Rapid HIV Testing
Policy, Procedures, and
Quality Assurance Plan

(Insert Agency Name)
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1. Introduction

This document outlines site-specific policy, including standards, procedures, and quality assurance measures for conducting Waived Rapid HIV Testing. This document also includes quality assurance activities for (Insert Agency Name) to adhere to when conducting Waived Rapid HIV Testing and Counseling.

Quality assurance (QA) refers to planned, ongoing, step-by-step activities designed to assure that:

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

QA activities should be in place during the entire testing process, from the time a client requests a rapid HIV test until the time the results are provided.

QA guidelines contained in this document are specific to the site named, and focus primarily on Waived Rapid HIV Testing. Guidance regarding QA for other aspects of HIV counseling and testing activities is available in through your state Health Agency and the Centers for Disease Control and Prevention (CDC).

This document provides procedures for the four Federal Drug Administration (FDA) Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waived Rapid HIV Test: Clearview® COMPLETE HIV-1/2 Antibody Test, Clearview® HIV-1/2 STAT-PAK, OraQuick® ADVANCE Rapid HIV-1/2 Antibody Test and the Uni-Gold™ Recombigen® HIV Test. Waived tests are very simple and, when performed at point-of-care where the service is provided by personnel trained to follow manufacturer’s instructions, are very accurate.

The Clearview® COMPLETE HIV-1/2 is manufactured for Inverness Medical Professional Diagnostics. The assay is a single-use immunochromatographic test for the detection of antibodies to Human Immunodeficiency Virus Types 1 (HIV-1) and Type 2 (HIV-2) in fingerstick whole blood, venous whole blood, and serum or plasma specimens. Read test results between 15 and 20 minutes.

The Clearview® HIV-1/2 STAT-PAK is manufactured for Inverness Medical Professional Diagnostics. The assay is a single-use immunochromatographic test for the detection of antibodies to Human Immunodeficiency virus Type 1 (HIV-1) and Type 2 (HIV-2) in fingerstick whole blood, venous whole blood, serum or plasma specimens. Read the test results between 15 and 20 minutes.

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.

The Uni-Gold™ Recombigen® HIV test is manufactured by Trinity Biotech PLC. It detects HIV-1 antibodies in whole blood. Uni-Gold™ produces results in 10 to 12 minutes.
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### Required Policies/ Guidance

- Waived Rapid HIV Testing Policy and Quality Assurance Guidelines
  - Testing procedures
  - Quality control procedures
  - Counseling procedures
  - Storage of test
  - Transport of test
  - Recordkeeping
  - Maintenance of laboratory equipment

- Exposure Control Plan (Universal Precautions and the Occupational Safety and Health Administration (OSHA) Bloodborne Pathogens Standard)

- CLIA Certificate of Waiver (application at: [www.cms.hhs.gov/clia](http://www.cms.hhs.gov/clia))


- Agency Confidentiality Policy

- Copy of State Law for Partner Notification

- Copy of Disease Reporting Protocols/List of Reportable Conditions

### Required Forms/ Electronic System

- Agency Memoranda of Agreement with (Insert State Health Agency)

- Agency Memoranda of Agreement with testing locations/sites

- Testing and Counseling Data Collection System

- Authorization to Release Information Form

- Rapid HIV Testing Informed Consent Form

- Staff/Volunteer Confidentiality Statement

- Agency liability insurance to conduct rapid HIV testing

- Contract with management and disposal company for biohazardous waste

- Rapid Test Client Result Form

- Rapid Test Kit Storage Temperature Log

- Control Kit Storage Temperature Log

- Rapid HIV Test Results Log

- External Kit Control Documentation Log

- Rapid HIV Test Discordant Test Report

- Rapid HIV Test Invalid Test Case Report

- Rapid HIV Test Problem Documentation Form

- Specimen Transfer Log

- Rapid HIV Test Kit and Control Inventory Log

- Staff Observation Checklist

- Rapid HIV Testing and Prevention Counseling Observation Form
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2. Waived Rapid HIV Testing

1.1 Policy Statement

(Insert Name of Agency) will offer confidential rapid HIV testing to all clients requesting HIV testing services.

1.2 Laws

(Insert State Statue #) Confidentiality of Sexually Transmitted Disease Records
(Insert State Statue #) HIV and/or HBV Infected Healthcare Workers
(Insert State Statue #) Healthcare Workers and Occupational Exposure
(Insert State Statue #) Partner Notification
(Insert State Statue #) HIV Testing

1.3 Standards

1. Clients must be tested in a confidential manner. Clients will be tested in a place that provides privacy.

2. Staff must not provide testing to persons under age 16 unless parental consent is given. In addition, according to manufacturer, testing cannot be performed on persons under age 12. While adhering to these limitations, agencies can determine the ages at which they offer testing services.

3. Staff must attend the following trainings before conducting rapid HIV testing:

4. Occupational Safety and Health Administration (OSHA);

5. Waived Rapid HIV Testing or Rapid HIV Testing;

6. Health Insurance Portability and Accountability Act (HIPAA);

7. CDC Test Decision Counseling;

8. (Insert state) HIV/STD Law courses; and

9. Your state may have additional requirements.

10. Staff conducting rapid HIV testing must determine, on an individual basis, the sobriety and/or mental status of each client. A rapid HIV test must not be performed or results provided if the tester believes that the client cannot comprehend the meaning of the test or may be a danger to him or herself or others.

11. Persons who have identified themselves as already testing HIV-positive must not be retested with a rapid HIV test. Those already HIV-positive should be encouraged to seek a serum blood test and counseling.

12. Staff must refer all reactive rapid HIV test results to (Insert state Health Agency) or a medical provider for confirmatory Western Blot or IFA testing.

13. Staff must refer all reactive rapid HIV test results for those clients not receiving a confirmatory test to Partner Counseling and Referral Services.

14. Staff must only provide testing to those clients who sign or give verbal informed consent (see attachment 2).

15. Staff must document client encounters on all necessary forms.

16. Staff must inform persons who have a reactive rapid HIV test result that the test is a screening test, and further testing must be done to confirm the result.

17. Staff must provide clients with all the HIV testing options available.

18. All testing sites must have a copy of the original CLIA certificate of waiver.

19. To release test results to others, an authorization to release information must be signed by client.

20. A Memorandum of Agreement (MOA)/Understanding (MOU) must be established with (Insert state Health Agency) prior to the start of testing. The MOA/MOU should include a referral process for confirmatory testing, and partner counseling and notification.
21. New staff must be observed the first time they conduct client testing and counseling. This observation will be documented. New staff must perform proficiency testing 6 months after performing the initial test and yearly thereafter (see attachment 13 and 14).

22. Staff must provide client with the appropriate manufacturer’s rapid HIV test subject-information pamphlet.

23. Staff must meet with supervisor and/or other staff on a regular basis for debriefing sessions.

24. All testing sites’ physical space, client flow, and time concerns must be evaluated on a periodic basis.

25. Each site will have a written Rapid HIV Test Exposure Control Plan (ECP), hold new employee training within 1 week of hire, and have annual updates by medical bloodborne pathogen experts (see attachment 1).

26. A rapid HIV test must not be used to screen blood or tissue donors.

27. Staff must provide prevention counseling to persons who will benefit from such counseling.

28. Staff must participate in proficiency testing according to Centers for Medicare & Medicaid Services (CMS)-approved proficiency testing programs.

29. Each site must have a method to detect and document problems that occur at any point in the testing process, especially those that may affect the accuracy of the test results (see attachments 4 to 10).
1.5 Quality Control Procedures

1.5.1 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.

*Clearview® COMPLETE:* A pink/purple line will appear in the CONTROL area if the test has been performed correctly and the device is working properly.

*Clearview® STAT-PAK:* A pink/purple line will appear in the CONTROL (C) area if the test has been performed correctly and the device is working properly.

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

*Uni-Gold:* A red/pink line appearing adjacent to the word “control” indicates that the test is running correctly.

1.5.2 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 your ability to properly perform the test and interpret the results.
- The positive controls will produce a reactive test result and have been manufactured to produce a faint line. The negative controls will produce a non-reactive test result.
- The test kit controls must 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 manufactory.

**Run the test kit controls under the following circumstances:**

1. With each new operator, prior to performing testing on patient specimen.
2. When opening a new test kit lot.
3. Whenever a new shipment of test kits are received.
4. If the temperature of the *Clearview® COMPLETE* test storage area falls outside of the 8 to 30°C (46 to 86°F).
5. If the temperature of the *Clearview® STAT-PAK* test storage area falls outside of the 8 to 30°C (46 to 86°F).
6. If the temperature of the *OraQuick* test kit storage area falls outside of 2–27°C (35–80°F).
7. If the temperature of the *Uni-Gold* test device and wash solution storage area falls outside of 2–27°C (35.6–80.6°F).
8. If the temperature of the *Clearview® COMPLETE* testing area falls outside of the 18 to 30°C (64 to 86°F).
9. If the temperature of the *Clearview® STAT-PAK* testing area falls outside of the 18 to 30°C (64 to 86°F).
10. If temperature of the *OraQuick* testing area falls outside of 15–37°C (59–99°F).
12. After every 25 test are conducted.
13. When setting up a new test site.
14. Whenever there is reason to suspect test kits may not be functioning properly, for example, two invalid test in a row or an excessive number of unexpected results.

1.5.3 Additional Materials Required

For Clearview® COMPLETE and Clearview® STAT-PAK

Clearview® COMPLETE and Clearview® STAT-PAK Rapid HIV-1/2 Test Control Pack: Each HIV Rapid Test Control Pack contains a Product Insert and three Vials (one HIV-1 Reactive Control, one HIV-2 Reactive Control and one Nonreactive Control) as described below:

- **HIV-1 Reactive Control**: One vial containing 0.25 mL of heat inactivated human plasma positive for antibodies to HIV-1, diluted in normal human plasma. Negative for Hepatitis B surface antigen, Hepatitis C antibody and HTLV I/II antibodies.
- **HIV-2 Reactive Control**: One vial containing 0.25 mL of heat inactivated human plasma positive for antibodies to HIV-2, diluted in normal human plasma. Negative for Hepatitis B surface antigen, Hepatitis C antibody and HTLV I/II antibodies.
- **Nonreactive Control**: One vial containing 0.25 mL of normal human plasma negative for antibodies to HIV-1 and HIV-2. Negative for Hepatitis B surface antigen, Hepatitis C antibody and HTLV I/II antibodies.

