VIRGINIA DEPARTMENT OF HEALTH
DIVISION OF DISEASE PREVENTION

Policies & Procedures for HIV Testing

and

Quality Assurance in HIV Testing Programs

2023 Edition

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Last Revised 07/20/2023

CHANGE LOG

This log will document future changes to the QA manual.

Date of Change	Description	Relevant Page
11/18/2022	Corrected text in Attachments F1 and F2 to remove information about antigen detection	45
07/20/2023	Updated home test kits to self-test kits	19-20
07/20/2023	Updated Priority Regional Box Rate A to Regional Flat rate and updated the link	21

INTRODUCTION

This manual outlines site-specific policies, including standards, procedures, and quality assurance measures for conducting waived rapid HIV testing. The policies, procedures, and quality assurance guidelines in this document apply to all waived rapid HIV testing programs that receive support (financial or material) from the Division of Disease Prevention (DDP).

HIV testing programs that do not receive DDP support are encouraged to use the standards described in this document, as they meet or exceed current identified public health best practices.

There are many approved methods to test human blood for HIV. This document provides policies and procedures for HIV test technologies being used in DDPsupported HIV testing programs:

- Alere Determine HIV 1/2 Ag/Ab Combo Test (ADCT)
- INSTI HIV-1/2 Antibody Test
- OraQuick Advance Rapid HIV 1/2 Antibody Home Test

The first section in this document is *Policies & Procedures for HIV Testing*. This section describes required policies for DDP-supported HIV testing programs (clinical and non-clinical), as well as, processes for ordering supplies, mailing test forms, reporting positive test results, and entering data.

The second section in this document is *Quality Assurance in HIV Testing Programs*. This section describes required quality assurance (QA) activities for DDP-supported HIV testing programs and applies to clinical and non-clinical programs. Clinical sites include local health department (LHD) clinics, hospital emergency departments, urgent care clinics, inpatient services, substance abuse treatment clinics, public health clinics, community clinics, pharmacies, correctional healthcare facilities, and primary care settings, any of which may be public or private. Non-clinical sites include community-based organizations (CBO), mobile testing units, universities, syringe-services programs, faith-based institutions, and other social service organizations where medical, diagnostic, and/or treatment services are not routinely provided, but where select diagnostic services, such as HIV testing, are offered.

Quality Assurance refers to planned, ongoing, step-by-step activities designed to ensure that: HIV testing is being performed correctly; results are accurate and reliable; correct practice is documented; and errors are found and corrected. QA activities should be in place during the entire testing process, from the time the agency receives its HIV test kits until the time a client receives their HIV test results.

SECTION I

POLICIES AND PROCEDURES FOR HIV TESTING

Minimum Requirements for HIV Test Counselors

Prior to initiating testing, new test counselors must complete required training, sign confidentiality agreements, provide evidence of hepatitis B (HBV) vaccination, undergo a competency assessment, and review the contents of this manual. Further details of each of these requirements is discussed below.

Training

Training courses for HIV testing in the Commonwealth of Virginia are provided by the Virginia HIV/AIDS Resource and Consultation Centers (VHARCC). VDH requires that testing staff and volunteers complete the *HIV Prevention Counseling Series* before providing HIV testing. The required courses in the series are:

- Facts of HIV
- Fundamentals of HIV Prevention Counseling
- Fundamentals of Waived Rapid HIV Testing

The trainings must be taken in the order listed above. Copies of training certificates must be kept in each test counselor's personnel or volunteer file.

For questions regarding the *HIV Prevention Counseling Series*, please contact your local VHARCC site using the information listed below.

Statewide training schedules can be accessed online (www.VHARCC.com).

Eastern Virginia:
Eastern Virginia Medical School
Tanya Kearney
(757) 446-6170
Kearnetk@evms.edu

Southwest and Central Virginia:
Virginia Commonwealth University HIV/AIDS Center
Dwight Rackley (804)
828-2210
bobby.rackley@vcu.edu

Northern and Northwest Virginia:
Inova Juniper Training Program
Rodney Lewis

(703) 321-2577
Rodney.Lewisjr@inova.org

For CDC guidelines for HIV testing in non-clinical settings, see Implementing HIV Testing in Non-clinical Settings: A Guide for HIV Testing Providers. For CDC guidelines for effective interventions, see https://www.cdc.gov/hiv/effective-interventions/index.html.

Competency Assessment

Before a counselor may perform testing independently, his or her ability to conduct the test must be demonstrated and documented by a person competent in testing procedures. A supervisor or trainer should use the Rapid HIV Testing and Prevention Counseling Competency Assessment form (**Attachment A**) to assess staff competency. This form assesses test counselors' ability to appropriately interact with the client, perform testing using the approved HIV testing diagnostic algorithm (**Attachment B**), and correctly perform required data collection using parts 1 and 2 of the Counseling, Testing, and Referral (CTR) form (**Attachments C1 and C2**).

After assessment, the supervisor or trainer must sign the form, which will be kept in the counselor's personnel file and will be available on site for review. New staff must perform proficiency testing six months after the initial test and annually thereafter.

Security and Confidentiality Agreements

Test counselors must sign an agency confidentiality agreement, as well as DDP's Verification of Receipt and Assurance of Key Requirements for Non-DDP Personnel (see **Attachment D** for an example), prior to coming in contact with clients and their protected health information. Signed agreements must be kept in the employee's personnel or volunteer file. Your agency's Overall Responsible Party is required to ensure that new Assurance of Key Requirements forms are signed annually.

DDP's full security and confidentiality procedures are available at this link. Questions about completing the Assurance of Key Requirements form should be directed to Brianna Carey at brianna.carey@vdh.virginia.gov.

Hepatitis B Vaccination

Within six months of initiating testing, all test counselors must provide evidence that they have received the complete hepatitis B (HBV) vaccination series or declined vaccination. Test counselors who have not received vaccination prior to their hiring should be directed to the LHD or another medical provider for vaccination. Test counselors who do not want to receive the HBV vaccine may sign a waiver declaring that they have been offered vaccination and declined (**Attachment E**). Vaccination records or waiver of vaccination must be kept in the tester's personnel or volunteer file.

HIV Testing Procedures

This section focuses on procedures to be carried out during every HIV testing session performed.

Gaining Informed Consent

All agencies receiving funding or material support from the Division of Disease Prevention (DDP) for non-clinical HIV testing must get written, informed consent from each client before conducting an HIV test. Informed consent means that the client is provided with adequate information to ensure that they understand the procedure for which they give their consent. Getting written consent in non-clinical test sites provides protection for both the client and the testing agency. The following information must be conveyed on the consent form:

- The difference between rapid and conventional testing
- The difference between a screening and confirmatory test
- The significance of HIV antibodies being present in a blood sample
- The procedure for a nonreactive result and a reactive result

Consent forms must contain identifying information for the person signing the form, as proof that the client has understood the material. In order to provide consent, a client must provide the following identifying information:

- Printed name
- Signature
- Date of signature
- Date of birth

Clinical sites that already obtain written consent for overall medical care do not need separate written consent for HIV testing, provided that the elements in the above lists are captured on the agency consent form.

Test counselors should offer all clients a copy of the Manufacturer's Subject Information Pamphlet. The client should be asked about support systems in place if the test is reactive. Once the client has been adequately informed about the testing process, they can sign the consent form/Testing Agreement (**Attachment F1 [English] and F2 [Spanish]**).

Required Data Collection

Every non-clinical test conducted using DDP funds or materials must have the following data elements collected:

- Identifying information ○ Full first and last name ○ Street address, including city, state, and ZIP code ○ Date of birth
- Demographic information ○ Sex at birth ○ Current gender ○ Ethnicity*
    - Race* ○ Previous HIV test

- Risk assessment ○ Whether client is at risk for HIV. The definition of "at risk" is below. If all criteria are met, the client is at risk for HIV:
    - Since their last HIV test, the client was (a) not taking daily PrEP, and (b) had unprotected vaginal or anal sex or (c) shared injection drug use equipment with (d) a person of unknown HIV status or an HIV-positive person with a detectable viral load.
    - Risk behavior in last five years:
        - Had sex with a male
        - Had sex with a female
        - Had sex with a transgender person
        - Injected drugs or other substances
        - Had sex with a person known to be HIV-positive
        - Participated in sex work ○ Client awareness of PrEP ○ Current use of daily PrEP by client ○ Use of PrEP by client in last 12 months
- Test information ○ Date of test ○ Test technology used ○ Temperature of testing room ○ Time test began ○ Time test was interpreted ○ Test result ○ Whether results were provided to the client ○ Indicate which test was the final test performed ○ Other co-infections for which the client was tested
- Screening and Referral ○ Screening status, eligibility, referral, and receipt of navigation for PrEP ○ Screening status, identified need, and referral or provision of service for:
    - Health benefits enrollment
    - Evidence-based risk-reduction intervention
    - Behavioral health services
    - Other social services

*If the client declines to answer questions about their race or ethnicity, the counselor should check "Declined" as their response. "Don't Know" should only be used when the **client** indicates no knowledge of their race, or does not identify with any of the given options; if the **counselor** is unable to collect a self-report from the client, or if the client indicates Hispanic ethnicity but does not indicate a race, use "Unspecified".

People who have identified themselves as HIV positive, and who are requesting a test to prove their status for any reason, such as medical care, case management, etc., need to be handled on a case-by-case basis. The counselor should ask if the client is currently receiving HIV medical care. If not, then the test counselor should begin an active referral using the process described in ***Confirmatory Testing and Linkage to HIV Medical Care***.

