIV-2) in oral fluid, fingerstick-whole blood, venipuncture-whole blood, and plasma specimens. Test results can be read in 20 to 40 minutes.

Waived tests are simple and accurate when performed at point-of-care by personnel trained to follow manufacturer's instructions.

QA refers to planned, ongoing, step-by-step activities designed to assure that:

1. Testing is performed correctly.
2. Results are accurate and reliable.
3. Errors are found and corrected.

QA activities shall be in place during the entire testing process. Agencies need to have a QA plan in place before initiating rapid testing, and QA activities shall be followed before, during, and after testing.

Laws

HIV/HBV Infected Healthcare Workers and Occupational Exposure. *Year 1993 SB 829 §32.1-45.1.* Deemed consent to testing and release of test results related to infection with human immunodeficiency virus or hepatitis B or C viruses. <http://leg1.state.va.us/cgi-bin/legp504.exe?000+coh+32.1-45.1+501054>

Partner Notification. *Year 1989 HB 1974 § 32.1-36.1. Section A number 11.* Confidentiality of test for human immunodeficiency virus; civil penalty; individual action for damages or penalty. <http://leg1.state.va.us/cgi-bin/legp504.exe?000+coh+32.1-36.1+702816>

Partner Notification. *Year 1989 HB 1974 § 32.1-37.2. Section B.* Consent for testing for human immunodeficiency virus; condition on disclosure of test results; counseling required; exceptions. <http://leg1.state.va.us/cgi-bin/legp504.exe?000+coh+32.1-37.2+702512>

HIV Testing. *Year 1995 HB 1921 § 54.1-2403.01.* Routine component of prenatal care. <http://leg1.state.va.us/cgi-bin/legp504.exe?000+coh+54.1-2403.01+702271>

HIV Testing. *Year 2008 § 32.1-37.2 Section A* Consent for testing for human immunodeficiency virus; condition on disclosure of test results; counseling required; exceptions <http://leg1.state.va.us/cgi-bin/legp504.exe?000+coh+32.1-37.2+703101>

Standards

1. Clients shall be tested in a confidential manner and in a location that provides privacy.
2. Agencies shall always abide by the manufacturer's insert regarding age restrictions. Agencies shall determine their own age restrictions for testing as long as they adhere to the limitations described above. Testing of minors shall include discussion of parental notification. If persons under the age of 18 receive a confirmed positive result, their parents or legal guardian may be notified. Minors shall be encouraged to share their results with their parents or legal guardian unless their safety will be compromised by such a disclosure.
3. Staff shall attend the following trainings before conducting rapid HIV testing:
 - Occupational Safety and Health Administration (OSHA) - written materials or film shall be reviewed each year by staff in lieu of training.
 - The Facts
 - The Fundamentals of HIV Prevention Counseling
 - The Fundamentals of Waived Rapid HIV Testing Training
4. Staff conducting rapid HIV testing shall determine, on an individual basis, the sobriety and/or mental status of each client. A rapid HIV test shall not be performed, nor shall results be provided, if the tester believes that the client cannot comprehend the meaning of the test or shall be a danger to him or herself or others.
5. Persons who have identified themselves as HIV-positive and who are requesting a test to prove their status for any reason, such as medical care, case management, etc., shall not be retested with a rapid HIV test. Instead, these individuals shall be referred to the local health department or an infectious disease clinic for serum testing. In some cases, HIV-positive individuals may present for testing in order to maintain their own confidentiality (i.e., large-scale testing events, a group of friends who all decide to be tested together, etc.). In these cases, a rapid test can be performed, but a confirmatory test need not be conducted. For continuity of paperwork, agencies shall follow up with the Virginia Department of Health (VDH) contract monitor when tests are done to maintain confidentiality as described above.
6. Staff shall provide testing only to those clients who sign the "HIV Test Facts and Permission to Release Information" form (*see Attachment 1*).
7. Staff shall document client encounters on all forms required by VDH.

8. Before conducting an HIV test, staff shall inform the client that the test is a screening test and further testing must be done to confirm a preliminary positive result. In delivering a preliminary positive HIV test to a client, staff shall again remind client that the test is a screening test and that a confirmatory test still needs to be conducted.
9. All testing sites shall have a copy of the original CLIA certificate of waiver. The most current/valid CLIA certificate shall be displayed at the agency's main headquarters. Copies shall be available at satellite sites (including one-time or temporary sites) in case of a surprise inspection.
10. In order to release test results to anyone other than the client and VDH, an authorization to release information must be signed by the client.
11. All new testing staff shall be observed the first time they conduct client testing and counseling by trained staff, the testing coordinator, or a colleague deemed competent. This observation shall be documented. New staff shall perform proficiency testing six months after performing the initial test and yearly thereafter (*see Attachment 2*).
12. Staff shall offer the client the appropriate manufacturer's rapid HIV test subject-information pamphlet.
13. Staff shall meet with a supervisor and/or other staff on a regular basis for debriefing sessions.
14. All testing sites' physical space and client flow shall be evaluated on a periodic basis.
15. Each agency shall have a written Rapid HIV Test Exposure Control Plan (ECP), hold new employee training within one month of hire, and ensure all testing staff attend annual OSHA updates (*see Appendix: Personnel Responsibilities*).
16. A rapid HIV test shall not be used to screen blood or tissue donors.
17. Staff shall offer the appropriate level of prevention counseling to all clients receiving testing.
18. Each site shall have a method to detect and document problems that occur at any point in the testing process, especially those that will affect the accuracy of the test results (*see Attachments 3, 4, & 5*).
19. Staff conducting testing services shall read and understand the manufacturer's instruction booklet.

Quality Control Procedures

Internal Quality Control

- The rapid HIV test has a built-in procedural control that demonstrates assay validity.
- The control line will appear on all valid tests, whether or not the sample is reactive or non-reactive.
- Controls shall be refrigerated per manufacturer's standards.

OraQuick: A reddish-purple line in the control ("C") area of the result window indicates that the test is running correctly.

External Quality Control

- Each rapid HIV test kit has a test kit control available separately from the rapid HIV test device.
- The test kit controls are specifically formulated and manufactured to ensure performance of the test, and are used to verify the tester's ability to properly perform the test and interpret the results.
- The positive controls will produce a reactive test result and are manufactured to produce a faint line. The negative controls will produce a non-reactive test result.
- **The test kit controls shall give the expected reactive or non-reactive result or the test results are not valid. If test kit controls do not provide expected results after being repeated, contact the product manufacturer and the VDH contract monitor.**

Controls shall be run under the following circumstances:

- with each new operator, prior to performing testing on a patient specimen
- when opening a new test kit lot
- whenever a new shipment of test kits is received
- if the temperature of the *OraQuick* test kit storage area falls outside of 35-80°F (2-27°C)
- if temperature of the *OraQuick* testing area falls outside of 59–99°F (15-37°C)
- when setting up a new test site of any kind. This would include a new room in the same building, a change in lighting, or an entirely new venue.
- whenever there is reason to suspect test kits are not functioning properly (e.g., two invalid test results in a row or an excessive number of unexpected results)
- at regular intervals determined by the testing site or contract agency

Test Kit Control Storage

- Store the OraQuick ADVANCE Rapid HIV-1/2 Test Kit Controls at 35-46°F (2-8°C).
- Do not use test kit controls beyond the expiration date printed on the outer carton.
- Open the test kit control vials only when you are performing tests.
- After use, recap and store the vials in their original container at 35–46°F (2–8°C).
- Dispose of unused portion of opened test kit control after 60 days.

Test Kit Control Procedures

- Gloves shall be worn when conducting test kit control procedures.
- A face shield and goggles shall be made available to prevent eye, nose, and mouth exposure.

Deviations from the procedures outlined in the test kit control or rapid HIV test pack insert will produce unreliable results. Test kit controls are intended for use in undiluted form. Adverse shipping and storage conditions or use of expired reagents will produce erroneous results.