For OraQuick ADVANCE

OraQuick Rapid HIV-1/2 Antibody Test Kit Controls: Each test kit control box contains a package insert and three vials (one HIV-1 positive control, one HIV-2 positive control, and one negative control) as described below:

- **HIV-1 Positive Control**: One black-capped vial containing 0.2 ml of photochemically inactivated human plasma positive for antibodies to HIV-1, treated with beta-propiolactone and ultraviolet irradiation. The plasma is negative for Hepatitis B surface antigen and Hepatitis C antibody.
- **HIV-2 Positive Control**: One red-capped vial containing 0.2 ml of photochemically inactivated human plasma positive for antibodies to HIV-2, dilated in a defibrinated pool of normal human plasma. The plasma is negative for Hepatitis B surface antigen and Hepatitis C antibody.
- **Negative Control**: One white-capped vial containing 0.2 ml of defibrinated pool of normal human plasma negative for antibodies to HIV-1 and HIV-2. The plasma is negative for Hepatitis B surface antigen and Hepatitis C antibody.

For Uni-Gold Recombigen

- **Uni-Gold Recombigen HIV Test Kit Controls**: Each test kit control box contains a package insert and two vials (one HIV-1 positive control, and one negative control) as described below. Both the positive and negative controls contain 0.1% Sodium Azide as a preservative.

- **HIV-1 Positive Control**: One red-capped vial containing 0.5 ml of inactivated human serum or plasma positive for antibodies to HIV-1, treated with beta-propiolactone and ultraviolet irradiation. The plasma is negative for Hepatitis B surface antigen and Hepatitis C antibody.
• Negative Control: One black-capped vial containing 0.5 ml prepared from defibrinated delipised human serum negative for antibodies to HIV-1, HIV-2, Hepatitis B surface antigen, and Hepatitis C antibody.

1.6 Test Kit Control Storage

For Clearview® COMPLETE and Clearview® STAT-PAK
1. The Clearview HIV Reactive/Nonreactive Controls should be stored at 2 to 8°C (36 to 46°F).
2. Do not use beyond the indicated expiration date.
3. Open the Control Vials only when you are performing tests.
4. Recap and store the Control Vials in their original container at 2° to 8°C (36° to 46°F) after use.

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

For Uni-Gold Recombigen
2. Store in the upright position at all times to prevent leakage.
3. Ensure cap is securely fastened when controls are not in use.
4. Once opened, Uni-Gold Recombigen HIV test kit controls are stable for 1 month.
5. Record the date to discard the test kit controls (1 month after opening) on the space provided on the box. This date cannot be after the expiration date of the test kit controls printed on the box.
6. Alterations in physical appearance may indicate instability or deterioration of Uni-Gold Recombigen HIV Controls. Solutions that are visibly cloudy should be discarded in accordance with safety procedures.

1.7 Test Kit Control Procedures

• Gloves must be worn when conducting test kit control procedure. A face shield and goggles should 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 may produce unreliable results.
• Test kit controls are intended for use in undiluted form.
• Adverse shipping and storage conditions or use of expired reagents may produce erroneous results.

• For Clearview® COMPLETE

2.6.1 for Clearview® COMPLETE
1. Read the Product Insert completely before using this product.
2. Follow the instructions carefully as not doing so may result in inaccurate Test Results.
3. Open a Control Vial containing the Control Reagent.
4. From the Clearview® COMPLETE, remove Buffer Vial – separate from top of Sampler and place in Disposable Rack provided with COMPLETE HIV-1/2 Assay.
5. From one of the control vials, using a fresh pipette, collect Control from vial.
6. Transfer Control to a fresh weight boat.
7. Collect Control from weight boat using sampling tip of Device.
8. With Buffer Vial in disposable rack, firmly press the Sampler tip through foil cover.
9. Continue pushing to the bottom of the Buffer Vial until Sampler and Buffer Vial snap together tightly.
10. Start timing – wait for 15 minutes. NOTE: the Sampler/Buffer Vial should be kept upright.
11. Read the Test Result between 15 and 20 minutes. In some cases a test line may appear in less than 15 minutes however, 15 minutes are needed to report a Nonreactive Test Result. Read Test Results in a well-lit area. Do not read Test Results after 20 minutes.
12. Discard the used pipet tips, Test Device and any other test materials into a biohazard waste container.
13. Reseal the Control reagent vials and store them in their original container at 2 to 8°C (36 to 46°F).

For Clearview® HIV-1/2 STAT-PAK Assay
1. Open a Control vial containing the Control Reagent.
2. Remove the Clearview® HIV-1/2 STAT-PAK Test Device from its pouch and place it on a flat Surface. (It is not necessary to remove the desiccant from the pouch).
3. Label the Test Device with Control Reagent name or identification number.
4. Touch the 5 uL Sample Loop provided to the Control Reagent, allowing the opening of the Sample Loop to fill with the liquid. Use separate unused specimen Sample Loops for each control Reagent.
5. Holding the Sample Loop vertically, touch it to the sample pad in the center of the Sample (S) well of the Test Device to dispense ~5 uL of Control Reagent onto the sample pad.
6. Invert the Running Buffer bottle and hold it vertically (not at an angle) over the sample well. Add 3 drops (~105 uL) of Buffer slowly, dropwise, into the SAMPLE (S) well.
7. Read the Test Result between 15 and 20 minutes after the addition of the Running Buffer. In some cases a test line may appear in less than 15 minutes however, 15 minutes are needed to report a Nonreactive Test Result. Read Test Results in a well-lit area. Do not read Test Results after 20 minutes.
8. Discard the used Sample Loop, Test Device and any other test materials into a biohazard waste container.
9. Reseal the Control Reagent Vials and store them in the original container at 2 to 8°C (36 to 46°F).

INTERPRETATION OF TEST RESULTS

1. The CONTROL LINE which appears closer to the top of the test strip, indicates that 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** which appears closer 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 after starting a valid test when HIV specific antibodies are present at detectable levels in the specimen.

3. **INVALID** A pink/purple line should 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. Any of the lines appear outside of the areas to the Control or Test is an INVALID test. An INVALID test cannot be interpreted. It is recommended that the test be repeated with a new Device.

**CLEARVIEW® COMPLETE HIV 1/2 ASSAY**

**Nonreactive Control:**
The *Nonreactive Control* will produce a NONREACTIVE Test Result. One pink/purple CONTROL line should be present closer to the top of the strip for COMPLETE HIV 1/2 Assay. There should be no visible line in the Test area of the Device. This indicates a NONREACTIVE Test Result.

**HIV 1 Reactive Control:**
The *HIV 1 Reactive Control* will produce a REACTIVE Test Result and has been manufactured to produce a faint pink/purple Test line. Two pink/purple lines, one line should be present closer to the bottom of the strip (TEST area) and a second line should be present closer to the top of the strip (CONTROL area) for the COMPLETE HIV 1/2 Assay. This indicates a REACTIVE Test Result. The intensities of the TEST and CONTROL lines may vary. If any visible line appears in the TEST and CONTROL areas, the result is REACTIVE.

**HIV 2 Reactive Control:**
The *HIV 2 Reactive Control* will produce a REACTIVE Test Result and has been manufactured to produce a faint pink/purple Test line. Two pink/purple lines, one line should be present closer to the bottom of the strip (TEST area) and a second line should be present closer to the top of the strip (CONTROL area) for the COMPLETE HIV 1/2 Assay. This indicates a REACTIVE Test Result. The intensities of the TEST and CONTROL lines may vary. If any visible line appears in the TEST and CONTROL areas, the result is REACTIVE.

**NOTE:** If the Test Result for the Nonreactive Control, HIV 1 Reactive Control or HIV 2 Reactive Control is not as expected, the test should be repeated using a new Test Device and Control Specimen. If the HIV Control Reagents do not produce the expected results, contact Inverness Medical Technical Support at (800) 637-3717 if you are unable to obtain a valid Test Result upon repeat testing.

**EXPECTED RESULTS**

**CLEARVIEW® HIV 1/2 STAT-PAK™ ASSAY**

**Nonreactive Control:**
The *Nonreactive Control* will produce a NONREACTIVE Test Result. A pink/purple CONTROL (C) line should be present adjacent to the result window labeled “C” for HIV 1/2 STATPAK Assay. There should be no visible line in the Test (T) area of the Device. This indicates a NONREACTIVE Test Result.

**HIV 1 Reactive Control:**
The *HIV 1 Reactive Control* will produce a REACTIVE Test Result and has been manufactured to produce a faint pink/purple TEST (T) line. A line should be present adjacent to the result window labeled “T” for HIV 1/2 STATPAK Assay. A pink/purple CONTROL (C) line should be present adjacent to the result window labeled “C” for HIV 1/2 STATPAK Assay. This indicates a REACTIVE Test Result. The intensities of the TEST (T) and CONTROL (C) lines may vary. If any visible line appears in the TEST (T) and CONTROL (C) areas, the result is REACTIVE.

**HIV 2 Reactive Control:**
The **HIV 2 Reactive Control** will produce a REACTIVE Test Result and has been manufactured to produce a faint pink/purple TEST (T) line. A line should be present adjacent to the result window labeled “T” for HIV 1/2 STATPAK Assay. A pink/purple CONTROL (C) line should be present adjacent to the result window labeled “C” for HIV 1/2 STATPAK Assay. This indicates a REACTIVE Test Result. The intensities of the TEST (T) and CONTROL (C) lines may vary. If any visible line appears in the TEST (T) and CONTROL (C) areas, the result is REACTIVE.