Agencies may collect additional information beyond what is required by DDP. However, all agencies must complete the ***Required Forms*** and have copies available for inspection by DDP.

Diagnostic Order & Procedures for Performing bioLytical INSTI and Alere Determine

The approved rapid-rapid diagnostic algorithm for rapid HIV testing uses the bioLytical INSTI as the frontline test, and the Alere Determine as the confirmatory test. Procedures for the Alere Determine and bioLytical INSTI test are described below. Further information about the diagnostic order of these tests can be found in **Attachment B – HIV Testing Algorithm**.

Procedures: bioLytical INSTI

Preparing the Test

1. Open the INSTI HIV-1/2 Test Membrane Unit by tearing at the notches on the top of each side of the foil pouch. Do not touch the center well of the Membrane Unit. Do not use if the foil pouch has been previously opened or if the packaging integrity is compromised in any manner. Once the Membrane Unit has been opened, it must be used immediately.
2. Place the Membrane Unit on the absorbent pad with the tab of the Membrane Unit facing the test counselor.
3. Remove supplemental materials from packaging: one bottle each of Sample Diluent (Solution 1), Color Developer (Solution 2), and Clarifying Solution (Solution 3), one singleuse precision pipette, one lancet, and one alcohol swab.

Performing the HIV Test

❖ Specimen Collection and Handling

1. Choose a collection site on the side of one of the center fingers of the client's non-dominant hand.
    a) To help increase blood flow, the fingers and hand should be warm to the touch. Clients can rub their hands together, run under warm water in the restroom, or squeeze them together to increase blood flow to the capillaries in the fingertips.
2. Clean the chosen site with an alcohol swab. Wipe well to remove any glycerin based soaps or lotions from the client's finger. Allow the site to dry completely to prevent additional pain/stinging.
3. Use of the 21-gauge single-use lancet provided with INSTI test is necessary to collect the 50 µL of blood need to conduct the test. Twist and pull the yellow tip out of the single-use lancet. Place the lancet at the desired site and press firmly until you hear a click to puncture the skin.
4. Discard the lancet into the biohazard waste container immediately after use.
5. Squeeze the finger gently to create a drop of blood. Wipe away the first drop of blood, as it may contain tissue fluid.
6. Squeeze the finger gently again while holding it downward until a large drop of blood forms. Apply pressure proximal to the site using thumb and forefinger of non-dominant hand to keep a bead of blood forming.

7. Place the pipette tip horizontally into the blood bead. The pipette tip must be completely submerged in blood for the capillary action to work and draw the blood to the black fill line. Do not squeeze the pipette bulb or cover the air hole between the black lines.
8. Fill the pipette to the black line to obtain 50 µL of blood.
9. If an air bubble develops on the end of the pipette tip or if the blood stops moving up the pipette, gently wipe the tip of the pipette with a gauze pad. Wipe the patient's finger with a gauze pad and squeeze the finger until a large drop of blood forms again.
    a) If the volume of blood is inadequate, perform a second finger puncture using a new lancet and pipette.
10. Wipe off any excess blood from the finger and have the patient apply pressure to the puncture until the bleeding stops and then bandage the patient's finger.

❖ Running the Test

1. Once the pipette is filled to the black line, the blood specimen will be transferred to the Sample Diluent.
2. Open the Sample Diluent (Solution 1) and align the tip of the pipette with the Sample Diluent. Squeeze the bulb of the pipette to transfer the blood specimen to the Sample Diluent. If the blood specimen does not release, cover the air hole on the black line with your fingers and squeeze again.
3. Recap the Sample Diluent bottle and mix by inversion for 5 seconds.
4. Pour the entire contents of the Sample Diluent bottle to the center of the Membrane Unit well.
    a. This must be done within 5 minutes of adding the Positive Control specimen to the Sample Diluent. The mixture should be absorbed through the membrane in less than 30 seconds; however, absorption times will vary slightly. Allow the solution to be absorbed completely, then immediately proceed to the next step.
    b. **IMPORTANT:** If at any period during the testing, the Sample Diluent, Color Developer, or Clarifying Solution stop flowing through the Membrane Unit, the procedure must be stopped and re-started with new INSTI components.
5. Re-suspend the Color Developer (Solution 2) by inversion for 5 seconds. Open the Color Developer and add the entire contents to the center of the Membrane Unit well. The colored solution should flow through completely in about 20 seconds. Allow the solution to be absorbed completely, then immediately proceed to the next step.
6. Open the Clarifying Solution (Solution 3) and add the entire contents to the center of the Membrane Unit well. This will reduce the background color and facilitate reading of the test result. Immediately read the result once the solution is through the well.

Reading and Interpreting Results

- Read the results immediately after absorption of the Clarifying Solution.
- **DO NOT** read the results if more than 5 minutes have elapsed following addition of the Clarifying Solution.
- See **Attachment G** for pictorial representations of INSTI test results.

	NONREACTIVE	REACTIVE	INVALID

Appearance of Result	The control spot at the top of the read frame furthest from the plastic tab on the Membrane unit shows blue color development **AND NO** blue spot is visible at the test spot, located below the control.	The control spot **AND** the test spot show blue color development. NOTE: One spot may be darker than the other.	The test is invalid if any of the following occurs: • There is no blue color on the control spot or test spot • There is blue color on the test spot, but not the control spot • There is a uniform tint across the membrane • Only blue specks appear on the membrane
HIV Antibodies	A Nonreactive test results means that HIV1/2 antibodies were not detected in the specimen.	A Reactive test result means that HIV-1/2 has been detected in the specimen.	
Interpretation	Negative for HIV-1/2.	PRELIMINARY POSITIVE for HIV-1/2 antibodies. The counselor must explain that the result is **preliminary positive** and that further testing is necessary to confirm the diagnosis.	An Invalid test result cannot be interpreted. The test was run incorrectly or insufficient specimen was added. Repeat the test with a new specimen, Membrane unit, kit components, and supporting materials. See ***Troubleshooting and Problem Solving Procedures***

Additional Considerations

- For a Reactive result, the intensity of the test spot does not necessarily correlate to the titer of antibody in the specimen.
    - In other words, a fainter test spot does not mean that the client has less antibody than if the test spot was very visible.
- Reading test results after more than 5 minutes has elapsed following addition of Clarifying Solution may yield erroneous results.
- Patients infected with HIV-1 or HIV-2 receiving Antiretroviral Therapy may produce false negative results.
- Specimens from patients with multiple myeloma may result in false Nonreactive or Invalid results.

- Patients with elevated hemoglobin levels may test false Nonreactive.
- A Nonreactive Result does not preclude the possibility of exposure to HIV or infection with HIV. An antibody response to recent exposure may take several months to reach detectable levels.
- A person who has antibodies to HIV-1/2 is presumed to be infected with the virus, except if that person has participated in an HIV vaccine study may develop antibodies to the vaccine and may or may not be infected with HIV.

Procedures: Alere Determine

Preparing the Test

1. Open the aluminum pouch containing the Alere Determine™ HIV-1/2 Ag/Ab Combo Cards.
2. Remove the desired numbers of test units from the 5 test unit Card by bending and tearing at the perforation. Removal of the test units should start from the right side of the Card to preserve the lot number which appears on the left side of the Card.
3. Wrap the desiccant package around the unused test units, return them to the aluminum pouch, and close the pouch with the zip lock. Store the unused cards and test units only in the aluminum pouch containing the desiccant package. Carefully close the zip lock, so that the cards are not exposed to ambient humidity during storage.
4. Slowly remove the protective foil cover from each test unit so that you avoid removing the sample pad. Lay the test unit flat in the work tray. The test must be used within 2 hours of removing the protective foil cover from each test unit. **Do not** touch the sample pad with your fingers.
   NOTE: Use of the work tray is optional. If the work tray is not used, place the test unit on a flat surface.

Specimen Collection and Testing

NOTE: The capillary tube must be used to collect the finger stick sample.

❖ To Optimize Whole Blood Circulation

1. Use the middle or ring finger
2. Warm the hand by washing in warm water (or holding it in a heating pad or hand warmer).
3. Use the "knuckle squeeze" method in which you squeeze, not milk, the patient's finger at the first knuckle using your thumb and forefinger.
4. 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.
5. Using a sterile lancet capable of producing 50 µL of blood, puncture the skin just off the center of the finger pad and wipe away the first drop with sterile gauze.

❖ To Collect an Adequate Sample Volume

1. Quickly express blood down the fingertip by gently squeezing across the entire finger, to the last joint (not to the end of the fingertip).
2. Do not "milk" the fingertip to accelerate bleeding.

3. Collect the second drop of blood by holding the capillary tube HORIZONTALLY, and touch the tip of the capillary tube to the blood sample. You have collected an adequate amount of blood when it has reached the black line on the capillary tube. You may need to employ the knuckle squeeze method to obtain an adequate sample.

   NOTE: Filling of the capillary is automatic – do NOT squeeze the bulb while sampling. Maintain this position until the flow of the sample has reached the fill line and stopped.

❖ To Add Sample to the Test Strip

1. Touch the tip of the capillary tube containing the blood sample to the sample pad (marked by the arrow symbol) and gently squeeze the top of the bulb. Avoid air bubbles. Wait until all the blood is transferred from the capillary tube to the sample pad.
2. **Caution:** Do not lift the capillary tube from the sample pad before all the blood has been transferred–a bubble may form which will prevent the complete transfer of sample.
3. If a sample will not expel, cover the small opening at the mark on the capillary with a gloved finger. Then squeeze the bulb until the sample is fully dispensed onto the sample pad.
4. When all of the blood is transferred to the sample pad, **wait one minute before adding the chase buffer** to ensure the chase buffer does not overflow the sample pad. Once the blood has been transferred to the sample pad, you cannot move the test.
5. Add one drop of chase buffer to the sample pad and start your timer.
6. Read the test result between 20 and 30 minutes after the addition of the chase buffer. Positive results can be read before 20 minutes if the pink/red control line in the control area is present. Negative results require the entire 20 minutes before reading. **Do not read test results after 30 minutes**.