1. Set up your workspace.
2. Open three (3) OraQuick test kits and place the three developer solution vials in the reusable test stand. Label each pouch, developer solution vial, and test device as HIV-1, HIV-2, and Non-reactive, respectively. The developer and test device should come from the same pouch.
3. Open a test kit control vial containing the control agent.
4. Insert the round end of an unused specimen loop into the vial of control reagent. Visually inspect the loop to make sure that it is completely filled with the control reagent. Use separate unused specimen collection loops for each control reagent. NOTE: Test kit control reagents are clear to straw-colored. Do not use if the reagent appears visually cloudy or discolored.
5. Immediately immerse the control reagent-filled specimen loop in the developer solution inside the developer solution vial of the corresponding control reagent (e.g., HIV-1 control agent into developer solution vial labeled HIV-1). Use the specimen collection loop to stir the specimen in the developer solution. Remove the specimen collection loop from the developer solution vial and discard the used loop in a biohazard waste container.
6. Remove the test device from the divided pouch without touching the flat pad. Insert the test device, flat pad first, into the developer solution vial containing

the specimen. Be sure that the result window faces forward and the flat pad touches the bottom of the developer solution vial.

7. Set the timer for 20 minutes. Do not touch or remove the test device from the vial until the results have been read. Read the results after 20 minutes, but no more than 40 minutes, in a fully lighted area.
8. Dispose of the used developer solution vial and the test device in a biohazard waste container.
9. Reseal the test kit control reagent vials and store them in their original container at 35-46°F (2-8°C).

Note: Each of these steps must be completed with each of the three control reagents. Make sure to recap each control immediately to avoid contamination.

INTERPRETATION OF TEST RESULTS

1. The **CONTROL LINE** (the line closest to the top of the test strip) indicates that the specimen was adequately applied, and there was proper hydration and migration of reagents. The control line will become visible within 15 minutes after starting the test, regardless of the HIV antibody status of the specimen.
2. The **TEST LINE** (the line closest to the bottom of the test strip, below the control line) indicates the presence of HIV specific antibodies. The test line will only become visible within 15 minutes of starting a valid test when HIV specific antibodies are present at detectable levels in the specimen.
3. **INVALID** - A pink/purple line will always appear in the CONTROL area, whether or not a line appears in the TEST area. If there is no distinct pink/purple line visible in the CONTROL area, then the test is INVALID. If any of the lines appear outside of the Control or Test areas, then the test is an INVALID test. An INVALID test cannot be interpreted. It is recommended that the test be repeated with a new device.

Expected Results

Negative Control: The negative control will produce a non-reactive test result. A line will be present only in the result window in the area adjacent to the triangle labeled "C." This indicates a non-reactive test result.

HIV-1 Positive Control: The HIV-1 positive control will produce a reactive test result and has been manufactured to produce a very faint test "T" line. A line will be present in the result window in the area adjacent to the triangle labeled "C" and a line will appear in the area adjacent to the triangle labeled "T." This indicates a reactive test result. The lines will not necessarily be the same intensity.

HIV-2 Control: The HIV-2 positive control will produce a reactive test result and has been manufactured to produce a very faint Test "T" line. A line will be present in the result window in the area adjacent to the triangle labeled "C" and a line will appear in the area adjacent to the triangle labeled "T." This indicates a reactive test result. The lines will not necessarily be the same intensity.

NOTE: If any of the test results for the negative control, the HIV-1 positive control, or the HIV-2 positive controls do not match, the test shall be repeated using a new test device, developer solution vial, and control specimen. If the test result for any of the controls is not as expected upon repeat testing, discontinue testing and follow agency procedures for contacting the VDH contract monitor and OraSure Technologies Customer Service at 800-672-7873.

All results shall be recorded on the "External Kit Control Log" (see Attachment 6).

Material Requirements

Materials provided in the master shipping carton:

- Test device (including an absorbent packet)
- Developer solution vial (containing 1 microliter)
- Reusable test stand
- Subject information pamphlet
- Customer letter
- Specimen collection loop (5 microliter)
- Package insert

Other materials required:

- Test control kit
- Timer capable of timing 20 to 40 minutes
- Clean disposable, absorbent workspace cover
- Latex, vinyl, or nitrile disposable gloves
- Biohazard waste container

Additional items required for fingerstick specimens:

- Antiseptic wipe
- Adhesive bandages
- Sterile safety retractable lancet
- Sterile gauze pads

General Test Preparation

- Escort client to the test location and have client sit in a stationary chair at the workspace.
- Record client identification, room temperature, date specimen collected, divided pouch lot#, and divided pouch expiration date on the "Rapid HIV Test Result

Log" sheet (*see Attachment 7*). For agencies using names on log sheets, be mindful of client confidentiality.

- Open the two chambers of the OraQuick Advance divided pouch by tearing at the notches on the top of each side of the pouch.
- To prevent contamination, leave the test device in the pouch until you are ready to use it.
- Write the client's identification code on the front of the test device. DO NOT cover the two holes in the back of the device with labels or other materials. Doing so will cause invalid results.
- Remove the developer solution vial from the pouch.
- Write the client's identification on solution vial.
- Hold the vial firmly in your hand.
- Carefully remove the cap from the vial, gently rocking the cap back and forth while pulling it off.
- Set the cap on the workspace cover.
- Slide the vial into the top of one of the slots in the blue stand provided by manufacturer. DO NOT force the vial into the stand from the front of the slot, as splashing will occur.
- Make sure the vial is pushed all the way to the bottom of the slot in the stand.

Oral-Fluid Specimen Collection and Testing

Step 1. *Collect*

- Have the client remove the device from its pouch.
- DO NOT allow the client to touch the flat pad.
- Check to make sure that an absorbent packet is included with the device. If no absorbent packet is present, discard the device and obtain a new pouch for testing.
- Direct the client to place the flat pad above client's teeth against the outer gum. Direct the client to gently swab completely around the outer gums - both upper and lower, one time around - using the flat pad. DO NOT allow the client to swab the roof of his/her mouth, or the inside of the cheek or tongue. NOTE: Both sides of the flat pad shall be used during this procedure.

If client is unclear on how to use the device, the tester shall demonstrate with an object besides the actual test, such as a coffee stirrer or tongue depressor. **Testers shall not swab the client.**

Step 2. *Test*

- Instruct the person being tested to insert the flat pad of the device all the way into the vial. Make sure that the flat pad touches the bottom of the vial. Note: Once the pad is in the vial, **it cannot be moved**. However, prior to placing the pad in the vial, the pad can be transported to the lab in its original foil packaging once the absorbent packet has been removed. The pad may stay in the foil packaging for up to 30 minutes before being transferred to the vial.

- The result window on the device should be facing the tester.
- Start timing the test. Record the time the specimen was collected on the "Rapid HIV Test Result Log" (*see Attachment 7*). *Look at time specimen is collected versus when test starts running.* DO NOT remove device from the vial while the test is running. Pink fluid will appear and travel up the results window. The pink fluid will gradually disappear as the test develops.
- While the test is developing, escort the client back to the counseling room and conduct prevention counseling to include an in-depth risk assessment and identification of safer behavioral goals and action step(s). If the test is running in the same room where counseling is taking place, the client must not be able to watch the test developing. A folded poster board or similar barrier can be used as a screen to separate the test from the client.
- Read the results after 20 minutes, but no more than 40 minutes, in a fully lighted area. A flashlight may be used to read test results; however, the flashlight must not be used behind the paddle to read test results.

Finger Stick-Whole Blood Specimen Collection and Testing

Step 1. *Collect*

- Using an antiseptic wipe, clean the client's finger. Allow the finger to dry thoroughly or wipe dry with a sterile gauze pad.
- Using a sterile, retractable safety lancet, puncture the skin just off the center of the finger pad.
- Hold the finger downward. Apply **gentle** pressure beside the point of the puncture.
- Wipe away this first drop of blood with a sterile gauze pad. Allow a new drop of blood to form.
- Pick up an unused specimen collection loop by the thick-handled end.
- Put the rounded end of the loop on the drop of blood. Make sure that the loop is completely filled with blood.