**NOTE:** If the Test Result for the Nonreactive Control, HIV 1 Reactive Control or HIV 2 Reactive Control is not as expected, the test should be repeated using a new Test Device and Control Specimen. If the HIV Control Reagents do not produce the expected results, contact Inverness Medical Technical Support at (800) 637-3717 if you are unable to obtain a valid Test Result upon repeat testing.

### 1.7.2 For OraQuick ADVANCE

1. Set up your workspace.
2. Open 3 OraQuick test kits and place the 3 developer solutions vials in the reusable test stand. Label each pouch, developer solutions vial, and test device as HIV-1, HIV-2, and Non-reactive, respectively.
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 correspondent control reagent, (for example, 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 devise, 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. Leave the test device in the developer solution vial and start the timer. Do not remove the test device from the vial until you have read the results. Read the results after 20 minutes, but no more than 40 minutes, in a fully lighted area. Recommend reading results at 25 minutes.
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 2–8°C (35–46°F).

**Expected Results**

**Negative Control:** The negative control will produce a non-reactive test result. A line should be present in the result window in the area adjacent to only 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 should be present in the result window in the area adjacent to the triangle labeled “C” and a line should 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 should be present in the result window in the area adjacent to the triangle labeled “C” and a line should 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 the test result for either the negative control, the HIV-1 positive control, or the HIV-2 positive control is not expected, the test should 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 contact OraSure Technologies Customer Service at 800-672-7873.

### 1.7.3 For Uni-Gold Recombigen

1. Read the package insert prior to using Uni-Gold Recombigen HIV Test Kit Controls.
2. Remove from storage at 2–8°C (35.6–46.4°F) and allow the controls to reach room temperature prior to use. Return controls to storage at 2–8°C (35.6–46.4°F) after use.
3. Mix contents of vials by inversion or gentle swirling.
4. Refer to test kit procedure section of the Uni-Gold Recombigen HIV pack inserts.
5. Treat Uni-Gold Recombigen HIV positive and negative controls as patient specimens.

**Expected Results**

Uni-Gold Recombigen HIV test kit controls do not have assigned values. Results should be determined in the same manner as used for unknown specimens when testing with the Uni-Gold Recombigen HIV test. Each laboratory should determine its own range of acceptable values.

**Reactive Test Result:** A line of any intensity appears in the device window adjacent to word "Test" and a second line of any intensity appears adjacent to word "Control." This indicates a reactive result that is interpreted as preliminary positive for HIV-1 antibodies.

**Non-Reactive Test Result:** A line of any intensity appears in the device window adjacent to word "Control," but no line appears in the device window adjacent to word "Test." This indicates a non-reactive result that is interpreted as negative for HIV-1 antibodies.

**Invalid Result:** No line appears in the device window adjacent to word "Control," whether or not a line appears in the device window adjacent to word "Test." This is an invalid result that cannot be interpreted. The test should be repeated in duplicate with fresh devices.

*NOTE:* If the test result for either the negative control or positive control is not expected, the test should be repeated using a new test device and control specimen. If the test result for any of the controls is not as expected upon repeat testing, discontinue testing and contact Trinity Biotech PLC Customer Service at 1-800-325-3424.

### Rapid HIV Testing Procedures

#### 2.7.1 for Clearview® Complete HIV ½

#### 2.7.1.1 Material Requirement
MATERIALS PROVIDED
Each Kit contains the components to perform 25 tests:
1 Product Insert for the COMPLETE HIV 1/2 assay
25 Copies of Subject Information Notice
25 Disposable Test Stands
25 Pouches, each containing:
• Sampler with a Test Strip inside
• Buffer Vial attached to the Sampler (~350 μL)
• Sterile Safety Lancet
• Bandage
• Desiccant Packet

MATERIALS REQUIRED BUT NOT PROVIDED
• Clock, watch, or other timing device
• Blood specimens
• Disposable gloves
• Sterile gauze
• Antiseptic wipes
• Biohazard disposal container

2.7.1.2 COLLECTION AND TESTING

SPECIMEN COLLECTION
Prior to specimen collection, provide test subjects with Subject Information Notice and pretest counseling according to CDC Guidelines for Rapid HIV Testing.

Fingerstick Whole Blood:
• Prepare to perform the fingerstick blood collection procedure.
• Clean the finger of the person being tested with an antiseptic wipe.
• Allow the finger to dry thoroughly or wipe dry with a sterile gauze pad.
• Using a sterile lancet, puncture the skin just off the center of the finger and wipe away the first drop with sterile gauze and avoid squeezing the fingertip to accelerate bleeding as this may dilute the blood with excess tissue fluid.
• Collect the sample from the second drop touching the Sampler tip of the device to the drop of blood until the Sampler tip is full.
• Test immediately, following Test Procedure Instructions.

All components for the Clearview COMPLETE HIV 1/2 assay are ready to use as supplied. Follow directions as indicated.

SPECIMEN TESTING
1. Open Pouch, Remove and Identify Components
   Identify Test Device, Buffer Cap and Test Stand
   *Note: If Desiccant Packet is missing or if absorbent pad (at top of Sampler) is missing or if sample filter (at bottom of Sampler) is missing, DO NOT USE. Discard device and use a new device.*
2. Write Patient ID on Stand
3. Separate Buffer Cap from Test Device
4. On a firm surface, drop the Buffer Cap in the Test Stand.
5. For fingerstick whole blood, touch blood drop with Sampler tip until the tip is full
6. Start the Test
   • With Buffer Cap in Stand, firmly press the Device tip through foil cover.
   • Push hard until Device is fully seated in the Buffer Cap.
     It will “snap” 3 times when properly seated.
• Snap 1: through foil
• Snap 2: into cap
• Snap 3: fully seated

7. Confirm Device is Fully Seated
   • The blue line directly above the arrows must line up with the clear line in the Stand
   • You will see pink/purple Buffer solution begin to flow upward
   • If You do not see Pink/Purple flow within 3 minutes, push again!
     (then start timer).

8. Start Timing – Wait for 15 Minutes
   NOTE: the Sampler/ Buffer Vial should be kept upright in the Test Stand.

2.7.1.3 READ TEST RESULTS
Read the test between 15 and 20 minutes.
NOTE: Reactive Test Results may be observed and read earlier than 15 minutes. To verify a Nonreactive
Test Result, wait the entire 15 minutes after starting the test.
Do not read results after 20 minutes.

2.7.1.4 INTERPRETATION OF TEST RESULTS
When the Clearview COMPLETE HIV 1/2 assay is properly performed, the appropriate pink/purple
lines will become visible. These are:

1. The CONTROL LINE - which appears closer to the top of the test strip, indicates that 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 - which appears closer 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 after starting a valid test when HIV specific antibodies are present at detectable
   levels in the specimen.

NONREACTIVE:
One pink/purple line in the CONTROL area, with no line in the TEST area indicates a NONREACTIVE
Test Result. A NONREACTIVE 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.
However, this does not exclude possible infection with HIV. Follow CDC guidelines to inform the
test subject of the Test Result and its interpretation.

REACTIVE:
Two pink/purple lines, one in the TEST area and one in the CONTROL area indicate a REACTIVE Test
Result. The line in the TEST area may look different from the line in the CONTROL area. Intensities
of the Test and Control Lines may vary. Test Result with visible lines in both TEST and CONTROL
areas, regardless of intensity, is considered REACTIVE. A REACTIVE Test Result means that HIV-1
and/or HIV-2 antibodies have been detected in the specimen. The Test Result is interpreted as
Preliminary POSITIVE for HIV-1 and/or HIV-2 antibodies. Follow CDC guidelines to inform the test
subject of the Test Result and its interpretation.

INVALID:
A pink/purple line should 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. Any line that appears outside of the Control Area or Test Area
is an INVALID test. An INVALID test cannot be interpreted. It is recommended that
the INVALID test be repeated with a new device.

INVALID
One pink/purple line in the CONTROL area, with Test line outside the TEST area, then test is INVALID. It is recommended that the INVALID test be repeated with a new device.

2.7.2 For Clearview HIV ½ STAT-PAK

2.7.2.1 MATERIALS PROVIDED
Each Kit contains the components to perform 20 tests:
20 STAT-PAK® Individually Pouched Test Devices
20 Copies of Subject Information Notice
20 Disposable 5μL Sample Loops
1 HIV Running Buffer (3.5mL)
1 Product Insert for the HIV 1/2 STAT-PAK® Assay

MATERIALS REQUIRED BUT NOT PROVIDED
• Clock, watch, or other timing device
• Disposable gloves
• Sterile gauze
• Antiseptic wipes
• Biohazard disposal container
• Sterile Safety Lancet

2.7.2.2 COLLECTION AND TESTING

SPECIMEN COLLECTION
● Prior to specimen collection, provide test subjects with Subject Information Notice and pre-test counseling according to CDC Guidelines for Rapid HIV Testing.
● Fingerstick Whole Blood: Prepare to perform the fingerstick blood collection procedure.
● Clean the finger of the person being tested with an antiseptic wipe.
● Allow the finger to dry thoroughly or wipe dry with a sterile gauze pad.
● Using a sterile lancet, puncture the skin just off the center of the finger and wipe away the first drop with sterile gauze and avoid squeezing the fingertip to accelerate bleeding as this may dilute the blood with excess tissue fluid.
● Collect the sample from the second drop touching the disposable Sample Loop provided to the drop of blood until the Sample Loop is full.
● Test immediately, following Test Procedure Instructions.

SPECIMEN TEST
Kit Component Preparation: All components for the Clearview HIV 1/2 STAT-PAK assay test are ready to use as supplied. Follow directions as indicated.
1. Remove the Clearview HIV-1/2 STAT-PAK test device from its pouch and place it on a flat surface. (It is not necessary to remove the desiccant from the pouch). Note: If Desiccant Packet is missing, DO NOT USE, discard test device and a new test device should be used.
2. Label the test device with patient name or ID number.
3. Touch the 5μL sample loop provided to the specimen, allowing the opening of the loop to fill with the liquid.
4. Holding the sample loop vertically, touch it to the sample pad in the center of the SAMPLE (S) well of the device to dispense ~5μL of sample (serum, plasma or whole blood) onto the sample pad.
5. Invert the Running Buffer bottle and hold it vertically (not at an angle) over the sample well. Add 3 drops (~105μL) of buffer slowly, dropwise, into the SAMPLE (S) well.
6. Read the Test Result between 15 and 20 minutes after the addition of the Running Buffer. Reactive Test Results (See Interpretation of Test Results section) may be observed and read earlier than 15 minutes. To verify a Nonreactive Test Result, wait the entire 15 minutes after starting the test. Do not read results after 20 minutes.