   NOTE: Discard the used capillary tube, test units, and any other test materials into a biohazard waste container.

Reading and Interpreting Results

Do not read test results after 30 minutes. See **Attachment H** for pictorial examples of reactive, nonreactive and invalid test results. If there is no control line, the results are invalid. In the event of an invalid result, repeat the test. If multiple invalid tests occur, testing should be discontinued until controls have been run.

Below are instructions for interpreting the result of an Alere Determine test.

❖ Antibody Reactive (Two Lines – Control and Ab Line)

A pink/red control line appears in the control area AND a pink/red Ab line must appear in the lower test area of the test unit. The intensity of the Ab and control lines may vary. Any visible pink/red color in both the control and lower test 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 **positive** for HIV-1 and/or HIV-2 antibodies. Counselors must explain to the client that the result is positive and that the test counselor will help link them to medical care.

- Antigen (HIV-1 p24) Reactive (Two Lines – Control and Ag Line)

  A pink/red control line appears in the control area AND a pink/red Ag line must appear in the upper test area of the test unit. The intensity of the Ag and control lines may vary. Any visible pink/red color in both the control and upper test areas, regardless of intensity, is considered reactive. A reactive test result means that HIV-1 p24 antigen has been detected in the specimen. The test result is interpreted as positive for HIV-1 p24 antigen. Counselors must explain to the client that the result is positive and that the test counselor will help link them to medical care.

- Antibody Reactive and Antigen (HIV-1 p24) Reactive (Three Lines – Control, Ab and Ag Lines)

  A pink/red control line appears in the control area **and** a pink/red Ab line appears in the lower test area **and** a pink/red Ag line appears in the upper test area of the test unit. The intensity of the Ab, Ag and control lines may vary. Any visible pink/red color in the control area, the lower test area and the upper test area, regardless of intensity, is considered reactive. The test result is interpreted as **positive** for HIV-1 and/or HIV-2 antibodies and HIV-1 p24 antigen. Counselors must explain to the client that the result is positive and that the test counselor will help link them to medical care.

- Nonreactive (One Line – Control Line)

  A pink/red control line appears in the control area of the test unit, and no pink/red Ab or Ag line appears in the lower test area and the upper test area of the test unit, respectively. A nonreactive test result means that HIV-1 or HIV-2 antibodies and HIV-1 p24 antigen were not detected in the specimen.

- Invalid (No Control Line)

If there is no pink/red control line in the control area of the test unit, even if a pink/red line appears in the lower test area or the upper test area of the test unit, the result is invalid and the test should be repeated. Refer to ***Troubleshooting and Problem Solving Procedures*** for instructions to document an invalid test result

Confirmatory Testing and Linkage to HIV Medical Care

Confirmatory Testing for a Preliminary Positive

A single rapid test cannot provide an HIV-positive diagnosis, only a preliminary positive result. In order to diagnose a new case of HIV, preliminary positive test results must be confirmed through additional testing. Confirmatory testing can be either a second orthogonal rapid test technology, or a conventional blood test. "Orthogonal" means that the two HIV test technologies must test for different HIV-specific antibodies. All rapid HIV testing programs must conduct their own confirmatory testing and/or have a system to link clients to a LHD for confirmatory testing.

Once a client has received an HIV-positive diagnosis by means of receiving reactive results on two orthogonal rapid tests, they should be referred directly to HIV care. Referring the client to a LHD or other provider to "double check" the result of the two rapid tests will only needlessly delay their linkage to care.

Because of their recent HIV risk or their rapid test result, some clients should receive a conventional test **instead of** a rapid test. Agencies that do not provide conventional testing must have a documented procedure for linking these clients to conventional testing at a LHD or other clinical site:

- Clients with discordant rapid test results
- Clients who test negative but have a known recent exposure to HIV
- Clients who need PEP due to an HIV exposure within the previous 72 hours, regardless of their rapid test result
- Clients with symptoms of acute HIV infection, regardless of their rapid test result

Active Referral

Agencies are responsible for providing active referral to medical care or a patient navigator for individuals diagnosed as a result of HIV testing. This includes clients who are referred to a LHD or another provider for confirmatory testing. Active referral to patient navigation or medical care must be documented. The Coordination of Care and Services Agreement (CCSA) form (**Attachment I**) has been approved by the Virginia Attorney General, and is an optional template to legally share PHI with another medical provider. Disease Intervention Specialists (DIS) may refer clients who receive a reactive test result at a LHD to HIV testing sites for assistance linking to HIV medical care. If this occurs, the HIV test counselor should complete the second page of the CCSA after successfully linking the client to medical care and fax it to the DIS as evidence that linkage has occurred. The CCSA should no longer be transmitted to DDP.

Linkage to Care

Clients who receive an HIV diagnosis should have a documented linkage to medical care within 30 days of diagnosis. Linkage is defined by the client having seen a physician who can prescribe antiretroviral therapy (ART), or having HIV-related lab work conducted (CD4 or viral load count, genotype and/or phenotype). Agencies are responsible for timely submission of forms documenting new HIV diagnoses, and timely entry of relevant information into e2Virginia.

Discordant Test Results

If the confirmatory testing yields a discordant result, a conventional test shall be conducted to confirm the client's reactive or nonreactive status, and the discordant test will be documented using the HIV & Hepatitis Testing Team Administrative Portal (https://redcap.link/hhptestingteam) If the conventional test is negative, the client should still be encouraged to return for repeat testing at a later date.

Clients who Report a Positive HIV Self-Test

Due to stigma, fear of their test result, or lack of available testing at another provider, some clients may seek an HIV self-test through the Virginia & Maryland Home Testing Program, a local CBO, or by purchasing one at a pharmacy.

The only over-the-counter HIV self-test currently approved by the FDA is the OraQuick InHome HIV Test, which uses an oral fluid sample. This test cannot be used as a substitute frontline test in DDP's diagnostic algorithm (**Attachment B**). If a client reports having had a positive HIV self-test, the test counselor must still perform both an INSTI, and a confirmatory Determine test in order to provide a rapid-rapid diagnosis.

Self-reported positive home test results that are followed by a negative rapid test should be treated as a discordant test result and reported as such in the HHP Testing Team Administrative Project.

Completing Reporting and Documentation

Required Forms

Agencies providing HIV testing supported by DDP should not use the CTR form with the client during the testing session. Instead agencies must maintain internal demographic and risk data collection forms for use with clients, then transfer the information to the CTR form. After completing the CTR form:

- Peel off the Form ID sticker from the back of the CTR form and place it onto all forms related to the test event for proper tracking before separating the original from the carbon copy.
- Mail the original (white copy) of the CTR form to DDP's Central Registry Unit using the ***Confidential Mailing Policy*** described below.
- Retain the carbon (yellow) copy for the length of time described by the ***Record Storage and Retention Requirements***.
- In addition to part 1 of the CTR form, you must complete the following forms for clients with a confirmed HIV diagnosis:

  ○ CTR form, Part 2 (**Attachment C2**) ○ Testing and Treatment History (TTH) Form (**Attachment J**) ○ Epi-1: Confidential Morbidity Report (**Attachment K**)

Reporting Clients with Confirmed HIV Diagnosis

Agencies must use the CTR test form Parts 1 and 2, and any other forms designated by VDH. The forms should be filled out accurately, completely, and legibly, and submitted to VDH's Central Registry Unit within 30 days of the test regardless of whether the client has returned for the results or successfully linked to care.

An Epi-1 must be submitted to the LHD where the client resides within three days of a positive diagnosis. The Epi-1 is a surveillance form that documents new cases of all diseases that require reporting. Printable Epi-1 forms are available at this link, or in the attachments section of this

manual. Agencies should print 3 copies of the Epi-1, and mail 2 of the copies to the LHD where the client resides. The agency should keep the third copy for its records. An Epi-1 should not be completed if a client has received **only** a preliminary positive result, and has not had a confirmatory test.

A Testing and Treatment History (TTH) form shall be completed and submitted for all confirmed positive results within seven days of diagnosis. If the client reported having a positive HIV selftest result, make sure to include this information in the "Notes" section of the TTH form.

For information about ordering required forms, see ***Ordering Forms and HIV Test Kits***.

A summary of required forms is below:

Form Name	Complete For	When to Mail
CTR part 1	All HIV Tests	Weekly
CTR part 2	Preliminary or confirmed positive clients (new or previous)	Within 30 days
Testing and Treatment History Form	Preliminary or confirmed positive clients (new or previous)	Within 7 days
Epi-1 (Confidential Morbidity Report)	Confirmed new or previous positive clients	Within 72 hours of diagnosis

In addition to submitting required forms by mail, in the event of an HIV diagnosis, the CTR Parts 1 and 2, Epi-1, and TTH forms must be faxed to the attention of DDP's Lab Liaison, Phyllis Morris, at 804-864-8052 within two business days after a positive test.

Confidential Mailing Policy

Forms containing protected health information may be submitted only through a secure mail system that meets or exceeds the following guidelines:

- Two envelopes must be used when mailing any HIV/STD test related forms.
    - Forms shall be placed inside the "first" envelope and securely sealed. The envelope must protect contents from being read or viewed, and a regular manila envelope will meet this requirement. The number and type of forms being sent shall be indicated on the outside of the inner envelope.