Step 2. *Mix*

- Immediately insert the blood-filled end of the loop all the way into the vial.
- Use the loop to stir the blood sample in the developer solution.
- Remove the used loop from the solution. Throw the used loop away in the biohazard waste container.
- Check the solution to make sure that it appears pink. This means that the blood was correctly mixed into the solution. If the solution is not pink, discard all the test materials in a biohazard waste container. Start the test over. Use a new pouch and a new blood sample.

Step 3. *Test*

- Remove the device from the pouch. DO NOT touch the flat pad.

- Check to make sure that an absorbent packet is included with the device. If no absorbent packet is present, discard the device and obtain a new pouch for testing.
- Insert the flat pad of the device all the way into the vial containing the blood sample. Make sure that the flat pad touches the bottom of the vial. The result window on the device should be facing the tester.
- Start timing the test. Record the time the specimen was collected on the "Rapid HIV Test Result Log" (*see Attachment 7*). *Look at time specimen is collected versus when test starts running.* DO NOT remove the device from the vial while test is running. Pink fluid will appear and travel up the results window. The pink fluid will gradually disappear as the test develops.
- While the test is developing, escort the client back to the counseling room and conduct prevention counseling to include an in-depth risk assessment and identification of safer behavioral goals and action step(s). If the test is running in the same room where counseling is taking place, the client must not be able to watch the test developing. A folded poster board or similar barrier can be used as a screen to separate the test from the client.
- Read the test results after 20 minutes, but no more than 40 minutes, in a fully lighted area. A flashlight may be used to read test results; however, the flashlight must not be used behind the paddle to read test results.

Reading Test Results

Look at the Result Window of the Test Device

Non-reactive: The test is non-reactive if a reddish-purple line appears next to the triangle labeled "C" and no line appears next to the triangle labeled "T."

Reactive: The test is reactive if a reddish-purple line appears next to the triangle labeled "C" and a reddish purple line appears next to the triangle labeled "T." One of these lines should be darker than the other. *NOTE: The test is reactive if any reddish-purple line appears next to the "T" triangle and next to the "C" triangle, no matter how faint these lines are.*

Invalid: Test is invalid if:

- No reddish-purple line appears next to the triangle labeled "C," or
- A red background in the results window makes it difficult to read the result after 20 minutes, or
- Any of the lines are NOT inside the "C" or "T" triangle areas.

Interpretation of Test Results

- A non-reactive test result means that HIV-1 and HIV-2 antibodies were not detected in the specimen. The test result is interpreted as negative for HIV-1 and HIV-2 antibodies.
- A reactive test result means that HIV-1 or HIV-2 antibodies have been detected in the specimen. The test result is interpreted as reactive/positive for HIV-1 and/or HIV-2 antibodies.

- An invalid test result means that there was a problem running the test, related either to the specimen or to the device. An invalid test cannot be interpreted. Repeat the test with a new pouch and a new oral fluid or fingerstick.

Confirmatory Testing Procedures

The OraSure® Oral Specimen Collection Device (not the OraQuick® Rapid HIV-1/2 antibody test device) shall be used to collect oral fluid specimens from clients with a preliminary positive/ reactive result.

Follow VDH's regulations or other applicable guidelines for ordering the appropriate confirmatory test.

Follow-Up Testing For Non-reactive Confirmatory Results

1. Rule out agency error (compromised temperature, controls not performed) versus a false-positive rapid HIV test result.
2. If the WB or IFA test is non-reactive:
 - For oral fluid specimens, a repeat confirmatory test with a blood specimen should be conducted, since the oral fluid test is less sensitive than the blood test. Reference algorithm (*see Attachment 8*) and follow up with VDH contract monitor.
 - For blood specimens, the client shall be advised to return for repeat testing four weeks after the initial reactive rapid HIV test result. This may be handled on a case-by-case basis and the individual client's situation should be the deciding factor as far as a timeline for follow-up testing.

Follow-Up Testing For Indeterminate Confirmatory Results

If the WB or IFA is indeterminate:

- If the confirmatory test was conducted with blood, the client shall be advised to return for repeat testing four weeks after the initial reactive rapid test result. However, this can be handled on a case-by-case basis by the agency. If the client wants additional testing right away, immediate retesting should be made available.
- If the confirmatory test was conducted with an oral fluid specimen, the WB or IFA test shall be repeated using a blood specimen.

HIV Prevention Counseling

Fundamentals of HIV prevention counseling with rapid HIV tests include:

- Keep the session focused on HIV risk reduction.
- Include an in-depth, personalized risk assessment and provide support for positive steps already made/attempted.
- Clarify critical, rather than general, misconceptions about HIV risk.
- Negotiate a concrete, achievable behavior-change step that will reduce risk of acquiring or transmitting HIV. Make sure the behavior is one the client is interested/motivated to try.
- Seek flexibility in the counseling technique and process, avoiding a “one-size-fits-all” approach.

Pre-Test Counseling

- Provide information about the HIV test, its benefits and its consequences. This can be done with face-to-face communication, videos, brochures, or pamphlets.
- Assess client readiness to test and receive results on the same day.
- Inform the client that confirmatory testing is needed if the rapid test result is reactive.
- Obtain permission.
- Conduct test.

Post-Test Counseling

- Provide test result early in the session.
- Explain the meaning of the test result in explicit, understandable language.
- Offer referrals as needed.

Testers shall not offer to show the test results to clients. However, if clients request to see their test results, allow them to do so, but make sure to keep them focused on risk reduction. It can be easy for clients to become focused on reading the device and the faintness of lines, etc. Showing clients the actual test can divert attention away from risk and risk reduction, both of which are important parts of the session. This can be detrimental to the client.

Non-reactive Rapid HIV Test Results

During the initial visit, the provider can definitively tell a client whose rapid HIV test result is non-reactive that he or she is not infected, unless the client has had a recent (within three months) known or possible exposure to HIV. Retesting should be recommended for those clients with recent risks, as sufficient time needs to elapse before antibodies develop that can be detected by the test. Explore risks and steps clients can take to avoid infection in the future.

Reactive Rapid HIV Test Results

Providing reactive results to clients without the benefit of a same-day confirmatory test can be a challenge. For all clients with a reactive rapid HIV test result, however, it is essential to:

- Explain the meaning of the reactive test result in simple terms, avoiding technical jargon.
- Emphasize the importance of confirmatory testing and schedule a return visit for the confirmatory test results.
- Explore how the client will cope while waiting for confirmatory testing results (e.g., whom might the client confide in for support?)
- Underscore the importance of taking precautions to avoid the possibility of transmitting infection to others while awaiting results of confirmatory testing.

Discuss where to obtain further services and/or information.

- Assess client's need for medical, prevention, and support services.
- Assess client's willingness to accept referral.
- Set an appointment and give the client the date, place, time, and contact person at the referred agency.
- Document the referral.
- Follow up with referred agency or client to see if referral was completed.

Discuss ways HIV is transmitted and how transmission can be prevented.