NOTE: Discard the used Sample Loop, Test Device and any other test materials into a biohazard waste container

**INTERPRETATION OF TEST RESULTS**

**REACTIVE**
One pink/purple line in the CONTROL (C) area, with no line in the TEST (T) area indicates a NONREACTIVE Test Result. A NONREACTIVE 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. However, this does not exclude possible infection with HIV. Follow CDC guidelines to inform the test subject of the Test Result and its interpretation.

**REACTIVE**
Two pink/purple lines, one in the TEST (T) area and one in the CONTROL (C) area indicate a REACTIVE Test Result. The line in the TEST (T) area may look different from the line in the CONTROL (C) area. Intensities of the Test and Control Lines may vary. Test Result with visible lines in both TEST (T) and CONTROL (C) areas, regardless of intensity, is considered REACTIVE. A Reactive Test Result means that HIV-1 and/or HIV-2 antibodies have been detected in the specimen. The Test Result is interpreted as Preliminary POSITIVE for HIV-1 and/or HIV-2 antibodies. Follow CDC guidelines to inform the test subject of the Test Result and its interpretation.

**INVALID**
A pink/purple line should always appear in the CONTROL (C) area, whether or not a line appears in the TEST (T) area. If there is no distinct pink/purple line visible in the CONTROL (C) area, then the test is INVALID. Any line that appears outside of the Control (C) Area or Test (T) Area is an INVALID test. An INVALID test cannot be interpreted. It is recommended that the INVALID test be repeated with a new device.

**1.7.3 For OraQuick ADVANCE**

**1.7.3.1 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

1.7.3.2 General Test Preparation

• Bring client to lab and have them sit in a chair at the workspace.
• Record client identification, room temperature, date specimen collected, divided pouch lot#, and divided pouch expiration date on the “Log of OraQuick Rapid HIV test results sheet.”
• 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 clients identification code on rear of test device. DO NOT cover the two holes in the back of the device with labels or other materials. Doing so may cause invalid results.
• Remove the developer solution vial from the pouch.
• Write clients 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 your workspace cover.
• Slide the vial into the top of one of the slots in the stand.
• DO NOT force the vial into the stand from the front of the slot as splashing may occur.
• Make sure the vial is pushed all the way to the bottom of the slot in the stand.

1.7.3.3 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 their teeth against their 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 their mouth, or the inside of their cheek or tongue. NOTE: Both sides of the flat pad may be used during this procedure.

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.
• The result window on the device should be facing towards you.
• Start timing the test. Record on the “Log of OraQuick Rapid HIV Test Results Sheet,” the time specimen collected. **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, bring the client back to counseling room and conduct prevention counseling to include in-depth risk assessment and identification of safer goal behavior.
• 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. Flashlight must not be used behind the paddle to read test results. **Recommend reading results at 25 minutes.**
• Refer to the Reading Test Results and Interpretation of Test Results section.

1.7.3.4  **Fingerstick-Whole Blood Specimen Collection and Testing**

**Step 1. Collect**

- Using an antiseptic wipe, clean the finger of the client. 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. Avoid squeezing the finger to make it bleed.
- 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 towards you.
- Start timing the test. Record the time the specimen was collected on the “Log of OraQuick Rapid HIV Test Results Form.” **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, bring the client back to counseling room and conduct prevention counseling to include in-depth risk assessment and the identification of safer goal behavior.
• 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. The flashlight must not be used behind the paddle to read test results. Recommend reading results at 25 minutes.
• Refer to the Reading Test Results and Interpretation of Test Results section.

1.7.3.5 Reading Test Results

Look at the Result Window of the Test Device

Non-reactive: 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: 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 may 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
  • If any of the lines are NOT inside the “C” or “T” triangle areas.

1.7.3.6 Interpretation of Test Results

• A non-reactive test results 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, either related to the specimen or to the device. An invalid result cannot be interpreted. Repeat the test with a new pouch and a new oral fluid or fingerstick.

1.7.4 For Uni-Gold Recombigen

1.7.4.1 Material Requirements

• Materials provided in the master shipping carton:
  – Test device (including an absorbent packet)
  – Wash solution vial (containing 5.0 ml)
  – Disposable pipettes (for use with venipuncture blood and controls)
  – Disposable fingerstick sample collection and transfer pipettes
  – Subject information leaflets
  – Package insert
• Other materials required:
  – HIV test kit control
  – Timer or stopwatch
- Test site with adequate lighting
- 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

1.7.4.2 General Test Preparation

- Bring client to lab and have them sit in chair at workspace.
- Record client identification, room temperature, date specimen collected, and lot# and expiration date on the “Log test results sheet.”
- Ensure that the subject information leaflet has been given to the client.
- Allow the kit (unopened devices and wash solution) to reach room temperature (15–27°C / 59.0–80.6°F), if previously stored in the refrigerator. This will take at least 20 minutes.
- Once at room temperature, remove the required number of test devices from their pouches.
- Check test kit expiration date. **DO NOT USE PAST EXPIRATION DATE.**
- Lay the device on a clean flat surface.
- Label the device with the appropriate client identification information.
- Use a worksite with adequate lighting.

1.7.4.3 Fingerstick-Whole Blood Specimen Collection and Testing

Step 1. Collect

- Using an antiseptic wipe, clean the finger of the client. Allow the finger to dry thoroughly or wipe dry with a sterile gauze pad.
- Using a sterile lancet, capable of producing a 50μl blood let, puncture the skin just off the center of the finger pad.
- Hold the finger downward. Apply gentle pressure beside the point of the puncture. Avoid squeezing the finger to make it bleed. Wipe away the first drop of blood with a sterile gauze pad. Allow a new drop of blood to form. If blood flow is inadequate, the client’s finger may have to be gently massaged at the finger base to produce a droplet of sufficient volume. Avoid ‘milking’ the finger.
- Collect the blood into the fingerstick sample transfer pipette provided, following the procedure presented below.
- Hold the pipette bulb gently in a horizontal position to the sample to be collected. This is important, as the specimen may not be adequately drawn in the pipette if the pipette is held in a vertical position.

Step 2. Mix

- Place the tip of the pipette into the sample, taking care not to squeeze the bulb. Maintain this position until the flow of sample into the pipette has stopped. The sample should fill to the mark on the
pipette. If sample is not collected to the mark, the pipette should be safely discarded and another specimen should be collected from another finger by repeating the sample collection process.

- Squeeze the bulb until the sample is fully discharged into the sample port. Should the sample not fully discharge, cover the small opening at the mark on the pipette with gloved fingers. Then squeeze the bulb until the sample is fully discharged.
- Allow the sample to absorb into the paper in the sample port. Ensure air bubbles are not introduced into the sample port.
- Dispose of the pipette in biohazard waste.

**Step 3. Test**

- Set the timer for 10 minutes and start timing the test.
- Read test results after 10 minutes, but not more than 12 minutes, of incubation time. If the test is not read between 10-12 minutes, repeat test on new device.
- Refer to the Reading Test Results and Interpretation of Test Results section.

*Note: Handle all blood samples and materials containing blood samples as if capable of transmitting infectious agents. Dispose of all test blood samples and materials used in test procedure in a biohazard waste container.*

**1.7.4.4 Reading Test Results**

*Look at the result window of the test device*

**Non-reactive**: Test is non-reactive if a line of any intensity appears in the device window adjacent to word "Control," but no line appears in the device window adjacent to word "Test." This indicates a non-reactive result that is interpreted as negative for HIV-1 antibodies.

**Reactive**: Test is reactive if a line of any intensity appears in the device window adjacent to word "Test" and a second line of any intensity appears adjacent to word "Control." This indicates a reactive result that is interpreted as preliminary positive for HIV-1 antibodies.

**Invalid**: Test is invalid if no line appears in the device window adjacent to word "Control," whether or not a line appears in the device window adjacent to word "Test.” This is an invalid result that cannot be interpreted. The test should be repeated in duplicate with fresh devices.

**1.7.4.5 Interpretation of Test Results**

- A non-reactive test results means that HIV-1 antibodies were not detected in the specimen. The test result is interpreted as negative for HIV-1 antibodies.
- A reactive test result means that HIV-1 antibodies have been detected in the specimen. The test result is interpreted as reactive/positive for HIV-1 antibodies.
- An invalid test result means that there was a problem running the test, either related to the specimen or to the device. An invalid result cannot be interpreted. Repeat the test with a new device.

**1.8 Confirmatory Testing Procedures**

*Your agency must have established procedures for referral of either test specimens, or persons being tested, for confirmatory testing when rapid HIV test results are reactive. All reactive rapid HIV test*
results must be followed up with either a Western Blot (WB), immunofluorescent assay (IFA), or viral load/Nucleic acid test for confirmation.

1. On the lab form accompanying the specimen being sent for confirmatory testing, indicate that the specimen is from a client who tested reactive with a screening rapid HIV test and specify the type of screening test used (e.g. Clearview® COMPLETE, Clearview® STAT-PAK, Uni-Gold Recombigen™ or OraQuick®).

2. Confirmatory testing can be done on blood plasma, blood serum, dried blood spots, or oral fluid specimens. Submit the type of specimen that is acceptable for the laboratory performing your confirmatory testing.

3. The OraSure® Oral Specimen Collection Device (not the OraQuick® Rapid HIV-1/2 antibody test device) can be used to collect oral fluid specimens from clients unwilling to follow-up with confirmatory testing that requires drawing blood from a vein to provide serum or plasma.