    - The "second" or outer envelope must be made of a material that is resistant to tears, punctures, and moisture, such as Tyvek. DDP will provide these envelopes for use by HIV testing sites and staff performing disease intervention activities.

- The recipient and sender name and address shall be placed on both envelopes. United Parcel Service (UPS) mailing labels for "return service" will be sent to local health districts and HIV testing sites. The UPS label shall be placed on the "second" or outer envelope. Double addressing gives an additional level of security that the package will reach the intended person/address.

- Mail shall be marked "Confidential, To Be Opened By Addressee Only."

- The frequency of mailing shall be at least weekly; this will avoid the risk of overstuffed envelopes which could be damaged in transit. It is suggested that mailings be combined where activities are occurring in multiple clinics at the same location if the volume is typically low. If UPS service has not been established, a call for pick-up will be necessary.

- CTR forms (both Part 1 and Part 2) may be included in the same envelope as Epi-1 forms, TTH forms.

- Protected health information including any of the following: client name, address, demographics, test results, etc., **may not** be communicated by email.

HIV Prevention Counseling

Fundamentals of HIV prevention counseling with rapid HIV tests include:

- Keep the session focused on HIV risk reduction by engaging the client in interactive dialogue, in addition to education.
- Conduct risk assessment and provide support for positive steps already made/attempted. For clients with significant risk, a more in-depth discussion may be required.
- Assess recent exposure and need for PEP.
- Clarify critical rather than general misconceptions about HIV risk. Include anti-stigma concepts such as U=U.
- Negotiate a concrete, achievable behavior-change step that will reduce risk of acquiring or transmitting HIV. Make sure the behavior is one the client is interested in/motivated to try. Include discussion of client awareness of, and interest in PrEP.
- Seek flexibility in the counseling technique and process, avoiding a "one-size-fits- all" approach.
- Screen clients for any unmet needs for additional social services, and making referrals as needed.

Pre-Test Counseling

- Provide information about the HIV test (what the test is looking for, how quickly it can detect infection, etc.). This can be done by face-to-face communication, video, brochure, or pamphlet.

- Assess client readiness to test and receive results in the same session.
- Inform the client that supplemental testing is needed if the first rapid test result is reactive, as well as the type of test (rapid or conventional) that is needed.
- Obtain consent.
- Prior to specimen collection, provide the client with the Subject Information Notice from the test manufacturer.
- Conduct test.
- Provide risk-reduction counseling.

Post-Test Counseling

- Provide test result early in the session.
- Explain the meaning of the test result in explicit, understandable language.
- Provide risk reduction counseling, if not already provided, including client awareness of and interest in PrEP.
- Offer referrals as needed.

Testers should not offer to show the test results to clients. If clients request to see their test results, allow them to do so, but make sure to keep the session focused on risk reduction. Showing clients the actual test can divert attention away from risk and risk reduction. For example, the client may focus on reading the device, the faintness of the lines, etc., instead of exploring risky behaviors they may be willing to change.

Nonreactive Rapid HIV Test Results

Clients who have a nonreactive test result but have had a recent (within four weeks) known or possible exposure to HIV should be given the recommendation to retest. Explore risks and step(s) clients can take to avoid infection in the future. Remember that clients who describe recent symptoms (fever, malaise, diarrhea, etc.) or very recent risk (within the last four weeks) should be referred for a conventional HIV test.

Reactive Rapid HIV Test Results

Providing reactive results to clients even with the benefit of a same-day confirmatory test can be a challenge. For all clients with a reactive rapid HIV test result, it is essential to:

- Explain the meaning of the reactive test result in simple terms, avoiding technical jargon.
- Give the client the opportunity to absorb the information and ask questions—deliver the result, then be quiet.
- Explore how the client will cope with their test result. For example, whom might the client confide in for support? What coping skills do they use during stressful times?
- Underscore the importance of taking precautions to avoid the possibility of transmitting infection to others while awaiting results of confirmatory testing or prior to initiating antiretroviral treatment.

- Reiterate the availability of free medical treatment/antiviral medication, and the benefits of achieving and sustaining an undetectable viral load.
- Reiterate that a health educator with the Local Health Department will also contact the client to make sure that they have been linked to care, and to discuss partner services.

Policies for HIV Testing Programs

The primary goal of testing is to identify people with HIV as soon as possible after infection and link them to care within 30 days. DDP believes there should be "No Wrong Door" to HIV testing, and as such, makes a variety of options available to clients to make testing a routine part of their healthcare, including antigen-antibody conventional testing in LHDs and other clinical settings, rapid testing in clinical and non-clinical settings, pharmacy-based testing, and in-home HIV testing. The policies and requirements outlined below apply to any agency receiving funding or materials from DDP. Policies are arranged in alphabetical order.

Age Requirements

HIV testing sites supported by DDP may provide rapid HIV testing services to any individual 13 years of age and older.

According to the Code of Virginia, parental consent is not required for minors to receive an HIV test. However, during the informed consent process, test counselors need to inform any minor that their parents or guardians are legally able to request the results. Minors should be encouraged to share their results with their parents or legal guardian unless their safety will be compromised. If the test results of the client could lead to an abusive or damaging situation, test counselors should discuss the situation with the client and, if results are positive, with the Community HIV Testing Coordinator.

Agencies must always follow the manufacturer's insert regarding age restrictions. None of the rapid tests approved for use in DDP-supported programs should be used on clients younger than 13 years old. Anyone presenting for testing under the age of 13 should be referred to a LHD for a blood draw.

Anonymous Testing

Name-based reporting is required in Virginia; therefore, anonymous testing is not permitted under any circumstances. Names and all other required data must be collected prior to testing being performed or an HIV self-test being distributed.

Collaboration on Testing Events

Agencies are encouraged to collaborate with other organizations for special testing events; however, no agency may give away or loan test kits to another organization, except with written

permission from one of the DDP Testing Program Coordinators. Any agency providing testing as part of a collaborative event must have staff present to administer tests at the event.

Destruction of Expired HIV Test Kits and Controls

CBO-based testing programs should make every effort to accurately anticipate the amount of test kits and external controls they need, so that few to none expire before they can be used. However, in the event that test kits and/or external controls expire unused, the following steps should be taken.

Report Expired Kits and Controls in the HHP Testing Team Administrative Portal

VHARCC training sites use expired test kits and controls during the Fundamentals of Waived Rapid Test Counseling. As such, prior to destroying any expired materials, agencies should first report their expired supplies in the HHP Testing Team Administrative Portal, so that DDP can determine whether the kits and/controls should be reclaimed for use in training, or if they can be destroyed on-site. Following each report, a member from the HHP Testing Team will contact the staff member reporting the expired materials with instructions for returning them to DDP, or approval to destroy them.

Destroying Expired Test Kits

The overarching principle of destroying expired test kits is to make sure that they are disassembled to the extent that they could not be used by someone who might find them after they are thrown away. To that end, test kits can be easily destroyed by physically damaging the test device (for instance, poking a hole in the INSTI membrane unit or slashing across a Determine test card), and pouring out or otherwise separating the developer solution. When unused, neither the test device nor the developer solution is a biohazard—so both can be disposed of in the regular trash. However, as an additional precaution, agencies should dispose of the test device and developer solution in separate trash receptacles.

Destroying Expired External Controls

External controls are considered biohazardous, and should not be poured into a drain. However, unlike expired test kits, they do not pose a risk of being reused if discovered after an agency disposes of them. As a result, agencies should use the same process as other biohazardous materials to dispose of expired controls: simply discard them in a biohazard bag.

Self-Test Kit Distribution

Self-Test HIV Kits provided by DDP should be stored and distributed according to the following policies and procedures. An emphasis should be placed on protecting the confidentiality of those individuals who request and/or receive said kits, while still collecting and recording the required information for DDP's program monitoring efforts.

Acquiring a REDCap Account:

A REDCap account is required in order to access the data collection instrument for HIV self-test distribution. CBO staff who already have a REDCap account should contact the Community HIV Testing Coordinator to be added to the REDCap project. CBO staff who do not have a REDCap account can request one at this link. In the account request form, select "I belong to a VDH partner organization," select "Office of Epidemiology" as the VDH work unit, and fill in the Community HIV Testing Coordinator's contact information as the VDH sponsor.

Ordering:
Self test kits should be ordered through the HIV & Hepatitis Testing Team Administrative Portal (See ***Ordering Forms and HIV Test Kits***). Agencies will be able to request a maximum of 60 kits (10 boxes) at one time.

Storage:

1. Kits should be stored per the manufacturer's guidelines.
2. Expiration dates of kits should be regularly monitored, and if an agency has multiple lots of kits, kits should be distributed in order of expiration date.

Distribution Procedures:

1. Prior to distributing a kit, the agency must collect the following information from the client, and assign a client ID. The client ID ***may not*** include elements of PHI or PII, including letters from the client's name or elements from their date of birth. This information should be entered in the CBO Home Test Data Entry project, which is accessible in REDCap.
    a) Full name
    b) Year of birth
    c) ZIP code
    d) Race/ethnicity
    e) Sex at birth
    f) Current gender
    g) Behavioral risk factors
        - Vaginal/anal/oral sex with a male
        - Vaginal/anal/oral sex with a female
        - Vaginal/anal/oral sex with a transgender person
        - Injection drug use
        - Commercial sex work
2. The agency must collect the client's phone number and arrange for communication to take place within a certain timeframe following distribution of the test kit. It's recommended that the agency discuss with the client to figure out the appropriate timeframe for the post-test call to take place.