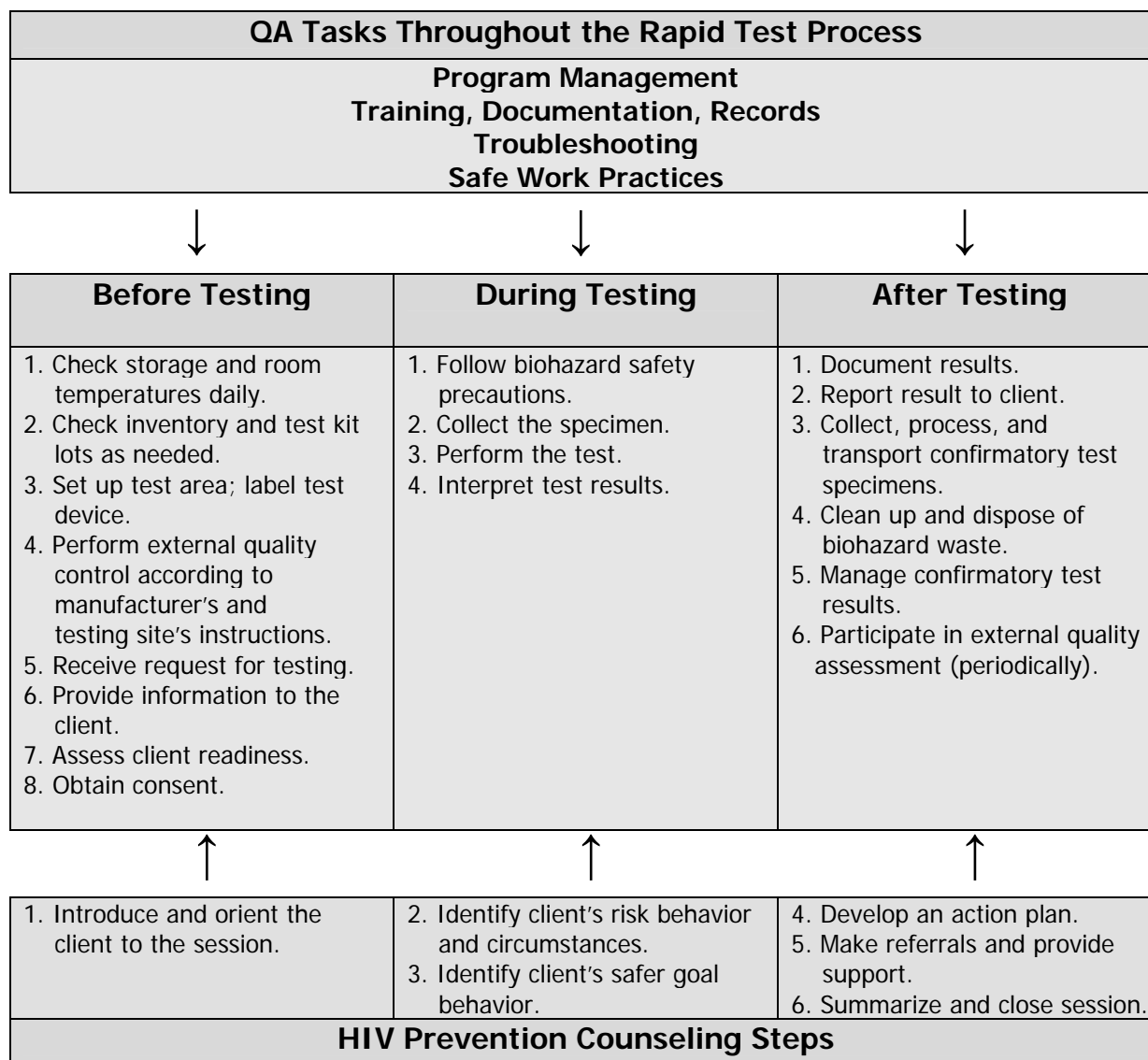
At the visit when the rapid testing is conducted, if the counselor thinks that the client's risks warrant additional prevention counseling after negotiating and discussing a risk-reduction step, the counselor can schedule a second appointment with the client for this purpose or refer them into an intervention at the agency or another location.

Ensuring Confidentiality

To ensure confidentiality, all completed forms, lab slips, and other supplies or logs with client names or identifiers shall be placed in a locked file when not in use. Agencies shall follow the "three doors" rule: all forms, lab slips, and any other supplies or logs with client names or identifiers shall be locked behind three doors, such as in a locked cabinet (one door), in a locked office (two doors), and in the locked building (three doors). The same procedures need to be followed when in the field. A locking file box shall be available for use by outreach testing staff. The box shall be returned to the agency at the end of the day. Confidential forms shall never be left in staff's personal car. (<http://www.pssl.com/!hPJ7bBShkYs5jTCQpqXmQA!/Vaultz-VZ01100-Locking-Media-Binder-Holds-128>)

Quality Assurance Section

Integrating HIV Prevention Counseling and Quality Assurance (QA) into the Rapid HIV Testing Process



Documentation for review shall, at a minimum, include:

- Information recorded on the laboratory slip (e.g., test kit expiration date, time and temperature of test kit operation, etc.);
- External Kit Control Log information;
- Test kit and control unit storage temperature logs;
- Training documentation; and
- Testing log

If questions or issues concerning the adequacy of QA procedures result from the review, the Counseling and Testing Coordinator shall initiate immediate corrective action.

If there are any issues that call into question the accurate functioning of the rapid HIV test kits, rapid HIV testing shall be suspended until the accurate functioning of test kits is verified by external control processes.

An annual review shall be conducted to monitor personnel qualifications, including continuing education requirements, competency assessments, and qualifications of new personnel. Documentation of training shall be kept in employee personnel files and shall be made available to contract monitors during site visits.

Troubleshooting and Problem Solving Procedures

A troubleshooting log for documenting problems or unusual occurrences can be invaluable for detecting patterns, for after-the-fact investigations when something fails, and as a basis for discussions regarding methods to improve the process. Significant problems shall be immediately reported to the appropriate supervisory personnel. Problems and unusual events shall be documented in the troubleshooting log that contains fields for describing the problem and actions taken to resolve the problem (*see Attachment 5*).

At a minimum, testing personnel shall be aware of troubleshooting procedures and events that require the notification of supervisory personnel, including all of the events listed in the troubleshooting table below. Additionally, testing personnel shall be specifically trained regarding:

1. What to do and to whom to report when QA requirements need corrective action (e.g., temperatures are out of range, thermometer/clock is missing, etc.).
2. When to discontinue testing (e.g., external controls fail, two invalid tests in a row, external controls not available on site, etc.).
3. How to document problems and actions taken (e.g., a troubleshooting log book to document problems and actions to resolve problems, including guidance regarding what is appropriate to enter in the log book, such as any invalid test results, any out of range temperatures, temperatures not checked at the right time, unusual client reactions, etc.).

Problem and Action Chart

Problem	Action
Control testing fails to yield accurate results.	Retest with a new control unit to determine whether failure was a result of test kits or units. (Do not test client specimens until proper functioning of the test kits has been verified.)
Second attempt at control testing fails with new control unit.	Do not test client specimens until problem is resolved. Notify supervisor, QA, and manufacturer. Consult troubleshooting log to identify possible reason for failure. Begin preparations to notify clients, who tested since last successful external control test, that previous HIV test result may not be reliable.

Invalid test result occurs while testing a client control unit.	Offer the client the option of retesting with a rapid HIV test or with a standard lab-based test.
Two invalid test results occur in a row while testing client specimen kits. If control fails, see above.	Offer clients standard testing. Do not test further client specimens until problem is resolved. Run controls to determine if invalid results are due to client sample or rapid HIV test kits.
Test kit storage area temperature exceeds recommended range.	Run external controls to verify that kits continue to function properly.

Competency Assessment

Before a trainee is permitted to perform testing alone for the first time, his or her ability to conduct the test shall be demonstrated and documented by a colleague designated by the agency as competent in testing procedures. A supervisor's signature on the training form is required. All forms shall be retained in trainee's personnel file and available on site for review.

- This assessment shall also be carried out at periodic intervals after training, such as every six months or other interval as determined by the testing site. This assessment can be carried out in many ways, but regardless of the method, every task for which a staff member is responsible shall be evaluated.
- A supervisor or trainer shall perform the assessment, using a combination of methods to determine competency. Examples of these methods are presented below.