4. Follow your State’s regulations or other applicable guidelines for ordering the appropriate confirmatory test. Performing an enzyme immunoassay (EIA) screening test as the initial step in confirmatory testing may be required by your State. However, reactive rapid HIV tests should always be confirmed with WB, IFA, or viral load/Nucleic acid test, even if a State required EIA test is nonreactive.

1.9 Follow-Up Testing For Non-reactive Confirmatory Results

1. Rule out specimen mix-up versus a false-positive rapid HIV test result.
   - For blood specimens, a confirmatory test should be repeated with a new specimen to rule out specimen mix-up.

2. If the WB or IFA test is non-reactive:
   - For oral fluid specimens, a repeat confirmatory test with a blood specimen should be done, since the oral fluid test is less sensitive than the blood test.
   - For blood specimens, the client should be advised to return for repeat testing 4 weeks after the initial reactive rapid HIV test result.

1.10 Follow-Up Testing For Indeterminate Confirmatory Results

- If the WB or IFA is indeterminate:
  - For blood specimens, the person should be advised to return for repeat testing four (4) weeks after the initial reactive rapid test result.
  - For oral fluid specimens, the WB or IFA test should be repeated using a blood specimen.
7. 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.
- Acknowledge and provide support for positive steps already made.
- Clarify critical rather than general misconceptions about HIV risk.
- Negotiate a concrete, achievable behavior-change step that will reduce HIV risk.
- Seek flexibility in the counseling technique and process, avoiding a “one-size-fits-all” approach.

1.11 Pre-Test Counseling

1. Provide information about the HIV test, its benefits and its consequences. This can be done by face-to-face communication, video, brochure, or pamphlet.
2. Assess client readiness to test and receive results on the same day.
3. Inform the client that confirmatory testing is needed if the rapid test result is reactive.
4. Obtain informed consent.
5. Conduct test.

1.12 Post-Test Counseling

1. Provide test result early in the session.
2. Explain the meaning of the test results in explicit, understandable language.

Non-reactive Rapid HIV Test Results
During the initial visit, the provider can definitively tell clients whose rapid HIV test result is non-reactive that they are not infected, unless they have had a recent (within 3 months) known or possible exposure to HIV. Retesting should be recommended for these clients because sufficient time needs to elapse before antibodies develop that can be detected by the test.

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.
- Underscore the importance of taking precautions to avoid the possibility of transmitting infection to others while awaiting results of confirmatory testing.

3. Discuss where to obtain further services and/or information.
- Assess client’s 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.

4. Discuss ways HIV is transmitted and how transmission can be prevented. This can be done while test is processing.
• Clients with non-negative HIV rapid HIV test results usually have only one test-associated opportunity. They will not have an opportunity to try out their risk-reduction plan or to discuss with the counselor their attempts at carrying it out before they receive their HIV result.
• At the visit when the rapid testing is done, if the counselor thinks that the client’s risks warrant additional prevention counseling after negotiating and discussing a risk-reduction step, he or she can schedule a second appointment with the client for this purpose.

8. Correcting Errors Procedures
If you happen to accidentally enter incorrect information or enter information in the wrong blank, draw a single line through the mistake(s) and initial the line in the margin. Do not use white out or other obliterate errors.

9. Documentation Procedures
To ensure confidentiality measures, all completed forms, lab slips, and devices with client names or identifiers must be enclosed in a locked file when not in use.

10. Responsible Persons
All trained agency staff.

11. References
Centers for Medicare & Medicaid Services (CMS)
http://www.user@cms.hhs.gov

College of American Pathologists (CAP)
http://www.@cap.org

Clinical Laboratory Improvement Act (CLIA)
http://www.phppo.cdc.gov/dls/clia

Food and Drug Administration (FDA)
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm

National Committee on Clinical Laboratory Standards (NCCLS)
http://www.nccls.org

Virtual Hospital: The Clinical Laboratory, Quality Assessment
http://vh.radiology.uiowa.edu/Providers/CME/CLIA/QualityAssessment.html

CDC Website for OraQuick Rapid HIV-1 Antibody Test
http://www.cdc.gov/hiv/pubs/rt-counseling.htm


Inverness Medical Professional Diagnostics
www.invernessmedicalpd.com

OraSure Technologies, Inc.
www.orasure.com

Trinity Biotech, Inc.
www.unigoldhiv.com
12. Quality Assurance Section

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

### QA Tasks Throughout the Rapid Test Process

- **Program Management**
- **Training, Documentation, Records**
- **Troubleshooting**
- **Safe Work Practices**

### Before Testing
1. Check storage and room temperature daily.
2. Check inventory and test kit lots as needed.
3. Set up test area; label test device.
4. Perform external quality control according to manufacturer's and testing site's instructions.
5. Receive request for testing.
6. Provide information to the client.
7. Assess client readiness.
8. Obtain consent.

### During Testing
1. Follow biohazard safety precautions.
2. Collect the specimen.
3. Perform the test.
4. Interpret test results.

### After Testing
1. Document results.
2. Report result to client.
3. Collect, process, and transport confirmatory test specimens.
4. Clean up and dispose of biohazard waste.
5. Manage confirmatory test results.
6. Participate in external quality assessment (periodically).

### HIV Prevention Counseling Steps

1. Introduce and orient the client to the session.
2. Identify client's risk behavior and circumstances.
3. Identify client's safer goal behavior.
4. Develop an action plan.
5. Make referrals and provide support.
6. Summarize and close session.
1.13 Quality Assurance (QA) Documentation Procedures

- The Counseling and Testing Coordinator, in conjunction with the Laboratory Director, should determine an appropriate process for reviewing all QA documentation on at least a monthly basis.
- The Counseling and Testing Coordinator, in conjunction with the Laboratory Director, should determine an appropriate process for reviewing all QA documentation on at least a monthly basis.
- The Laboratory Director is responsible for the final review of all quality assurance documentation. (Site supervisors should monitor QA and QA documentation on an ongoing basis.)
- Documentation for review must at a minimum include:
  - Analytic process information recorded on the laboratory slip (e.g., test kit expiration date, time and temperature of test kit operation, etc.);
  - External Quality Control log information;
  - Test kit and control unit storage temperature logs; and
  - Training documentation.
- If the review results in questions or issues concerning the adequacy of QA procedures, the Laboratory Director and/or Counseling and Testing Coordinator should 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 should be suspended until the accurate functioning of test kits is verified by external control processes.
- The review process should occur during the first 2 weeks of each month for the previous month.
- An annual review should be conducted to monitor personnel qualifications, including continuing education requirements, competency assessments, and qualifications of new personnel.

1.14 Troubleshooting and Problem Solving Procedures

A troubleshooting log for documenting problems or unusual occurrences can be invaluable for detecting patterns, for after-the fact investigation when something fails, and as a basis for discussion regarding ways to improve the process. Significant problems should be immediately reported to the appropriate supervisory personnel. Problems and unusual events should be documented in a troubleshooting log that contains fields for describing the problem and actions taken to resolve the problem.

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

1. What to do and whom to report to when QA requirements need correction (for example, light bulb is out, temperatures are out of range, thermometer/clock missing, etc.)
2. When to discontinue testing (for example, external controls fail, or two invalid in a row, and external controls not available on site, etc.)
3. How to document problems and actions taken (for example, 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, forgot to check temperatures at right time, unusual client reactions, etc.)
<table>
<thead>
<tr>
<th>Problem</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control testing fails to yield accurate results</td>
<td>Retest with a new control unit to determine whether failure was a result of test kits or control units. (Do not test client specimens until proper functioning of the test kits has been verified).</td>
</tr>
<tr>
<td>Second attempt at control testing fails with new control unit.</td>
<td>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 client who tested since last successful external control test that previous HIV test result may not be reliable. If other stock/lots rapid HIV tests functioning of this stock/lot has been verified by external control testing. Otherwise offer only standard testing.</td>
</tr>
<tr>
<td>Invalid test result occurs while testing a client control unit</td>
<td>Offer the client the option of retesting with a rapid HIV test or with a standard lab-based test.</td>
</tr>
<tr>
<td>Two invalid test results occur in a row while testing client specimen kits. If controls fail, see above.</td>
<td>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.</td>
</tr>
<tr>
<td>Test kit storage area temperature exceeds recommended range.</td>
<td>Run external controls to verify test kits continue to function properly.</td>
</tr>
</tbody>
</table>

13. Skill Inventory Procedures  
(see attachments 13 and 14)

1.15 Competency Assessment

Before a trainee is permitted to perform testing alone for the first time, his or her ability to conduct the test should be demonstrated and documented.

- This assessment should also be carried out at periodic intervals after training, such as every 6 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 should be evaluated.
- A supervisor or trainer should 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 should be observed as they:

- Check and record the temperatures of the testing and storage areas.
- Set up the testing area, label the device, 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 the staff member performing the finger-stick, collecting the blood on a test loop and placing it into the testing vial.
- Observe how the test is performed on a client. If such observation will interfere with actual client-provider interactions, observe test performance on a volunteer.
- 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 may be used as a source of specimens in the panel. In addition, specimens may be obtained from laboratories performing confirmatory testing or from other commercial sources.
- 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 oral reporting of results to a test subject (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 should 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.

14. Quality Assurance Duties and Activities

Although there is 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.

1.16 Personnel

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

<table>
<thead>
<tr>
<th><strong>Responsibilities</strong></th>
<th><strong>Conducted By (Staff Person)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Develop and update site QA plan</td>
<td>[Insert Name Here]</td>
</tr>
<tr>
<td>Final approval of site QA plan</td>
<td>[Insert Name Here]</td>
</tr>
<tr>
<td>Conduct or assign QA tasks, including external control processes, test kit storage, and control unit storage</td>
<td>[Insert Name Here]</td>
</tr>
<tr>
<td>Provide for test kit distribution and inventory processes</td>
<td>[Insert Name Here]</td>
</tr>
<tr>
<td>Initial review of QA documentation</td>
<td>[Insert Name Here]</td>
</tr>
<tr>
<td>Final review of QA documentation</td>
<td>[Insert Name Here]</td>
</tr>
</tbody>
</table>
### Responsibilities

<table>
<thead>
<tr>
<th>Responsibilities</th>
<th>Conducted By (Staff Person)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oversee testing process</td>
<td>[Insert Name Here]</td>
</tr>
<tr>
<td>Ensure personnel are qualified for assigned duties</td>
<td>[Insert Name Here]</td>
</tr>
<tr>
<td>Conduct periodic competency evaluation</td>
<td>[Insert Name Here]</td>
</tr>
</tbody>
</table>

#### 1.17 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.]

#### 1.18 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 may want to break this down into several distinct responsibilities (see below).]