Post-Test Procedures:

1. Post-test counseling is a required component of home testing. Agencies must arrange for post-test communication to occur, and should make effort to ensure that post-test information is collected for every test distributed.
2. During post-test communication with the client, the agency must collect the following information:
    a) How long the client waited to use the test
    b) The exact date the client used the test (if they remember)
    c) The result of the test
3. After post-test communication with the client, the agency must log in to the REDCap project to access the client's record and update the record with the information acquired from the client.

Getting Postage Labels through DDP:

CBOs distributing home tests by mail may choose to have DDP provide paid postage labels so as not to incur costs for their agency. In order for this to occur, agencies must have USPS Regional Flat Rate Box on hand. These boxes can be ordered for free through the USPS website (link). After the agency has boxes on hand, use the following procedures when a home test needs a postage label created:

1. When entering a home test in the REDCap project, indicate "By mail" when asked how the client will receive their home test.
2. A new question will populate below asked who will pay for postage. Indicate "VDH".
3. Additional questions will populate below, asking you to fill in the email address for the staff person who should receive the label, as well as the client's name and mailing address.
4. Once you save this record, the REDCap project will generate an automated email to the agency staff indicated above, letting them know that should expect to receive a postage label for the ClientID in question.
5. The REDCap project will also generate an automated email to DDP staff the following morning at 8:00am alerting them that there are records that need a postage label.
6. DDP staff will use encrypted email to send a postage label to the staff member indicated in the record.

Incentive Policy

Below is the text of DDP's Policy on the Use of Incentives.

Incentive: S*omething which encourages a person to do something; something that incites or has a tendency to incite determination or action.*

Incentives may be used to support recruitment and retention of clients, particularly for multiplesession interventions and for participation in surveys and questionnaires. Incentives should be of value to the recipients and considered a motivation, a thank-you, or to offset costs

incurred by participants. The value of incentives should not be so great as to be coercive. The size of the incentive should be in proportion to the time or effort of the participants. For example, an incentive used for a two-session intervention should not be as large as the incentive for a sixsession intervention. **Payments for transportation, meals, and childcare should be included in the total value of incentives** being provided for an intervention.

DDP must approve the use, amount, and type of incentives to be used by either staff or contractors. The type and amount of incentives should be listed in the supply line items of contractors' budget justifications and a description of their use should be referenced in the work plans.

Non-cash incentives are preferred over cash incentives. Lottery tickets, alcohol, and cigarettes may not be used as incentives. When possible, non-monetary incentives for food should allow healthy eating choices to be made.

In some cases, monetary incentives can be used but must be strictly monitored. Pre-paid debit cards can be purchased from major credit card companies, which may alleviate the need to use cash in some cases. These cards often have fees associated with them. Efforts to use gift cards to stores or for services needed by the clients are preferred.

Incentives should be stored in a secured, locked location known only to staff persons who need access.

An incentive distribution log must be maintained. The log should include the date the incentive was provided, the grant program, and who provided and received each incentive. The log should be reviewed monthly by a supervisor or management, and checked against the number of participants for the intervention/program and the current inventory of incentives. In order to protect the confidentiality of clients, clients should not sign the incentive log directly, but can be asked to sign a receipt for the incentive which can later be reconciled against the log book.

Gift card serial numbers should be recorded when the cards are purchased and should be tracked during distribution. Supervisors and contractors must establish a checks and balances system to ensure that gift cards are not being distributed, inappropriately, to staff or friends, etc.

Staff should avoid carrying large amounts of cash or incentives with them.

HIV Testing

In general, the use of incentives for HIV testing is not encouraged. This is due, in part, to the large volume of HIV testing that takes place as well as the need to avoid coercion in the decision to test.

Exceptions are made for Social Networking Strategies in which recruiters are provided with incentives for referring or bringing in their network associates. Network associates are also

given incentives for coming in. It should be noted that the network associates who come in should be provided with incentives whether they decide to test or not.

Incentives for testing may be used for specials events such as HIV awareness days (https://www.hiv.gov/events/awareness-days) or special/collaborative community screening events. In these circumstances, the incentives should be provided to people who receive their test results.

Research Studies/Surveys/Questionnaires/Interventions
Incentives may be used to recruit individuals for participation in studies, surveys, or questionnaires being conducted as part of needs assessment, surveillance, program evaluation, research, or to assess client satisfaction. Again, the amount of the incentive should be proportionate to the amount of time being requested of the individual and the difficulty in accessing the population to be reached.

Use of incentives is an approved and CDC-recommended component of programmatic and other research protocols. Because the interview component may be lengthy, CDC's protocols may require that each person be offered a gift card as an incentive. Each individual can only receive one gift card, and all incentives (gift cards) are strictly monitored to ensure appropriate use and distribution.

Incentives may be used to encourage continued participation in multiple-session or variable length interventions; however, incentives should not be provided at every session. They may be provided at periodic intervals as clients adhere to agreed-upon appointments or as otherwise negotiated with clients during the initiation of the intervention. One example is the individuallevel intervention, Choosing Life: Empowerment! Action! Results! (CLEAR). This multiplesession intervention has five core sessions with 21 optional sessions. For more information on CLEAR and other effective, high impact interventions go to https://www.cdc.gov/hiv/effectiveinterventions/index.html.

Location Requirements

Agencies that receive either funding or material support from DDP to conduct non-clinical testing should not primarily conduct testing at clinical sites. A clinical site is defined as a space where clinical services can be or are regularly performed. Special exceptions may be made for buildings that contain both clinical *and* non-clinical space (for example, a clinic that also has a drop-in center or a lounge), provided that there is adequate separation between the clinical and non-clinical space, and provided that testing expands access beyond traditional business hours. Special exceptions may also be made for agencies that partner with LHDs to offer after-hours testing opportunities to priority populations (see ***Priority Populations***). Agencies seeking an exception should communicate their request to the Community HIV Testing Coordinator.

A valid CLIA Certificate of Waiver (either original or copied) must be available for inspection wherever testing occurs. Testing agencies must display the original CLIA waiver in the testing

room at the agency's main headquarters. Copies of the CLIA waiver must be available at satellite testing sites (including one-time or temporary sites) and available for clients to see if requested.

Testing may only be conducted in areas which fall within the operating temperature range for the test kits being used, and in areas which ensure privacy and confidentiality for all clients presenting for services. Agencies are encouraged to use white noise machines, confidentiality screens, and other devices to enhance the level of privacy offered at areas where testing takes place.

All sites where testing occurs should be evaluated for physical space and client flow on a periodic basis. This evaluation can identify potential problems like lack of privacy, lack of cleanliness, and client discomfort before they become barriers to successful testing.

Ensuring Confidentiality
To ensure confidentiality, follow the "three lock" rule. Place all completed forms, lab slips, and other supplies or logs with client names or identifiers in a locked file when not in use. The locked file can then be placed in a locked cabinet, inside of a locked office. As another example, a file can be inside a locked cabinet, inside a locked file room, inside a locked building.

Ensuring Confidentiality Off-Site
The setup of off-site testing events can differ from venue to venue, but all must provide privacy for the counselor and client. A separate area for each counselor is required at testing events. This is defined as, at a minimum, a table and chairs that are blocked from public view by curtains, room dividers, or space partitions. White noise machines may be helpful to ensure confidentiality in settings where conversations may be overheard.

When testing off-site, staff must secure all specimens, CTR (900) test forms, and other documents until they can be submitted or returned to the contractor's office. A locking file box (such as the kind available at this link) needs to be available for use by the testing staff. If staff do not immediately return to the office, documents must remain in the **physical presence** of the responsible staff member at all times. Confidential forms should never be left unattended at any time, including in places such as the trunk of a car.

If the confidentiality of clients cannot be ensured at an off-site location, the agency should immediately stop testing at that location.

Ordering Required Forms, and HIV Test Kits

Required forms and HIV test kits can be ordered through the HIV & Hepatitis Testing Team Administrative portal. The portal is accessible at https://redcap.link/hhptestingteam. After placing your order through the portal, you will be contacted by the appropriate member of the testing team with confirmation that your order has been placed.

Outreach

Outreach to priority populations helps create awareness about the availability and importance of HIV testing. Agencies conducting HIV testing should use strategic targeting and recruitment efforts to reach individuals at increased risk for HIV infection (see ***Priority Populations***). This may include community, street, and online outreach. Street or venue-based outreach makes use of outreach workers engaging the focus population at a physical location, such as a bar/club, community center, hotel, etc. Online outreach involves reaching the focus population through online venues, such as chat rooms, social networking/dating sites, and mobile phone applications.

However, agencies should be mindful of the extent to which various outreach events impact the amount of testing they perform. Outreach focused on promoting HIV testing should result in an increase in the amount of HIV testing performed. Agencies receiving funding for HIV testing may be asked to redirect or cease outreach efforts which consume staff time without a corresponding increase in tests performed. Agencies are also encouraged to review their testing data against local HIV prevalence data to ensure that outreach and testing activities are being offered to the right populations in the right areas.

Agencies may refer to the CDC guide, *Implementing HIV Testing in Non-clinical Settings*, for more detailed information about targeting focus populations through outreach. The guide is available at this link.

Partner Elicitation Protocol (for approved agencies) & Partner Services

DESCRIPTION

Partner Elicitation (PE) is a one-on-one, client-centered, post-test discussion about at-risk partners of persons confirmed to have HIV infection. The standards for PE are based on CDC Guidance for HIV Partner Services (HPS). The goal of PE is to assist those diagnosed with HIV to develop a plan for notifying partners of their possible exposure to HIV.