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

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

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

- Observe how the test is performed on a client. Explain to the client that the tester is being observed by another tester in the agency for quality review. In the event that the client declines, have the staff observed through role play.
- Observe the staff member performing the finger-stick, collecting the blood on a test loop and placing it into the testing vial or assess their instructions to the client on collecting the oral specimen.
- Evaluate the use of universal or standard precautions and procedures for biohazard and sharps (e.g., lancets, needles) waste disposal.
- Review results obtained on a panel of referenced specimens that show a range of results, such as five specimens that include non-reactive, weakly reactive, and reactive results. Control materials supplied by the manufacturer shall be used as a source of specimens in the panel

- Appraise the individual's ability to interpret results. This might include using previously used test devices or pictures of devices that show non-reactive, weakly reactive, reactive, and invalid results.

To assess task performance after testing:

- Review test records and quality control results documentation.
- Observe conveying of results to client (if trainee's responsibility).
- Observe venous blood and/or oral-fluid specimen collection and handling for confirmatory testing. If the frequency of rapid HIV test reactive results is low, the trainee shall be observed collecting blood and/or oral fluid from a staff volunteer and demonstrate how it is processed for confirmatory testing.
- Verify that confidentiality is maintained.

Quality Assurance Duties and Activities

Although there are specific quality assurance duties assigned to various personnel, *every* person involved in the testing process has the responsibility to both (1) complete the QA duties assigned to them, and (2) bring any other QA issues noted to the attention of appropriate supervisory personnel.

Personnel

Agencies shall have a completed Personnel Responsibilities Form (*see Appendix*) available for review onsite during site visits.

RAPID HIV TEST EXPOSURE CONTROL PLAN

The purpose of this exposure plan is to eliminate or minimize employee occupational exposure to blood and other potentially infectious materials, and to comply with OSHA Bloodborne Pathogen Standards.

"Universal Precautions," as defined by the Centers for Disease Control and Prevention (CDC), is a set of precautions designed to prevent transmission of HIV, hepatitis B virus (HBV), hepatitis C virus (HCV), and other bloodborne pathogens, when providing first aid or health care. Under Universal Precautions, blood and certain body fluids of all patients are considered potentially infectious for HIV, HBV, HCV, and other bloodborne pathogens. Universal Precautions apply to blood and other body fluids containing visible blood, semen, and vaginal secretions. Universal Precautions do not apply to feces, nasal secretions, sputum, sweat, tears, urine, or vomit unless they contain visible blood. Universal Precautions do not apply to saliva except when visibly contaminated with blood. Universal Precautions involve the use of protective barriers such as gloves, gowns, aprons, masks, or protective eyewear that can reduce the risk of exposure of the health care worker's skin or mucous membranes to potentially infectious materials.

Gloves shall be worn:

- When touching blood, body fluids requiring Universal Precautions, mucous membranes or non-intact skin of all patients, and
- When handling items or surfaces soiled with blood or body fluids to which Universal Precautions apply. Gloves shall be changed after contact with each client. Hands

and other skin surfaces shall be washed immediately with soap if contaminated with blood or body fluids. Hands shall be washed immediately after gloves are removed.

1. Use gloves in situations where hands shall become contaminated with blood or other body fluids that require Universal Precautions.
2. Use gloves for performing fingersticks.
3. Use gloves when handling the rapid test device during testing. Masks and protective eyewear or face shields shall be worn to prevent exposure of the mucous membranes of the mouth, nose, and eyes where droplets of blood or body fluids are likely to be generated. Gowns or aprons shall be worn during procedures that are likely to generate splashes of blood or body fluids requiring Universal Precautions. General infection control practices shall further minimize the already minute risk for salivary transmission of HIV. These infection control practices include the use of gloves for contact with mucous membranes and hand washing after exposure to saliva. Hand-washing facilities shall be made available to the employees who are exposed to blood or other potentially infectious materials. OSHA requires that these hand-washing facilities be readily available after exposure. If hand-washing facilities are not feasible, Agency will provide either an antiseptic cleanser in conjunction with clean cloth/paper towels or antiseptic towelettes. If these alternatives are used, hands are to be washed with soap and running water as soon as feasible.

WORK PRACTICE CONTROLS

In work areas where fingersticks are conducted and/or rapid test device are processed, employees are not to eat, drink, apply cosmetics or lip balm, smoke, or handle contact lens. Food and beverages are not to be kept in refrigerators, freezers, shelves, cabinets, or on countertops or bench tops where blood or other potentially infectious materials shall be present.

IMPLEMENTATION OF SAFER MEDICAL DEVICES

The Needlestick Safety and Prevention Act was signed into law on November 6, 2000, in response to the advances made in technological developments that increase employee protection. Safer medical devices replace sharps with non-needle devices or incorporate safety features designed to reduce the likelihood of injury. Safer medical devices that are appropriate, commercially available, and effective shall be utilized. An effective, safer medical device is one that, based on reasonable judgment, will decrease the risk of an exposure incident involving a contaminated sharp. Since employees are more comfortable using different types of retractable lancets, they shall have input in the identification, selection, and evaluation of effective work practice and engineering controls. After initial use of the device by employees, there needs to be a continued evaluation of the devices. It will be necessary to replace the device originally selected with a more suitable device.

SAFETY PROCEDURES

All rapid HIV testing shall be conducted in a manner that will minimize splashing, spraying, splattering, and generation of droplets of blood or other potentially infectious

materials. Specimens of blood or other potentially infectious materials shall be placed in a container that prevents leakage during the collection, handling, processing, storage, and transport of the specimens. Label the container used for this purpose. Any specimens that could puncture a primary container will be placed within a secondary container that is puncture resistant. If outside contamination of the primary container occurs, the primary container shall be placed within a secondary container that prevents leakage during the handling, processing, storage, transport, or shipping of the specimen.

PERSONAL PROTECTIVE EQUIPMENT

All personal protective equipment (PPE) used at the Agency shall be provided without cost to employees. PPE will be chosen based on the anticipated exposure to blood or other potentially infectious materials. The protective equipment shall be considered appropriate only if it does not permit blood or other potentially infectious materials to pass through or reach employees' clothing, skin, eyes, mouth, or other mucous membranes under normal conditions of use and for the duration of time the protective equipment shall be used.

PERSONAL PROTECTIVE EQUIPMENT ACCESSIBILITY

Each rapid testing employee shall ensure that the appropriate PPE in the appropriate sizes is readily accessible at the worksite. Hypoallergenic gloves or other similar alternatives shall be readily accessible to those employees who are allergic to the gloves normally provided.

PERSONAL PROTECTIVE EQUIPMENT CLEANING AND DISPOSAL

All PPE shall be disinfected, replaced, or disposed of by employee. All garments that are penetrated by blood shall be removed immediately or as soon as feasible. All PPE shall be removed before leaving the work area. When PPE is removed, it shall be placed in an appropriately designated area or container for storage, decontamination, or disposal.

GLOVES

Gloves shall be worn where it is reasonably anticipated that employees will have hand contact with blood, other potentially infectious materials, non-intact skin, and mucous membranes when performing fingersticks, handling used rapid test devices, or touching contaminated items or surfaces. Contaminated gloves used at the Agency are not to be washed or decontaminated for re-use and are to be replaced as soon as practical when they become torn, punctured, or when their ability to function as a barrier is compromised.

EYE AND FACE PROTECTION

Masks, in combination with eye protection devices (such as goggles or glasses with solid side shield or chin-length face shields) shall be worn whenever splashes, spray, splatter or droplets of blood or other potentially infectious materials will be generated and eye, nose, or mouth contamination can be anticipated.

HOUSEKEEPING PROCEDURES

Each employee shall ensure that the work site is maintained in a clean and sanitary condition. All contaminated work surfaces shall be decontaminated after completion of procedures and immediately, or as soon as feasible, after any spill of blood or other potentially infectious materials, as well as at the end of the work shift. Any broken contaminated equipment shall not be picked up directly with the hands. Dustpans and hand brooms shall be available for use.

Disposal of all regulated waste shall be in accordance with applicable federal, state and local regulations, and follow a set **Agency Hazardous Materials Waste Management Plan**.