<table>
<thead>
<tr>
<th><strong>Receive Test Kit Delivery</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Responsibilities</td>
</tr>
<tr>
<td>When</td>
</tr>
<tr>
<td>By whom</td>
</tr>
<tr>
<td>Corrective action(s)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Next Inventory Process Item</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Responsibilities</td>
</tr>
<tr>
<td>When</td>
</tr>
<tr>
<td>By whom</td>
</tr>
<tr>
<td>Corrective action(s)</td>
</tr>
</tbody>
</table>
1.19 Monitoring Test Kit Storage Area Temperature

Storage area for test kits must be equipped with an accurate thermometer. Temperature control log must be posted on storage unit. Test kit storage area must be continuously maintained within temperature range specified by manufacturer in the package insert.

<table>
<thead>
<tr>
<th>Test Kit Temperature Monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Responsibilities</strong></td>
</tr>
<tr>
<td><strong>When</strong></td>
</tr>
<tr>
<td><strong>By whom</strong></td>
</tr>
<tr>
<td><strong>Corrective action(s)</strong></td>
</tr>
</tbody>
</table>

1.20 Monitoring Control Unit Storage Area Temperature

Refrigerated storage area for control units must be equipped with an accurate thermometer. Temperature control log must be posted on storage unit. Control unit storage area must be continuously maintained within temperature range specified by manufacturer in the package insert.

<table>
<thead>
<tr>
<th>Control Unit Temperature Monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Responsibilities</strong></td>
</tr>
<tr>
<td><strong>When</strong></td>
</tr>
<tr>
<td><strong>By whom</strong></td>
</tr>
<tr>
<td><strong>Corrective action(s)</strong></td>
</tr>
</tbody>
</table>

1.21 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.

<table>
<thead>
<tr>
<th>External Controls: New Setting/Change of Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Responsibilities</strong></td>
</tr>
</tbody>
</table>
### External Controls: New Setting/Change of Conditions

| 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 Test 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

<table>
<thead>
<tr>
<th>Responsibilities</th>
<th>Document problem, run controls, and record results on external quality control log.</th>
</tr>
</thead>
<tbody>
<tr>
<td>When</td>
<td>Whenever two invalid tests, more than 2 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.</td>
</tr>
<tr>
<td>By whom</td>
<td>[Insert name and/or position here of the person responsible for this activity.]</td>
</tr>
<tr>
<td>Corrective action(s)</td>
<td>[Describe corrective action here (for example, if controls fail, discontinue client testing, report to supervisor, and enter actions taken in troubleshooting log for each step to resolution.)]</td>
</tr>
</tbody>
</table>

---

#### 1.22 Storage

Current training documentation will remain in personnel files until separation. Other documentation, including QA documents and logs, will be stored for 5 years.

#### 1.23 Review of QA Documentation

##### Initial Review of QA Documentation

<table>
<thead>
<tr>
<th>Responsibilities</th>
<th>Review all QA logs</th>
</tr>
</thead>
<tbody>
<tr>
<td>When</td>
<td>Monthly</td>
</tr>
<tr>
<td>By whom</td>
<td>[Insert name and/or position here of the person responsible for this activity.]</td>
</tr>
<tr>
<td>Corrective action(s)</td>
<td>[Describe corrective action here (for example, follow-up with personnel responsible for documenting QA, document explanation in troubleshooting log, if necessary revise procedures, etc.)]</td>
</tr>
</tbody>
</table>

##### Final Review of QA Documentation

<table>
<thead>
<tr>
<th>Responsibilities</th>
<th>Review all QA logs.</th>
</tr>
</thead>
<tbody>
<tr>
<td>When</td>
<td>Quarterly</td>
</tr>
<tr>
<td>By whom</td>
<td>[Insert name and/or position here of the person responsible for this activity.]</td>
</tr>
<tr>
<td>Corrective action(s)</td>
<td>[Describe corrective action here.]</td>
</tr>
</tbody>
</table>
1.24  Updating QA Plan

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

### Update QA Plan

<table>
<thead>
<tr>
<th>Responsibilities</th>
<th>Review product package insert for changes in requirements; incorporate changes into policies and procedures; include changes to correct problems or difficulties.</th>
</tr>
</thead>
<tbody>
<tr>
<td>When</td>
<td>Annually in December</td>
</tr>
<tr>
<td>By whom</td>
<td>[Insert name and/or position here of the person responsible for this activity.]</td>
</tr>
<tr>
<td>Corrective action(s)</td>
<td>[Describe corrective action here.]</td>
</tr>
</tbody>
</table>

### Review Updated QA Plan

<table>
<thead>
<tr>
<th>Responsibilities</th>
<th>Review updated QA plan for compliance with any changes in requirements.</th>
</tr>
</thead>
<tbody>
<tr>
<td>When</td>
<td>By January 30 each year.</td>
</tr>
<tr>
<td>By whom</td>
<td>[Insert name and/or position here of the person responsible for this activity.]</td>
</tr>
<tr>
<td>Corrective action(s)</td>
<td>[Describe corrective action here]</td>
</tr>
</tbody>
</table>

### Rapid HIV Test Activities Skills Inventory

<table>
<thead>
<tr>
<th>Responsibilities</th>
<th>Observe Rapid HIV Test testing techniques.</th>
</tr>
</thead>
<tbody>
<tr>
<td>When</td>
<td>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.</td>
</tr>
<tr>
<td>By whom</td>
<td>[Insert name and/or position here of the person responsible for this activity.]</td>
</tr>
<tr>
<td>Corrective action(s)</td>
<td>[Describe corrective action here.]</td>
</tr>
</tbody>
</table>
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

<table>
<thead>
<tr>
<th>Responsibilities</th>
<th>OSHA training of all staff person on bloodborne pathogens. Each testing site is required to have an OSHA card or book.</th>
</tr>
</thead>
<tbody>
<tr>
<td>When</td>
<td>By January 30 each year.</td>
</tr>
<tr>
<td>By whom</td>
<td>[Insert name and/or position here of the person responsible for this activity.]</td>
</tr>
<tr>
<td>Corrective action(s)</td>
<td>[Describe corrective action here.]</td>
</tr>
</tbody>
</table>

### HIPAA Training

<table>
<thead>
<tr>
<th>Responsibilities</th>
<th>HIPAA Training</th>
</tr>
</thead>
<tbody>
<tr>
<td>When</td>
<td>By January 30 each year</td>
</tr>
<tr>
<td>By whom</td>
<td>[Insert name and/or position here of the person responsible for this activity.]</td>
</tr>
<tr>
<td>Corrective action(s)</td>
<td>[Describe corrective action here.]</td>
</tr>
</tbody>
</table>

### Biohazard Waste Management Disposal

<table>
<thead>
<tr>
<th>Responsibilities</th>
<th>Dispose of biohazard materials (biohazard trash bags) at medical facility where testing or (insert name of contract agency).</th>
</tr>
</thead>
<tbody>
<tr>
<td>When</td>
<td>When biohazard container is full or as needed.</td>
</tr>
<tr>
<td>By whom</td>
<td>[Insert name and/or position here of the person responsible for this activity.]</td>
</tr>
<tr>
<td>Corrective action(s)</td>
<td>[Describe corrective action here.]</td>
</tr>
<tr>
<td><strong>Exposure Control Plan at Each Testing Site</strong></td>
<td></td>
</tr>
<tr>
<td>-----------------------------------------------</td>
<td></td>
</tr>
<tr>
<td><strong>Responsibilities</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>When</strong></td>
<td>Before testing begins at each site, and counselors must receive a copy before initiating their first rapid test.</td>
</tr>
<tr>
<td><strong>By whom</strong></td>
<td>[Insert name and/or position here of the person responsible for this activity.]</td>
</tr>
<tr>
<td><strong>Corrective action(s)</strong></td>
<td>[Describe corrective action here.]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Hepatitis B Vaccine</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Responsibilities</strong></td>
</tr>
<tr>
<td><strong>When</strong></td>
</tr>
<tr>
<td><strong>By whom</strong></td>
</tr>
<tr>
<td><strong>Corrective action(s)</strong></td>
</tr>
</tbody>
</table>
15. List of Attachments

1. **Rapid HIV Test Exposure Control Plan (EPC):** All testing programs must have an ECP prior to conducting rapid HIV testing.

2. **Rapid HIV Test Informed Consent Form:** This form must be completed by every client before any specimen collection and must include Subject Information pamphlet. These forms are kept in clients file.

3. **Rapid HIV Test Result Form:** This form should be used to provide client a copy of their test result. The client must sign an authorization to release information.

4. **Rapid Test Kit Storage Temperature Log:** Documentation of storage room temperature must be recorded daily for rapid HIV test kits. These forms should be completed on a regular basis and kept in temperature log notebook.

5. **Test Kit Control Storage Temperature Log:** Documentation of storage area temperature must be recorded daily for control kits. Any corrective action taken because of control testing must be documented on this log. These forms should be completed on a regular basis and kept in temperature log notebook.

6. **Rapid HIV Test Result Log:** This form must be completed on each client. The completed form will be kept in a notebook. A copy of preliminary positive results form must accompany client to the health department if blood (venipuncture) HIV confirmatory test is to be performed.

7. **External Kit Control Documentation Log:** This form must be used to document the outcome of Kit Control results.