BENEFITS

The goal of conducting PE at Community-Based Organizations (CBO) is to provide the client with a more convenient, comfortable, and efficient opportunity for a partner services interview. This benefits the client by removing the need for them to have a separate Partner Services interview with a Disease Intervention Specialist (DIS). It also improves the overall Partner Services process, as clients who have already built rapport with the CBO staff conducting the PE interview may be more likely to disclose the names of their partners, and those partners who are identified have a chance to be notified, tested, and treated more quickly.

CONFIDENTIALITY

Confidentiality for all persons involved in HPS must be maintained by the testing site. Clients **must** be assured that their confidentiality is maintained at all times, as well as the confidentiality of their partners, when discussing Partner Elicitation and HPS.

POLICIES

CBO staff are **NOT,** under any circumstances, to attempt to locate and contact partners. According to the Code of Virginia, only health department DIS may conduct partner locating and notification activities. Once a client's test results are confirmed positive, that person should be provided the opportunity to discuss individuals who may benefit from an HIV test. The HIV positive client is encouraged to voluntarily and confidentially disclose the identifying, locating, and exposure information for each partner.

- Counselors shall use the proper format and order when conducting PE interviews: providing the result, assessing the client's reaction and addressing immediate concerns, performing a psychosocial assessment, eliciting partners, discussing risk reduction, and linking the client to care (or to a CHW or similar position for linkage).
- Counselors should discuss the "Client Referral" process, in which a client notifies partners themselves and refer them in for counseling and testing. The counselor will inform the client of the specified timeframe (48 hours) in which the partner(s) should come in for testing.
- Agencies must document all partner information in REDCap (see "Documenting Interviews" below).
- Counselors should close the session with information referencing testing time and date for partners. Counselors need to explain to the client that if partners have not come in for testing after 48 hours, the local health department will attempt to notify partners confidentially.
- PE activities should be done at the time the client is given the positive result, unless the client is unable to engage in the activity at that time. PE can be done in any venue where the agency can ensure confidentiality, but the agency should consider that interviews will typically last between one and two hours.
    - If client is unable to engage in the activity, an alternative time should be scheduled within two business days
    - If an alternative time is not scheduled, the information should be forwarded immediately to VDH following the procedures outlined below so the DIS can begin investigation
- If a client is diagnosed with other STIs in addition to HIV, or reports symptoms that are emblematic of an STI (such as a syphilitic chancre or palmar plantar rash), the CBO staff should not engage in PE and should instead immediately report the case so that it can be assigned to a DIS for interview.
    - Do not provide the client a detailed explanation of PE; just inform the client that the health department will contact the client to discuss treatment and next steps
    - The CBO staff should complete linkage to care for HIV.

TRAINING

Only staff with adequate HIV testing and counseling experience will be considered to receive training on PE. The minimum qualifications are:

- At least one year of testing experience.
- Delivery of at least one positive test result.
- Completion of the following online Passport to Partner Services modules available at TRAIN Virginia (training plan ID 4299): ○ Unit 1 – Infectious Disease and Human Anatomy (course ID 1089343) ○ Unit 2 – Syphilis (course ID 1089344) ○ Unit 3 – Chlamydial Infection (course ID 1089346) ○ Unit 4 – Gonorrhea (course ID 1089348) ○ Unit 6 – HIV infection and AIDS (course ID 1089351) ○ Introduction to Partner Services (course ID 1089355) ○ Communication Skills (course ID 1089357) ○ Interviewing Module (course ID 1090635)
    - Units 1, 2, 3, and 5

When CBO staff have completed required online trainings, they should provide evidence (certificates or screenshots showing courses are marked completed) to their supervisor, who will confirm that information when scheduling in-person training with the Community HIV Testing Coordinator, Field Operations & Training Coordinator, or Regional STD Program Coordinator.

In-person training will take place twice a year, and will last 2.5 days. After the conclusion of training, CBO Staff will be issued a Certificate of Attendance signed by the Community HIV Testing Coordinator, and the Field Operations & Training Coordinator. The Certificate will also have a blank line for the RSPC's signature.

CBO Staff who perform at a high level during training may be given preliminary qualification to conduct interviews immediately after training. However, following the completion of in-person training, all CBO Staff must participate in a final sign-off interview conducted by the Regional STD Program Coordinator (RSPC) for the region where the CBO operates within 90 days. If the interview and documentation are completed to the satisfaction of the RSPC, they will approve the CBO staff to begin conducting interviews. Agencies are encouraged to have their staff perform practice interviews prior to the final assessment by the RSPC so that they are wellprepared.

The RSPC will use the ***Partner Elicitation Skills Inventory*** **(Attachment L)** to assess CBO Staff performance during the sign-off interview. Following the sign-off interview, if the RSPC determines that a CBO test counselor has met the expected standards for conducting PE, they will sign the blank line on the Certificate of Attendance.

If the RSPC determines that a CBO test counselor has not met the expected standards for conducting PE after their sign-off interview, the test counselor should continue to practice, and seek a second sign-off interview within the following 90 days.

If the RSPC determines that the test counselor has still not met the expected standards for conducting PE after their second sign-off interview, the test counselor must repeat partner elicitation training.

After receiving final sign-off from their RSPC and beginning to conduct interviews, CBO Staff will have their skills assessed by the RSPC on an annual basis. These assessments should be scheduled by the CBO through the RSPC.

DOCUMENTING INTERVIEWS

All partner elicitation interviews performed by CBOs will be documented in REDCap. Counselors who do not have REDCap access should request an account at this link after they have the in-person portion of their training scheduled.

Purpose of Using REDCap

The project has eight instruments, which have been arranged to minimize redundant data entry by CBO staff. For example, the first instrument collects information which would typically be written on the paper interview record, and on each individual partner's field record. The REDCap project reduces data entry burden by automatically applying this information to each partner's field record.

The REDCap project also facilitates easier and faster transmission of information from the CBO to the Regional STD Program Coordinator (RSPC) and the Central Registry Unit (CRU).

Once CBO staff at an agency have been trained to use the REDCap project, they are no longer required to submit paper Interview or Field records.

Accessing the REDCap Project

Following an interview, CBO staff can access the REDCap Interview/Field Record project by logging into REDCap, or using this link: https://redcap.link/ddp-irfr. This is a public survey link, and will not require users to sign in with a password. The REDCap project should be used to document all interviews, even if no partners were elicited. **CBOs are only permitted to conduct partner elicitation for clients who are mono-infected with HIV**. If the client is also infected with another STI, or has symptoms indicative of an STI, they must be referred to CRU for assignment to a DIS. In order to indicate that a DIS needs to conduct the interview, write "Patient not interviewed" in the notes box on the Epi-1.

Completing the Interview Record & Field Record

The REDCap project uses skip logic, which shows or hides some fields depending on the information provided by CBO staff. Below is a summary of how to complete each of the

instruments—but not all instruments will need to be completed for every interview, depending on what kind of information is elicited.

Index Patient Demographics & Contact Information
This instrument collects basic information about the interview (CBO name, interviewer name, interview type) and the index patient, including their name, demographics (date of birth, race, gender, etc.), locating information (phone number, address, emergency contact), and information about their living situation (institution, time at their address, others with whom they live).

After all the information on the index patient has been entered, click the check mark button at the bottom of the screen to submit the information.

Re-Interview Questions
This instrument will only appear if "Re-interview" was selected as the interview type on the Index Patient Demographics & Contact Information instrument. This instrument is used to find out what kinds of new information were elicited during the re-interview. Any question with a "yes" answer on this instrument will prompt the REDCap project to show additional screens to collect whatever new information was elicited. For example, if the CBO staff answers "yes" to the question, "Did the client identify any new symptoms?" the REDCap project will prompt the CBO staff to complete the Signs/Symptoms instrument on the following screen.

Interview/Condition Reporting
This instrument collects information about history and follow-up for the condition being reported (method of case detection, previous HIV status, linkage to care), and more detailed information about the interview (date, place, interview period, etc.). This instrument also asks whether signs/symptoms, or partners were elicited during the interview.

Signs/Symptoms
This instrument collects information about the observed or reported signs and symptoms that the client experienced, including the type of sign/symptom and its duration and location. Signs/Symptoms is a repeating instrument—one instance should be completed for each sign/symptom that was elicited during the interview. This instrument will only be shown if the CBO staff indicated that the client experienced signs/symptoms either in the Interview/Condition Reporting or Re-Interview Questions instrument.

Risk/Social History
This instrument collects information about the client's risk behavior and social history, including sexual partners (number, gender, types of sex, venues), additional risk factors, drug use, travel history, and social history.

Partners, Contacts, Associates
This instrument collects identifying, and locating information for any partners, social contacts, or associates elicited during the interview. Partners, Contacts, Associates is a repeating instrument—one instance should be completed for each individual that was elicited during the interview. This instrument will only be shown if the CBO staff indicated that individuals were elicited either in the Interview/Condition Reporting or Re-Interview Questions instrument.

Narrative
This is the final instrument, and contains only a notes box, which CBO staff should use to enter a detailed narrative of the interview. It is highly recommended that CBO staff compose their narrative in a word processing software (such as Microsoft Word) and then copy/paste the narrative into the notes box in the REDCap project. Once this instrument is completed, the IR/FRs will be marked as complete, and the RSPC for the region will be alerted that new documents are ready for their review.

Upon receiving the alert, the RSPC will assign the record to the relevant agency's Data Access Group (see "Review and Approval by the RSPC"). This will allow CBO staff to view the record in REDCap, and print a PDF of the IR and FRs for their own recordkeeping. To access this PDF, follow the instructions below to access the Record Home Page for a given record, then click the "Choose action for record" drop-down, and select "Download PDF of record data for all instruments (compact)".