DISPOSABLE LANCETS AND REGULATED WASTE

Contaminated lancets shall be discarded immediately or as soon as feasible in containers that are capable of being sealed, puncture resistant, leak proof on sides and bottom, and labeled or color-coded. During use, containers for contaminated sharps shall be easily accessible to personnel and located as close as is feasible to the immediate area where sharps are to be used. The containers shall be maintained upright throughout use and replaced routinely and not be allowed to overfill. When moving containers of contaminated sharps from the area of use, the containers shall be closed immediately before removal during handling, storage, transport, or shipping. The container shall be placed in a secondary container if leakage of the primary container is possible. The second container shall be capable of being sealed, constructed to contain all contents, and prevent leakage during handling, storage and transport, or shipping. The second container shall be labeled to identify its contents. Reusable containers shall not be opened, emptied, or cleaned. Other regulated waste shall be placed in containers that are closable and constructed to contain all contents and prevent leakage of fluids during handling, storage, transportation or shipping. The waste shall be labeled or color-coded and closed before removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping. Each employee shall ensure biohazard labels are affixed to containers of regulated wastes, refrigerators containing blood, or other potentially infectious materials. The universal biohazard symbol shall be fluorescent orange or orange-red. Red bags or containers shall substitute for labels; however, regulated waste shall be handled in accordance with the rules and regulations of the appropriate State Health Agency.

HEPATITIS B VACCINATION AND TESTING OF IMMUNITY

Hepatitis B vaccine and vaccination series shall be made available to all Agency employees that provide community-based counseling and testing. The Agency shall ensure that the hepatitis B vaccine and vaccination series are made available at no cost to the employee. The hepatitis B vaccination will be made available: 1) after the employee has received the bloodborne pathogen training; 2) within ten working days of initial assignment; and 3) to all employees who have occupational exposure unless the employee has previously received the complete hepatitis vaccine series, and antibody testing has revealed that the employee is immune or the vaccine is contraindicated for medical reasons. If the employee initially declines hepatitis B vaccination but later decides to accept the vaccination, the vaccination shall be made available. All

employees who decline the hepatitis B vaccination shall sign the OSHA-required waiver, indicating refusal. If the U.S. Public Health Service recommends a routine booster dose of hepatitis B vaccine at a future date, such booster shall be made available.

POST-VACCINATION TESTING OF IMMUNITY

Testing for immunity against hepatitis B shall be performed two to three months after completion of the hepatitis B vaccination series.

POST-EXPOSURE EVALUATION AND FOLLOW-UP

Following the report of an exposure incident, the exposed employee shall seek medical evaluation immediately for the post-exposure evaluation. Please see the employing agency's Post-Exposure Prophylaxis (PEP) Plan manual or procedural equivalent for guidance. Documentation of the routes of exposure, circumstances under which the exposure occurred, and other information related to the exposure shall be addressed by the licensed healthcare professional who is evaluating the exposure incident.

OSHA TRAINING

All employees shall receive the OSHA bloodborne pathogen exposure training annually.

HIV Test Facts and Permission to Release Information

You have agreed to take an HIV antibody test that will show if you have HIV, the virus that causes AIDS. You are being tested confidentially, which means you must give your name and, if your test is confirmed positive, it must be reported to the health department. The health department will protect your identity and your records. Testing provided by _____ is voluntary.

People get HIV most often by having unprotected sex or sharing needles/syringes with an infected person. If you get HIV, it can take up to 12 weeks (3 months) to develop antibodies. People with a recent risk behavior should retest at six month mark..

With medical care, most people with HIV stay healthy for years. People who find out early do better than people who find out after HIV has damaged their immune systems over a long period of time. People who know they have HIV can also avoid passing the virus to others.

What Kind of Test Will Be Done?

- If you are receiving a **rapid test**, you will have an oral fluid test (not saliva), taken from swabbing the outside of the upper and lower gums between the teeth and cheek. The results of a rapid test will be ready in about 20 minutes.
- If you are receiving a **conventional test**, you will have an oral fluid test, taken from the inside of your cheek. The test will be sent to a laboratory and you will need to return to get your results in 3-4 days.

What does my Test Result Mean?

If your rapid or conventional HIV test is negative, no antibodies to HIV were found. This means that as of the day you took your HIV test, you did not have HIV; however If you recently (within last 12 weeks) had unprotected sex or shared needles/syringes, there is a chance you could still be infected and you should get re-tested in about two months. If you test negative and have not engaged in any recent risk behaviors, you are not infected with HIV. Continue to protect yourself from getting infected.

If your rapid test is reactive or preliminary positive, you will need a confirmatory, or follow up test, to determine if you have HIV. The follow up test will be a conventional oral fluid, which must be sent to a laboratory. You will need to return on another day to get your test results within 3-4 days.

If your confirmatory test is positive, this means you are infected with HIV. The test counselor will provide you with referrals for medical care, education and support services. You will also be asked to participate in partner services, which includes confidential partner notification, counseling, and risk reduction planning.

If your confirmatory test is indeterminate, it may mean that you are still in the process of developing antibodies. It is important that you retest.

By signing this form, I am indicating that I have received information about HIV testing and the procedures offered in this facility. I also understand that my records are protected by Federal and State confidentiality laws.

Client's Legal Name

Date

Rapid HIV Testing and Prevention Counseling Observation Form

Counselor: _____ Observer: _____ Date: _____

Step 1:

Introduce/orient client. *Did the counselor:*

- Introduce him/herself by name
- Explain role
- State duration of session
- Explain test options
- Explain procedures

Provide Information. *Did the counselor provide information about:*

- Test benefits
- Test results
- Importance of results
- HIV risk and transmission
- Sources of additional information

Obtain informed consent. *Did the counselor:*

- Determine if client understood the written consent
- Offer verbal consent if testing is anonymous

Assess client readiness. *Did the counselor assess the client's:*

- Readiness to receive test result the same day
- Support system
- Possible reaction to a reactive test result
- Emotional state
- Mental status

Conduct the test. *Did the counselor:*

- Explain what he/she was doing
- Appear organized
- Follow test procedures
- Complete labeling
- Document
- Use safety precautions

Step 2:

Identify current risk behaviors and circumstances (while test is processing)

Did the counselor help the client identify risk behaviors with regard to:

- Sex or needle-sharing partner(s)
- Circumstances
- Timeframes

Behaviors/patterns identified:

Step 3:

Identify safer goal behaviors that the client is willing to adopt.

Behaviors identified:

Interpret test result. *Did the counselor correctly interpret the result?*

- Yes
- No

Report test result. *Did the counselor:*

- Explain the meaning of a non-reactive test and the need for further testing based on date of last risk exposure
- Explain the meaning of a reactive screening test result and the importance of a confirmatory test
- Explain the meaning of an invalid test outcome and the need to be retested
- Assess the client's emotional reaction to the test result

Step 4:

Identify a personal action plan. *Did the counselor help identify a plan that:*

- Is realistic for the client
- Included small steps
- Included a follow-up plan

Steps identified:

Step 5:

Provide support and referrals. *Did the counselor:*

- Assess the client's referral needs
- Make any referrals
- Choose appropriate referrals
- Refer client to known/trusted sources
- Facilitate an active referral
- Document the referral(s)
- Make a follow-up plan

Referrals made:

Step 6:

Summarize and close the session. *Did the counselor:*

- Ask the client for questions or comments
- Summarize the action plan
- Summarize the referral plan
- Offer support
- Offer his/her business card or contact information

General Questions:

Did the counselor keep the session focused on HIV risk reduction?

- Yes No
-
-

Did the counselor ask open-ended questions? Yes No

Did the counselor avoid 'information overload' by clarifying only major misconceptions and giving information simply? Yes No

Did the counselor provide skills-building opportunities for the client when appropriate?