8. **Rapid Test Discordant Test Report:** All confirmatory test results that are non-reactive must be followed up with a Discordant Test Result. QA manager should be notified of all discordant test results.

9. **Rapid Test Invalid Test Case Report:** This form must be used to document all invalid test (no result is recorded after the test is processed).

10. **Rapid HIV Test Problem Documentation Form:** A troubleshooting log for documenting problems or unusual occurrences can be invaluable for detecting patterns, for after-the fact investigation when something fails, and a basis for discussion regarding ways to improve the process.

11. **Specimen Transfer Log:** This log should be used when test are sent out for confirmatory testing.

12. **Rapid HIV Test Kit and Control Inventory Log:** This log should be used to track rapid test shipments, expiration dates, used, discards, and lot#.

13. **Staff Observation Checklist:** This form should be used to assess staff rapid HIV testing performance.

14. **Rapid HIV Testing and Prevention Counseling Observation Form:** This form should be used to assess staff counseling performance.

15. **HIV Prevention Counseling and Rapid HIV Testing Flowchart:** This flowchart should be used to guide staff through the testing and counseling process.

16. **Sharps Injury Log:** This log should be used to document all punctures of skin occurring from contaminated sharps.

17. **Rapid Test Outreach Safety Protocols:** The protocols should be used when conducting outreach activities.

18. **Shock and Fainting Protocols:** The protocols should be used to handle clients that may experience shock and fainting.
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 the Occupational Safety and Health Administration (OSHA) Bloodborne Pathogen Standards.

“Universal Precautions,” as defined by the Centers for Disease Control and Prevention (CDC), are a set of precautions designed to prevent transmission of the human immunodeficiency virus (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, and vomitus 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 should be worn:
- When touching blood, body fluids requiring Universal Precautions, and 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 should be changed after contact with each client. Hands and other skin surfaces should be washed immediately with soap if contaminated with blood or body fluids. Hands should be washed immediately after gloves are removed.

1) Use gloves in situations where hands may 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 should 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 should be worn during procedures that are likely to generate splashes of blood or body fluids requiring Universal Precautions.

General infection control practices should 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 Name) will provide either an antiseptic cleaner 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 may 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 must 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 may be necessary to replace the device originally selected with a more suitable device.

**SAFETY PROCEDURES**

All rapid HIV testing will 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 will be placed in a container that prevents leakage during the collection, handling, processing, storage, and transport of the specimens. The container used for this purpose will be labeled. 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 (Agency Name) will be provided without cost to employees. Personal protective equipment will be chosen based on the anticipated exposure to blood or other potentially infectious materials. The protective equipment will be considered appropriate only if it does not permit blood or other potentially infectious materials to pass through or reach the employees clothing, skin, eyes, mouth, or other mucous membranes under normal conditions of use and for the duration of time the protective equipment will 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 will 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 will 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 (Insert Agency Name) 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) are required to be worn whenever splashes, spray, splatter or droplets of blood or other potentially infectious materials may be generated and eye, nose, or mouth contamination can be anticipated.

HOUSEKEEPING PROCEDURES
Each employee shall ensure that the worksite is maintained in a clean and sanitary condition. All contaminated work surfaces will 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 will not be picked up directly with the hands. Dustpans and hand brooms will be available for use.

Disposal of all regulated waste shall be in accordance with applicable federal, state and local regulations, and follow the (Agency Name) 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 must 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 may substitute for labels; however, regulated waste must be handled in accordance with the rules and regulations of (Insert Your State Health Agency).

HEPATITIS B VACCINATION AND TESTING OF IMMUNITY
Hepatitis B vaccine and vaccination series will be made available to all (Insert Agency Name) employees that provide Community-Based Counseling and Testing (CBC&T). (Insert Agency Name) will 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 10 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 at a later date decides to accept the vaccination, the vaccination will 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 should be performed 2 to 3 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 should seek medical evaluation immediately for the post-exposure evaluation. Please see (Agency Name) Post-Exposure Prophylaxis (PEP) Plan manual. Documentation of the routes of exposure, circumstances under which the exposure occurred, and other information related to the exposure will be addressed by the licensed healthcare professional who is evaluating the exposure incident.

OSHA TRAINING
All employees must receive the OSHA bloodborne pathogen exposure training annually.
Rapid HIV Test Informed Consent Form

I hereby give (agency name) the authority to perform the rapid HIV test (test name here) on:

(Date) ____________________________________________________________ at

(Location) _________________________________________________________

I have read the subject information brochure, or it was explained to me, and I fully understand its contents.

Name (Please Print) Last: ____________________________ First:_______________________

Date: _____________________    Signature:___________________________________

Verbal Agreement (check one): □ Yes    □ No

Street Address:__________________________________________________________

City: _____________________________    State: _______    Zip Code: ______________

Patient ID#___________________

Tester’s Name (Please Print):______________________________________________
Rapid HIV Test Result Form

Client Name: ________________________________ Date: _________________

Date of Birth: ____________  Sex:___________    Race: ___________

Testing Location: _______________________________________________

HIV Antibody Screening Test Result:

Reactive   Negative/Non- Reactive

Follow-Up Appointment (date/time/location): _____________________________

Client Signature: ________________________________

Counselor Signature: ________________________________
Rapid HIV Test Kit Storage Temperature Log

(Enter Agency Name) Site: (Enter test site) CLIA # (Enter Agency #)

Thermometer location: __________________________________________________________
Month/year: ______/_____

Acceptable temperature ranges: Clearview® COMPLETE (8 to 30°C or 46 to 86°F)
Clearview® STAT-PAK (8 to 30°C or 46 to 86°F)
OraQuick (2º to 27º C or 35° to 80° F)
Uni-Gold Kit & Wash Solution (2º to 27º C or 35° to 80° F)

<table>
<thead>
<tr>
<th>Date/Time</th>
<th>Temperature (Indicate C or F)</th>
<th>Corrective action taken when temperature is out of range</th>
<th>Storage location</th>
<th>Initials</th>
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Initial Review __________________  ____/____/_____  Final Review ___________________  ____/____/_____  
signature                  date                           signature                     date

Waived Rapid HIV Testing Policy, Procedures, and Quality Assurance Plan  Attachment 4
Test Kit Control Storage Temperature Log

(Check daily, as scheduled, or after trigger event such as power outage.)

Thermometer location: _________________________________________________________

Month/year: ______/______

Acceptable temperature range: Clearview® (36 to 46°F)
OraQuick (35 to 46° F)
Uni-Gold (35 to 46° F)

<table>
<thead>
<tr>
<th>Date/Time</th>
<th>Temperature (Indicate C or F)</th>
<th>Corrective action taken when Temperature is out of range</th>
<th>Storage location</th>
<th>Initials</th>
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Initial Review __________________   ____/____/____ Review __________________  ____/____/____

signature                         date                                   signature                     date
### Rapid HIV Test Result Log

<table>
<thead>
<tr>
<th>Client Identification</th>
<th>Room Temp</th>
<th>Date Specimen Collected</th>
<th>Time Specimen Collected</th>
<th>Pouch Lot#</th>
<th>Pouch Expiration Date</th>
<th>Test Wait Time* (in minutes)</th>
<th>Test Result</th>
<th>Initials of Person who Performed Test</th>
<th>Report Time**</th>
<th>Initials of Person who Reviewed Test and date</th>
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*Test Wait Time= Time from starting test to reading test results (in minutes)

**Report Time= Time that the test results is reported to the client
### External Kit Control Log for Month/Year

<table>
<thead>
<tr>
<th>Date</th>
<th>Site</th>
<th>Initials</th>
<th>QC code</th>
<th>Test Kit Lot #</th>
<th>Exp date</th>
<th>Control Kit Lot #</th>
<th>Closed vial exp</th>
<th>Open vial exp</th>
<th>Start time/ temp</th>
<th>End time/ temp</th>
<th>Result (circle one)</th>
<th>Start time/ temp</th>
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### Code (reason or running external controls)

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)

### Control Vial Expiration Dates

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.

### Result Codes

- R: Reactive
- N: Non-reactive
- I: Invalid

### **Acceptable Control Results**

Both non-reactive and reactive control units must yield correct results. If either yields an incorrect result, result of external quality control procedure is unacceptable. 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 ________________________ / / Final Review ______________________________ / /
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 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 number: ______________________________

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 Year___  Dose 2 Year___  Hepatitis B Yes  No  Unknown  Dose 1 Year___  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.  Test Read Time:________:_______ a.m/p.m.

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

Test Start Time:____:______ a.m./p.m.  Test Read Time:_______:_______ a.m./p.m.

Test Result:  Reactive  Non-reactive  Invalid
Rapid Test Invalid Test Case Report

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

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 result 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 no, 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
(Enter Agency Name)   Site: (Enter test site)   CLIA # (Enter Agency #)

## Rapid HIV Test Problem Documentation

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<tr>
<th>Date</th>
<th>Initials</th>
<th>Lot #</th>
<th>Expiration date</th>
<th>Problem</th>
<th>Corrective Action Taken</th>
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### Specimen Transfer Log

Referral Laboratory  

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<tr>
<th>Specimen Tracking Number</th>
<th>Test Subject ID*</th>
<th>Rapid Test Result</th>
<th>Date Specimen Collected</th>
<th>Time Specimen Collected</th>
<th>Collected by</th>
<th>Referral Lab Req Completed</th>
<th>Date Confirmed Result Received</th>
<th>Confirm Test Result</th>
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*ID = Identification  
*Lab Req = Laboratory Requisition  
*(NOTE: If you use more than one referral laboratory, add a column to record each one)*
Rapid HIV Test Kit and Control Inventory Log

For rapid test shipment received, enter the date received, lot numbers, lot number expiration date, and number of test received below.

<table>
<thead>
<tr>
<th>Date Received (mm/dd/yy)</th>
<th>Lot Number(s)</th>
<th>Expiration Dates(s) (mm/dd/yy)</th>
<th>Number Test Kits Received</th>
<th>Number of Kit Controls Received</th>
<th>Number of Wash Solutions (UniGold)</th>
</tr>
</thead>
<tbody>
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For inventory control, indicate below the number of damaged tests received, used test, or unusable tests for the shipment(s) above. Damaged test should be claimed to the shipper and expired tests should be discarded according to biohazard standards. For unusable tests, indicate the reason (i.e., stored out of range, spilled, damaged in the field, etc.)