Corrections to Field Records and Entering Re-Interviews
In the event that CBO staff needs to return to an existing record due to a typo or a missed field, the REDCap project will need to be accessed from the back end. To log in to REDCap, visit https://redcap.vdh.virginia.gov and select the "CBO Interview/Field Record" project. Then, select "Record Status Dashboard" from the sidebar on the left side of the screen. A full list of records the agency has entered will appear. Click on the green circle for whichever instrument you need to edit, then click the "Edit response" button on the next screen. After making the correction, click "Save & Exit Form" on the top right-hand side of the screen.

If new information becomes available as the result of a re-interview, **do not edit the existing interview/field record**. Instead, begin a new record, and mark "Re-interview" as the interview type on the first screen. After completing that instrument, CBO staff will be directed to a screen with questions about the type of new information elicited by the re-interview. Any "yes" answer on this screen will then populate the relevant instrument(s) in the survey queue. For example, if CBO staff mark that the client reported a new named partner, they will need to fill out the Partners, Contacts, Associates instrument on the following screen.

For re-interviews, CBO staff are required to provide a re-interview narrative, as would be the case with an original interview. After the re-interview narrative is provided in the Narrative

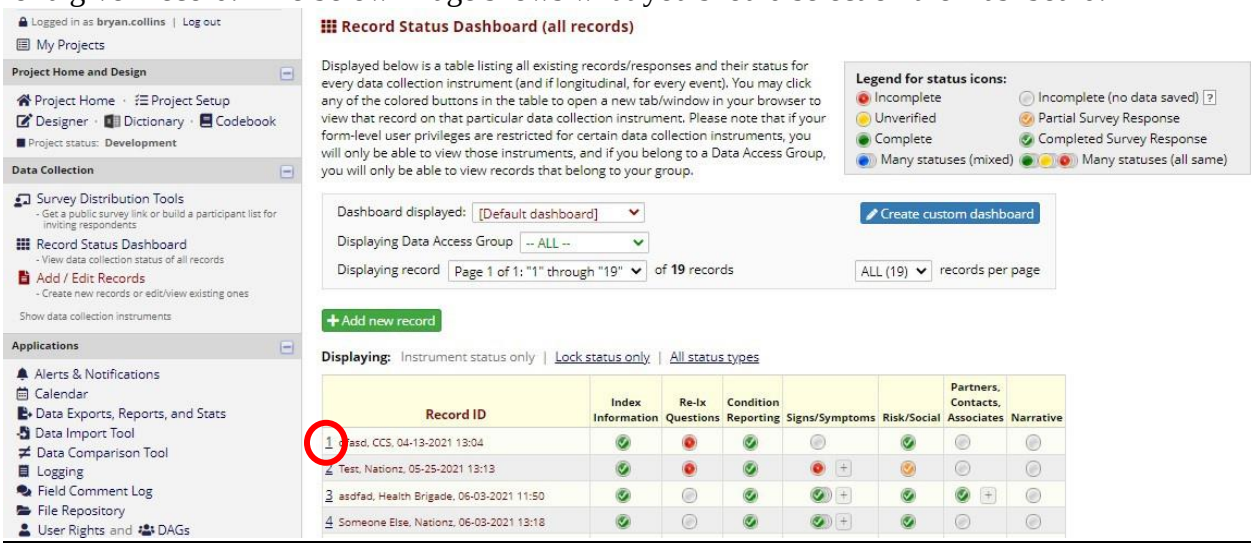
instrument, and the IR/FR is submitted, the RSPC will receive an email alert to review the new document.

Review and Approval by the RSPC

After the narrative is completed and the record has been submitted, the RSPC will receive an email alerting them that a submission is ready for their review. This email will contain a link that will prompt the RSPC to log in to REDCap, and will then open the Index Patient Demographics/Contact Information instrument in form view.

Review

Prior to reviewing the record, the RSPC will assign the record to the Data Access Group (DAG) for the agency that submitted the IR/FR. This will allow the agency to see the records it has entered in REDCap, and print copies for their own recordkeeping. To assign the record to a DAG, access the Record Status Dashboard from the lefthand sidebar, and click on the ID number for a given record. The below image shows what you should select on the Dashboard.



Clicking on the Record ID number will bring up the Record Home Page for the selected record. At the top of the screen will be a drop-down box that says, “Choose action for record”. Click this box, then select, “Assign to Data Access Group”. At this point, a pop-up window will appear with options for each agency. Select the agency that submitted the record, then click “Assign to Data Access Group”. A message will appear confirming that the record has been assigned to the Data Access Group.

After assigning the record to the appropriate agency’s DAG, review the interview records and field records. If the data provided is inadequate, contact the agency to provide feedback and request a re-interview. If the data provided is adequate, you are ready to approve the IR and FRs for transmission to CRU.

Note: If the CBO Staff who conducted the interview logged in to document the interview in REDCap, the record will automatically be applied to the agency's DAG, so this step will not be necessary.

Approval

Below the record ID will be a box labeled "RSPC USE ONLY". This box contains two fields. The first field, "Approve this Interview Record for transmission to CRU" should only be completed after the RSPC has reviewed the full interview record, and is satisfied that it is ready to be sent to CRU. The second field in the RSPC Use box is a free-text notes field. Any notes provided in this box will also be visible to CRU/CBO staff who visit the record, so **no identifying information from other cases should be placed in this box**.

In order to enter information in either field, click the "Edit response" button in the area above the record ID. After entering information, make sure to click the "Save and Exit Form" button in the top right-hand corner of the screen.

In addition to approving the interview record, the RSPC will approve each field record. To navigate to the field record(s), access the sidebar on the left side of the screen, and click "Partners, Contacts, Associates". This will open the first field record entered by the CBO staff. To navigate between field records, click the drop-down list labeled Current Instance at the top of the screen.

As with the interview record, an "RSPC Use" box will contain a field to initiate the individual or keep as marginal, and a notes box. Once a field record has been saved with a value in the "Initiate this person" field, CRU will receive an email alert that a field record is ready to be reviewed and entered their data system.

Summary of CBO PE process:

1) Provide pre-test counseling to client, provide HIV test.
2) Counsel client re: meaning of and implications of positive result and address any immediate concerns raised
3) Perform psychosocial assessment to collect information about client, including: emergency contact, address history, sexual/behavioral risk factors, drug use, venues/hangouts
4) Conduct health education specific to HIV, specifically including:
    a. Asymptomatic nature of HIV
    b. Long-term complications of untreated HIV
    c. Availability of PrEP for uninfected people
    d. Undetectable = Untrasmissible
5) Elicit partners, associates, and social contacts
6) Develop risk-reduction plan
7) Link to care
8) Up to two business days after interview, counsel and test partners who report to test site.

9) After two business days, document interview and any partners elicited in REDCap. Any partners who are marked for notification by the health department will be assigned to a DIS. If the locating information provided is not adequate to locate/identify partners, the CBO may be asked by the RSPC to re-interview the client.
    a. Re-interviews must be completed within seven days of the request by the RSPC, and documented in REDCap. Clients who are unable to return to the agency may be re-interviewed over the phone.
10) Questions requiring technical assistance should be addressed to the VDH Field Operations and Training Coordinator
    a. Technical assistance requests can also addressed to the RSPC.

Summary of Local Health Department process:

1. Upon receipt of the REDCap Interview Record/Field Record, the RSPC will assign the case to the CBO's Data Access Group, and review the documents submitted.
    a. IRs and FRs that have been completed satisfactorily will be approved and submitted to the Central Registry Unit by the RSPC.
    b. The RSPC will communicate with the CBO about gathering additional information for any incomplete/inadequate IRs and FRs.
2. The Central Registry Unit will enter information about index patients and partners into their data system, and assign any partners needing notification to a DIS.

Please note: **<u>All</u>** partners named are to be documented on the appropriate forms and submitted to the health department, including partners that the client has indicated they will notify themselves.

Priority Populations

Any client seeking an HIV test should be able to access one. However, testing programs should prioritize populations disproportionately impacted by HIV, including gay, bisexual and other men who have sex with men (MSM), persons who inject drugs (PWID), people of transgender experience, racial and ethnic minorities, youth, and persons living in low-income or high-prevalence areas. Clients with extremely high risk (i.e., individuals who had unprotected sex with an HIV positive person in the past two weeks, or show symptoms of acute infection) may be tested, but should also be provided or referred to a site that can conduct a conventional lab-based HIV test.

Record Storage and Retention Requirements

Contractors must retain original CTR test forms and other testing information containing patient identifiers for

- 2 years for CTR part 1 for negatives
- 10 years for CTR parts 1 & 2 for positives
- 10 years for Epi-1/TTH
- 5 years for any client financial or referral information

- 1 year for risk assessments/data collection forms (such as client info forms, etc)
- 2 years for quality assurance and quality control records

When keeping HIV forms, the retention date begins January 1 of the year after the test was done. For example, a negative CTR test form created in 2019 would be kept for two years (January 1, 2020 through December 31, 2021) and can be destroyed after January 1, 2022. Custodians of records must ensure that information in confidential or privacy-protected records is protected from unauthorized disclosure through the ultimate destruction of the information. Ultimate destruction is accomplished through cross-cut shredding, pulping, burning, overwriting, or otherwise physically destroying media. Deleting only the specific confidential or privacyprotected information within computer files or other electronic storage media is not acceptable.

Contractors should use the Blank RM-3 Form located at http://www.lva.virginia.gov/agencies/records/forms.asp to document record disposal.