- Yes No
-
-

(Enter agency name)

CLIA# (Enter agency #)

Rapid Test Discordant Test Case Report

This form is to be completed for ALL testing situations that involve a reactive rapid HIV test result and an indeterminate or non-reactive Western Blot or IFA test result.

If the Western Blot or IFA is non-reactive or indeterminate, please REPEAT the confirmatory test(s) on a new blood specimen collected four (4) weeks after the initial confirmatory specimen was collected.

Part 1: To be completed by the testing site

Site name: _____

Person completing report: _____ State: _____

Telephone: _____

Client Demographics

Client Code: _____ Age: _____

Gender: Male Female M to F Transgender F to M Transgender Unknown

Race (check one): American Indian/Alaskan Native Asian Black or African American
 Native Hawaiian or Other Pacific Islander White Other Unknown

Ethnicity (check one): Hispanic or Latino Not Hispanic or Latino

Client ever previously tested: Yes No Client ever tested positive? Yes No

HIV Risks (check all that apply):

Heterosexual sex MSM IDU Sex with HIV-positive person Other

If female, number of births _____ Contact information obtained? Yes No

Vaccination History: Hepatitis A Yes No Unknown Dose 1 _____ Dose 2 Year _____

Hepatitis B Yes No Unknown Dose 1 _____ Dose 2 Year _____

Rapid HIV-1 Test

Specimen Type: Blood OMT

Date of Reactive Rapid Test: ____/____/____ Kit Lot#: _____

Test Start Time: ____:____ a.m./p.m. Rapid Read Time: ____:____ a.m./p.m.

Repeat Rapid Test Conducted? Yes No If yes, Test Kit Lot# _____

Test Start Time: ____:____ a.m./p.m. Rapid Red Time: ____:____ a.m./p.m.

Test Result: Reactive Non-reactive Invalid

(Enter agency name)

CLIA# (Enter agency #)

Rapid Test Invalid Test Case Report

This form is to be completed for ALL testing situations that involve an invalid rapid test result.

Part 1: To be completed by the testing site

Site name: _____ Date: _____

Person completing report: _____ Test Kit Lot#: _____

Client Code: _____ Age: _____

Client Gender: Male Female M to F Transgender F to M Transgender Unknown

Race (check one): American Indian/Alaskan Native Asian Black or African American
 Native Hawaiian or Other Pacific Islander White Other Unknown

Ethnicity (check one): Hispanic or Latino Not Hispanic or Latino

Reason rapid test was invalid (check all that apply):

- No control line appeared in the test window.
- A red background in the result window made it difficult to read result after 20 minutes (OraQuick).
- A line was outside of the control triangle area.
- A line was outside of the test triangle area.
- The test was not read within the allotted period.
- Other (specify): _____

Was a rapid test repeated on this client? Yes No

If not, what was the reason a repeat test was not performed?

- Client opted to test at another test site.
- Client refused a repeat test.
- Client left the testing site.
- Client was not ready to receive results.
- Client opted for an OraSure (Oral Mucosal Transudate) test.
- Client opted for a venipuncture blood test.
- Lab technician was unable to obtain an additional specimen.
- Do not know
- Other (specify): _____

If yes, what was the result? Reactive Non-reactive Invalid

Were external controls run immediately following the invalid rapid test?

- Yes, after the first test was invalid Yes, after the second test was invalid
- Yes, after the second test was valid No

If yes, what were the results of the control tests run?

- Both positive and non-reactive controls passed Both controls failed
- Non-reactive control failed, positive control passed Controls were not run
- Positive control failed, non-reactive control passed

External Kit Control Log for ____/____ (Month/Year)

Date	Site	Initials	QC Code	Test Kit		Control Kit			Non-reactive Control			Positive Control			Result Acceptable? **	
				Lot #	Exp. date	Lot #	Closed vial exp	Open vial exp	Start time/ temp	End time/ temp	Result (circle one)	Start time/ temp	End time/ temp	Result (circle one)	Yes	No
									: °	: °	R N I	: °	: °	R N I	Yes	No
									: °	: °	R N I	: °	: °	R N I	Yes	No
									: °	: °	R N I	: °	: °	R N I	Yes	No
									: °	: °	R N I	: °	: °	R N I	Yes	No
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									: °	: °	R N I	: °	: °	R N I	Yes	No
									: °	: °	R N I	: °	: °	R N I	Yes	No
									: °	: °	R N I	: °	: °	R N I	Yes	No
									: °	: °	R N I	: °	: °	R N I	Yes	No
Code (reason for running external controls)				Control Vial Expiration Dates					Result Codes		**Acceptable Control Results					
1. New setting 2. New operator 3. New test kit lot 4. New test kit shipment 5. Environmental change-temperature outside range in storage area 6. Environmental change-temperature outside range in test area 7. Environmental change-low lighting 8. Scheduled, periodic test 9. Other (document reason on back of form)				Closed vial expiration: expiration date printed on control unit package by manufacturer Open vial expiration: eight weeks (OraQuick) and one month (UniGold) from the date vials are opened. This date should be written on the packaging when first opened and recorded above when used. Control unit may not be used if either open or closed expiration date has passed.					R (Reactive) N (Non-reactive) I (Invalid)		Both non-reactive and reactive control units must yield correct results. If either yields an incorrect result, result of external quality control procedure is <u>unacceptable</u> in this case. DO NOT conduct client tests until problem is resolved. Document problem and corrective action taken on back of this form.					

Initial Review _____ / ____ / ____
signature date

Final Review _____ / ____ / ____
signature date

(Enter agency name)

Site: (Enter test site)

CLIA# (Enter agency #)

Rapid HIV Test Result Log

Client Identification	Room Temp.	Date Specimen Collected	Time Specimen Collected	Pouch Lot#	Pouch Expiration Date	Test Wait Time* (in minutes)	Test Result N = Non-reactive R = Reactive I = Invalid	Initials of Person who Performed Test	Report Time**	Initials of Person who Received Test and Date

* Test Wait Time = Time from starting test to reading test results (in minutes)

** Report Time = Time that test results are reported to the client

Appendix: Personnel Responsibilities

The personnel designated below are responsible for the specified QA duties listed at [Insert Site Name Here].

Personnel Responsible for QA

Responsibilities	Conducted By (Staff Person)
Develop and update site QA plan	[Insert Name Here]
Final approval of site QA plan	[Insert Name Here]
Conduct or assign QA tasks, including external control processes, test kit storage, and control unit storage	[Insert Name Here]
Provide for test kit distribution and inventory processes	[Insert Name Here]
Initial review of QA documentation	[Insert Name Here]
Final review of QA documentation	[Insert Name Here]
Oversee testing process	[Insert Name Here]
Ensure personnel are qualified for assigned duties	[Insert Name Here]
Conduct periodic competency evaluation	[Insert Name Here]

Test Kit Storage

[Describe test kit storage location (for example, cabinet 3 in room 102) and storage conditions (for example, cabinet is to be locked or room is to be locked; which personnel have key, or where is key located; where in cabinet thermometer is to be located, etc.)]

[If a primary site will store test kits for distribution to other satellite sites, describe that process here, including how frequently test kits will be distributed, who is responsible for distribution, and processes for returning test kits to primary site, if any; describe and account for this arrangement in inventory procedures, as well.]

Monitoring Test kit Inventory

[Describe process for monitoring inventory here, including who will receive deliveries, how they will be documented, how you will track/reconcile tests used with tests remaining, etc. Depending upon inventory control procedures, you shall want to break this down into several distinct responsibilities (see below).]

Receive Test Kit Delivery	
Responsibilities	[Describe actions here (e.g., receives boxes, records on inventory log with initials, writes delivery date on box, stores in cabinet, etc.)]
When	[Describe when shipment arrives.]
By Whom	[Insert name and/or position here of the person responsible for this activity.]