Testing Usage Log

<table>
<thead>
<tr>
<th>Date Received mm/dd/yy</th>
<th># of Damaged Tests Received</th>
<th># of Clients Tested</th>
<th># used for Counselor Competency Testing</th>
<th># of Control Tests Used</th>
<th># of Expired Tests</th>
<th># of Unusable Tests (damaged, stored out of range, spilled, etc.)</th>
<th>Total # of Tests (should equal number of tests received)</th>
</tr>
</thead>
<tbody>
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</table>
### Staff Observation Checklist

**Instructions:** Fill in dates when the employee observes and performs each objective or procedural step, as applicable. If the employee will not be trained to perform a specific task, enter N/A for not applicable. The employee should initial/date when each step has been completed and the supervisor should initial/date when he/she agrees that the employee met the objective or performed the specific task competently. This form should remain in the employee's personnel records.

Employee Name: _____________________________________

<table>
<thead>
<tr>
<th>Objective/Procedural Step</th>
<th>Date Observed</th>
<th>Date Performed</th>
<th>Employee's Initials</th>
<th>Supervisor's Initials</th>
</tr>
</thead>
<tbody>
<tr>
<td>Read testing procedures.</td>
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<tr>
<td>Read Biohazard Exposure Control Plan.</td>
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<tr>
<td>Determined if requirements for acceptable testing environment are met (e.g., temperature, lighting, level work space).</td>
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<tr>
<td>Conducted negative and positive external controls.</td>
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<tr>
<td>Gave person getting tested the subject information brochure.</td>
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<tr>
<td>Labeled test device components and appropriate paperwork.</td>
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<tr>
<td>Collected fingerstick specimen and put specimen in appropriate test device.</td>
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<tr>
<td>Inserted test device, timed test, and read result.</td>
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<tr>
<td>Disposed of lancet and other biohazardous waste appropriately.</td>
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<tr>
<td>Recorded results on report form and log sheet.</td>
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<tr>
<td>Recorded internal and external quality control (QC) results in QC log.</td>
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<tr>
<td>Recorded results in QC log.</td>
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<tr>
<td>Reported test result to the person being tested.</td>
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<tr>
<td>Referred person or collected specimen for confirmatory testing.</td>
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<tr>
<td>Sent confirmatory test specimen to referral laboratory and documented submission.</td>
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<tr>
<td>Received referral laboratory results and recorded results.</td>
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<tr>
<td>Explained what to do if QC results show a problem.</td>
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</tbody>
</table>
(Insert Agency Name)   Site: (Insert test site)

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

Behavior(s) identified:

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

Yes
No

Report test results. 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 skill-building opportunities for the client when appropriate?*   □ Yes □ No

_____________________________________________________

_____________________________________________________
HIV Prevention Counseling and Rapid HIV Testing Flowchart

Provide information and obtain consent*
- Introduce and orient client.
- Explain the differences between rapid testing and conventional HIV testing and the meaning of the test results.
- Assess readiness for same-day test result.

Administer Test

Prevention Counseling
- Identify risk behavior and circumstances
- Identify safer goal behavior

Interpret Test Result

* Prenatal:
Explain the benefits of knowing HIV status, in order to make an informed decision regarding HAART.

Reactive Result:
1. Explain the meaning of screening test result.*
2. Emphasize result must be confirmed.
3. Emphasize the importance of precautions to avoid possible transmission of HIV.*
4. Facilitate confirmatory test.

Non-Reactive Result:
1. Explain the meaning of a non-reactive result.
2. Explain the importance of taking another HIV test based on risk behaviors and date of last exposure.

Invalid Test:
1. Follow QA guidelines.
2. Explain to client that the test must be repeated.
3. Tell client why invalid test occurred.
4. Repeat test.

Prevention Counseling
- Develop action plan
- Make referrals; provide support
- Summarize and close
OSHA’s Bloodborne Pathogens Standard requires an employer to establish and maintain a Sharps Injury Log for recording all punctures of skin occurring from contaminated sharps. The purpose of the log is to aid in the evaluation of devices being used in healthcare and other facilities and to identify devices or procedures/techniques requiring additional attention or review. This log must be kept in addition to the Injury and Illness Log required by OSHA. The Sharps Injury Log should not list the names of affected employees (to maintain confidentiality) but, at a minimum, it should contain the type and brand of device involved in the incident, the department or work area where the exposure incident occurred, and an explanation of how the incident occurred. The log should include all sharps injuries occurring in a calendar year and it must be retained for 5 years following the end of the year to which it relates.
Outreach Safety Protocols

Do:
Carry identification at all times (preferably making it visible).
Disseminate accurate information.
Stay client centered (within the limits of your role).
Know where your teammate is at all times.
Maintain eye contact with team member(s).
Maintain confidentiality.
Keep your supervisor advised of your whereabouts.
Consult your supervisor about difficult situations.
Maintain a relationship with the local police.
Know the limits of your job.
Make appropriate referrals.
Offer reasonable assistance when it is requested.
Avoid debate and escalating controversy.
Always be courteous.
Leave the area immediately if there appears to be any potential for violence.
Leave the area immediately if a member of the team feels uncomfortable.
Have a back up plan, an emergency plan and/or escape plan.
Work in teams of two or more during testing activities.
Dress in appropriate clothing.

Don't:
Participate in illegal activities.
Drink alcohol while on the job.
Argue with a teammate or a client.
Carry weapons.
Give money or gifts to clients.
Knock on doors.
Enter a private residence.
Drive clients in your car.
Distribute outreach materials to client in their cars.
Distribute materials while seated in a car.
Enter shooting galleries or crack houses to perform testing activities.
Bring media into an area without permission from a community member.
Buy or receive drugs.
Buy or receive property from a client.
Buy or receive sexual favors from a client.
Linger with anyone who is carrying drugs.
Eat/smoke while distributing outreach material or conducting testing activities.
Wear jewelry/clothes/makeup that is inappropriate.
Shock and Fainting Protocols

Handling Shock During Rapid Testing:

a. Causes: Heart attack, severe or sudden blood loss, exposure to extreme heat or cold, severe allergic reaction, very low blood sugar (diabetes), and excessive alcohol consumption.

b. Symptoms: Weakness; trembling; restlessness; confusion; pale or blue-colored lips, skin, or fingernails; cool, moist skin; weak, fast pulse; rapid, shallow breathing; nausea and vomiting; enlarged pupils; extreme thirst; and loss of consciousness.

   1. If client is not breathing, get emergency care, and perform CPR.
   2. If client is unconscious, conduct first aid until emergency care arrives.
   3. Lay the person down face-up.
   4. Elevate the feet about 1 foot with a box or rolled blanket. This causes blood to flow from the legs to the head and vital organs in the body. (Do not raise feet or lower the head if you suspect the person has a head, neck, back or leg injury.)
   5. Loosen tight clothing; cover the person with a coat or blanket to prevent heat loss.
   6. Monitor breathing and pulse frequently.
   7. Do not give the client any food or liquids. If the client asks for water, moisten their lips, but do not allow them to drink any fluids.
   8. Reassure the person. Make him or her as comfortable as you can.
   9. If the client vomits, roll him or her on the side so the vomit does not back up into their windpipe and lungs.

Handling Fainting During Rapid Testing:

Facts on Fainting

1. Background: fainting occurs when the blood supply to the brain is momentarily inadequate, causing a loss of consciousness, which is usually brief. Fainting can have no medical significance, or the cause can be a serious disorder. Therefore, treat loss of consciousness as a medical emergency until the signs and symptoms are relieved and the cause is known.

2. There are many reasons why people faint. Medical reasons include:
   - Low blood sugar (hypoglycemia)
   - Anemia
   - A rapid loss of blood such as caused by internal bleeding or a tubal pregnancy.
   - Abnormal heart rhythm, heart attack, or stroke.
   - Heat stroke or heat exhaustion
   - Eating disorders such as anorexia or bulimia.
3. Other things that can lead to feeling faint or fainting include:

- A sudden change in body position like standing up too quickly (postural hypotension).
- Extreme pain.
- Sudden emotional stress or fright.
- Anxiety
- Certain prescription medicines, including those that lower high blood pressure, tranquilizers, antidepressants, or even some over-the-counter medicines when taken in excessive amounts.

The risk for fainting increases in hot, humid weather, a stuffy room, or when excessive amounts of alcohol have been consumed.

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Treatment</th>
</tr>
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</table>
| - Feel a sense of dread  
- Sudden lightheadedness or dizziness  
- See spots before eyes  
- Partial or complete loss of consciousness  
- Upset stomach or nausea  
- Tingling or numbness in the extremities  
- Change in heart rate  
- Pale skin with sweating  
- Recovery of consciousness within 1-2 minutes | - Catch the person before he or she falls.  
- Before fainting, sit down and lower the head between the knees or have the client lie down and elevate legs above the heart level. This promotes blood flow to the brain.  
- If a client who is about to faint can lie down right away, he or she may not lose consciousness.  
- Watch the airway carefully. People who lose consciousness may vomit. Turn the client’s head to the side so the tongue doesn't fall back into the throat.  
- Apply cool, wet cloths to forehead.  
- If the client faints and doesn't regain consciousness in 1 to 2 minutes, dial 911 or call for emergency medical assistance.  
- Check for breathing. If breathing has stopped, the problem is more serious than a fainting spell. Initiate cardiopulmonary resuscitation (CPR) and call 911 for emergency medical care. |

Don’ts

- Don't slap or shake anyone who's just fainted.  
- Don't try to give the client anything to eat or drink, not even water, until fully conscious.  
- Don't allow the client to get up until the sense of physical weakness passes. Then observe client closely for a few minutes to be sure he or she doesn't feel faint or faint again.