Corrective Action(s)	[Describe problem-solving action here – e.g., if delivery doesn't match order, if units are expired, etc. – refuse delivery? Contact supervisor? Contact manufacturer?]
----------------------	---

Next Inventory Process Item	
Responsibilities	Inventory and reconcile inventory to Rapid HIV Test Daily Log
When	Weekly
By Whom	[Insert name and/or position here of the person responsible for this activity.]
Corrective Action(s)	[Describe problem-solving action here.]

Monitoring Test Kit Storage Area Temperature

Storage area for test kits shall be equipped with an accurate thermometer. A "Test Kit Storage Temperature Log" (see Attachment 9) shall be posted on storage unit. Test kit storage area shall be continuously maintained within temperature range specified by manufacturer in the package insert.

Test Kit Temperature Monitoring	
Responsibilities	Record temperature from thermometer in test kit storage space onto temperature control log.
When	9:00 a.m., Monday through Friday
By Whom	[Insert name and/or position here of the person responsible for this activity.]
Corrective Action(s)	[Describe corrective action here (e.g., report to supervisor, adjust temperature, run controls, etc.) and specify the person responsible.]

Monitoring Control Unit Storage Area Temperature

Refrigerated storage area for control units shall be equipped with an accurate thermometer. A "Test Kit Control Storage Temperature Log" shall be posted on storage unit (see Attachment 10). Control unit storage area shall be continuously maintained within temperature range specified by manufacturer in the package insert.

Control Unit Temperature Monitoring	
Responsibilities	Record temperature from thermometer in control unit refrigerator onto temperature control log.
When	9:00 a.m., Monday through Friday
By Whom	[Insert name and/or position here of the person responsible for this activity.]
Corrective Action(s)	[Describe corrective action here and specify the person responsible.]

Running External Quality Controls

External quality controls will be run according to the manufacturer's instructions. Results will be recorded on the "External Quality Control Log" (see Attachment 6).

External Controls: New Setting/Change of Conditions	
Responsibilities	Run controls and record results on external quality control log.
When	Each new lot of testing kits, new control kits, invalid test results, temperature falls outside the allowable range for storage of test kit device or controls, discordant test results, or if room temperature is outside of allowable range. Conduct external controls every 25 rapid tests.
By Whom	[Insert name and/or position here of the person responsible for this activity.]
Corrective Action(s)	[Describe corrective action here (e.g., report to supervisor, do not begin testing, etc.)]

External Controls: New Shipment/Lot	
Responsibilities	Run controls and record results on external quality control log.
When	When shipment arrives or later, before using the new stock. If later, make sure inventory process includes a step in which arriving boxes are marked to indicate whether controls have been run.
By Whom	[Insert name and/or position here of the person responsible for this activity.]
Corrective Action(s)	[Describe corrective action here.]

External Controls: Test Storage Out of Temperature Range	
Responsibilities	Document problem, run controls, and record results on external quality control log.
When	Run external controls when maximum/minimum thermometer registers below 35 degrees or above 80 degrees. Suspend rapid HIV testing until controls are run.
By Whom	[Insert name and/or position here of the person responsible for this activity.]
Corrective Action(s)	[Describe corrective action here - e.g., if controls fail, discontinue client testing, report to supervisor, enter actions taken in troubleshooting log for each step to resolution, etc.]

External Controls: Periodic Intervals	
Responsibilities	Run controls every 25 tests based on Rapid Test Daily Log and record on external quality control log.
When	Every 25 rapid tests

By Whom	[Insert name and/or position here of the person responsible for this activity.]
Corrective Action(s)	[Describe corrective action here - e.g., if controls fail, discontinue client testing, report to supervisor, enter actions taken in troubleshooting log for each step to resolution, etc.]

External Controls: Suspected Test Kit Failure	
Responsibilities	Document problem, run controls, and record results on external quality control log.
When	Whenever two invalid tests, more than two positive results in one week, or other event that leads you to believe test kits are not working. Also, see comments in "Out of Temperature Range" chart above.
By Whom	[Insert name and/or position here of the person responsible for this activity.]
Corrective Action(s)	[Describe corrective action here - e.g., if controls fail, discontinue client testing, report to supervisor, enter actions taken in troubleshooting log for each step to resolution, etc.]

Storage

Current training documentation will remain in personnel files until separation. Other documentation, including QA documents and logs, will be stored for five years. Lab forms and patient records will be stored for 10 years.

Review of QA Documentation

Initial Review of QA Documentation	
Responsibilities	Review of all QA logs
When	Monthly
By Whom	[Insert name and/or position here of the person responsible for this activity.]
Corrective Action(s)	[Describe corrective action here (for example, follow-up with personnel responsible for documenting QA, document explanation in troubleshooting log, if necessary revise procedures, etc.)]

Final Review of QA Documentation	
Responsibilities	Review all QA logs
When	Quarterly
By Whom	[Insert name and/or position here of the person responsible for this activity.]
Corrective Action(s)	[Describe corrective action here.]

Updating QA Plan

QA plan will be updated on an annual basis to ensure compliance with new requirements, and to review and improve existing problems.

Update QA Plan	
Responsibilities	Review product package insert for changes in requirements; incorporate changes into policies and procedures; include changes to correct problems for difficulties.
When	Annually in December
By Whom	[Insert name and/or position here of person responsible for activity.]
Corrective Action(s)	[Describe corrective action here.]

Review Update QA Plan	
Responsibilities	Review updated QA plan for compliance with any changes in requirements.
When	By January 30 of each year
By Whom	[Insert name and/or position here of the person responsible for this activity.]
Corrective Action(s)	[Describe corrective action here.]

Rapid HIV Test Activities Skills Inventory	
Responsibilities	Observe Rapid HIV Test testing techniques
When	Rapid HIV testing personnel will be observed at least twice a year conducting rapid HIV test. Each rapid HIV testing personnel will conduct CDC proficiency testing at least once a year.
By Whom	[Insert name and/or position here of the person responsible for this activity.]
Corrective Action(s)	[Describe corrective action here.]

Safety

All appropriate safety measures will be observed, in compliance with the U.S. Department of Labor Occupational Safety and Health Administration (OSHA) standards for bloodborne pathogens, and Universal Precautions, as outlined by the CDC.

OSHA Bloodborne Pathogen Training	
Responsibilities	OSHA training of all staff persons on bloodborne pathogens. Each testing site is required to have an OSHA card or book.
When	By January 30 of each year
By Whom	[Insert name and/or position here of the person responsible for this activity.]
Corrective Action(s)	[Describe corrective action here.]

HIPAA Training	
Responsibilities	HIPAA training
When	By January 30 of each year
By Whom	[Insert name and/or position here of the person responsible for this activity.]
Corrective Action(s)	[Describe corrective action here.]

Biohazard Waste Management Disposal	
Responsibilities	Dispose of biohazard materials (in biohazard trash bags) at medical facility where testing or [insert name of contract agency.]
When	When biohazard container is full or as needed.
By Whom	[Insert name and/or position here of the person responsible for this activity.]
Corrective Action(s)	[Describe corrective action here.]

Exposure Control Plan at Each Testing Site	
Responsibilities	Ensure that a copy of the Exposure Control Plan is located at each testing site and that each testing counselor signs an acknowledgement that they receive a personal copy of the Exposure Control Plan.
When	Before testing begins at each site, and counselors shall receive a copy before initiating their first rapid test.
By Whom	[Insert name and/or position here of the person responsible for this activity.]
Corrective Action(s)	[Describe corrective action here.]

Hepatitis B Vaccine	
Responsibilities	All HIV testing personnel receive the hepatitis B vaccine. Employees who initially decline the hepatitis B vaccination and later decide to accept the vaccination, while still covered under the standard, shall receive the vaccination. All employees who decline the hepatitis B vaccination offered shall sign the OSHA-required waiver indicating their refusal.
When	Before testing begins at each site, and counselors shall receive a copy before initiating their first rapid test.
By Whom	[Insert name and/or position here of the person responsible for this activity.]
Corrective Action(s)	[Describe corrective action here.]