If the contract agency ceases operations prior to the end of the appropriate retention period, or if VDH deems that confidentiality is not being maintained, all CTR test forms and other testing information containing patient identifiers must be returned to DDP for storage.

Records containing Social Security numbers must be destroyed in compliance with 17 VAC 15120-30, follow link for full code: http://law.lis.virginia.gov/admincode/title17/agency15/chapter120/section30/.

Referral to Conventional HIV/STI Testing at a Local Health Department

While LHD intake staff conduct financial eligibility screening with all clients, individuals referred by an agency providing services on behalf of DDP will not be charged for conventional HIV, HBV, hepatitis C (HCV), and/or STI testing at a LHD. Agencies should maintain a form that can be printed on agency letterhead documenting an individual's receipt of services and referral for follow-up HIV/HBV/HCV/STI testing. This form should contain the name and date of birth for the client in question, the date of service, and an original staff signature. The form should **not** contain test results, form barcodes, or other information which could reveal the type of service an individual received which resulted in a referral to testing at the health department. See **Attachment M** for a sample template.

Refusing Service

Agencies should not provide testing to anyone who meets the following criteria[1]:

- Children under the age of 13.

[1] *Every effort should be made to refer the client to other agencies that are better suited to meet their needs.*

- Persons that disclose to the counselor that they could or would do physical harm to themselves or another person if their test results are positive.
- Persons who are intoxicated or under the influence of drugs (these people cannot give informed consent).
- Persons who are actively displaying signs of mental illness or are developmentally impaired and cannot give informed consent.
- Persons who are employed by the agency providing testing. (see ***Testing of Persons Known to the Test Counselor***)

People that have identified themselves as HIV positive and who are requesting a test to prove their status for any reason, such as medical care, case management, etc., need to be handled on a case-by-case basis. Although Ryan White guidelines specify that retesting is not required for linkage to care, circumstances may arise where retesting may expedite the linkage process. Please contact the Community HIV Testing Coordinator before testing occurs. In some cases, HIV positive individuals may present for testing in order to maintain their own confidentiality (i.e., large-scale testing events, a group of friends who all decide to get tested together, etc.). In these cases, a rapid test can be performed, but a supplemental test need not be conducted. In such a case, agencies will contact their Community HIV Testing Coordinator to advise that the client is already aware of their status and should not be contacted by health department representatives.

Self-Administration of Test Kits

Agency staff are prohibited from using DDP test kits/materials to self-administer CLIA-waived rapid tests. DDP materials may not be used to test yourself.

Testing of Persons Known to the Test Counselor

HIV test counselors may provide testing to friends or acquaintances, provided that both parties are comfortable with the counselor performing the test and learning the test result. If either the client or test counselor is uncomfortable with the situation, locate another staff person to provide services to the client. The counselor should verify that the client is comfortable with the new test counselor performing the counseling and knowing their test result. Testing for friends and acquaintances may not be conducted "off the books". A CTR form must be completed for all tests.

Test counselors may not perform HIV testing on their co-workers. Agencies should assist their staff in locating another test site for services.

Testing the General Public / Mass Testing

HIV tests and testing materials provided by DDP may not be used for large-scale testing events at churches, festivals, health fairs, or mass testing events in other low risk settings. Testing may be expanded and offered to the general public only for the national HIV awareness days listed at this link.

Testing in Correctional Facilities

Any agency planning to test in a correctional facility must obtain a Letter of Agreement granting permission for testing. In addition to the agreement, a written plan must be in place to provide a medical appointment for those that test positive. Additional questions about testing in correctional facilities should be directed to the CHARLII Contract Monitor at susan.carr@vdh.virginia.gov.

Virginia Laws Pertaining to HIV Testing

All information collected from clients is used for epidemiological purposes and is confidentially reported to and maintained by VDH.

All reactive results are reported to VDH and a case is opened for each infected individual. A DIS interviews the client to identify any sexual/drug use partners who may have been exposed to HIV, then begins the process of contacting partners, notifying them that they may have been exposed to HIV, and explaining that they should be tested for HIV.

Parents and legal guardians can legally request the test results of their minor children. The agency may not notify a parent/legal guardian that their child has presented for a test, but, if a parent/legal guardian is aware of the test, they can request the results from the testing agency.

Agency records can also be subpoenaed by a court. If your agency receives a subpoena for client test results or medical records, please consult your agency attorney for guidance and notify your VDH Testing Specialist.

Confidentiality Statute

Virginia Code § 32.1-36.1 governs the legal duty health care workers have when administering, storing, and disseminating HIV testing information. For more information see http://law.lis.virginia.gov/vacode/32.1-36.1/.

HIV/HBV Infected Healthcare Workers and Occupational Exposure. Deemed consent to testing and release of test results related to infection with human immunodeficiency virus or hepatitis B or C viruses. http://law.lis.virginia.gov/vacode/title32.1/chapter2/section32.1-45.1/.

Partner Notification. Confidentiality of test for human immunodeficiency virus; civil penalty; individual action for damages or penalty. http://law.lis.virginia.gov/vacode/title32.1/chapter2/section32.1-36.1/.

Consent for testing for HIV; condition on disclosure of test results; counseling required; exceptions. http://law.lis.virginia.gov/vacode/title32.1/chapter2/section32.1-37.2/.

HIV Testing. Routine component of prenatal care. http://law.lis.virginia.gov/vacode/title54.1/chapter24/section54.1-2403.01/.

Written Test Results

DDP maintains a template for providing written negative test results, which is used by some LHDs. To obtain a copy of this template, contact the Community HIV Testing Coordinator.

1. Follow your agency's standard procedures for responding to clients' requests for their medical records.
2. Written proof of HIV test results should include the client's name, date of test, and an explanation of what the results mean.
3. The format of documentation provided to clients should prevent its use for unintended purposes by requiring original signatures in blue ink, use of watermarks, letterhead or other mechanisms that discourage photocopying.
4. The CTR form must not be provided to clients as proof of HIV test results. It is not a laboratory slip, but a data collection form, and is not appropriate to be provided as proof of HIV test status. The CTR form also provides additional information including HIV risk, which may not be appropriate to share with a third party.

SECTION II

QUALITY ASSURANCE IN HIV TESTING PROGRAMS

Quality Assurance Introduction

Quality Assurance guidelines contained in this document focus on the two approved rapid HIV testing technologies in DDP's diagnostic algorithm for HIV. This document provides procedures for the Federal Drug Administration CLIA-waived rapid HIV tests: Alere Determine HIV-1/2 Ag/Ab Combo (ADCT), and bioLytical Laboratories INSTI HIV-1/2 Antibody Test Kit.

The Determine HIV-1/2 Ag/Ab Combo is manufactured by Alere. Determine is a rapid point-ofcare test that detects both HIV-1/2 antibodies and free HIV-1 p24 antigen. Test results can be read between 20 and 30 minutes.

The INSTI HIV-1/2 Antibody Test Kit is manufactured by bioLytical Laboratories. It is a rapid in vitro qualitative test for the detection of antibodies to HIV Type 1 and Type 2 in human whole blood, fingerstick blood, serum or plasma. Test results can be read between 1 and 5 minutes.

CLIA-waived tests are simple and accurate when performed at point-of-care by personnel trained to follow the manufacturer's instructions. Part of any rapid testing is a commitment to quality control so that test results are reliable and consistently obtained.

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

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

QA activities must be in place during the entire testing process. Agencies need to have a QA plan in place before initiating rapid testing, and QA activities must be followed before, during, and after testing. This section outlines required QA activities and standards.

Overview of Routine Quality Assurance Activities

Below is an overview of the routine QA activities required of all sites conducting DDPsupported HIV testing, and the frequency with which the activities shall occur:

- **Log storage temperature of HIV test kits:** Daily
- **Log storage temperature of HIV test kit controls:** Daily
- **Log temperature of HIV testing area:** Whenever a test is performed
- **Log test start and end time and test result (Attachment N):** Whenever a test is performed

- **Run external quality controls:**
  - When a shipment is received ○ When a new lot is used ○ When a new operator will conduct testing for the first time ○ When a new field testing site is being set up for the first time ○ At periodic intervals at the agency's office
- **Observe each operator performing testing and counseling:** Annually
- **Update Agency Quality Assurance Plan:** Annually
- **Update Personnel Responsibilities Appendix (Attachment O):** Annually
- **Re-train operators on proper protection against Bloodborne Pathogens:** Annually
- **Renew CLIA waiver:** Biennially (every two years)

Other non-routine QA activities are also required under certain circumstances. A full description of requirements for routine and non-routine QA activities is outlined in the sections below.

Agency Quality Assurance Plan

Each testing program will have a completed Agency QA Standards Document (**Attachment P**), which must include, at a minimum: an Exposure Control Plan; procedures to train new test counselors within one month of their date of hire; and continuing education requirements for test counselors.

Quality Control Procedures Common to Determine and INSTI

- In addition to the internal controls, each rapid HIV test kit has a set of external controls available separately from the rapid HIV test device.

- Controls shall be run under the following circumstances:
  - With each new operator, prior to performing testing on a patient specimen ○ When opening a new test kit lot
  - When a new shipment of test kits is received, even if the lot number is the same as that of previous test kits.
  - If the temperature of the test kit storage area falls outside of 2-30ºC (36-86ºF) ○ If the temperature of the testing area falls outside of 15-30ºC (59-86ºF) ○ When setting up a new site where testing will be routinely done.
  - Whenever there is reason to suspect test kits are not functioning properly (e.g., two invalid test results in a row or an excessive number of unexpected results).
  - At regular intervals determined by the testing site.

- Always wear gloves when handling control vials and performing external control procedures.

- The test kit controls are specifically formulated and manufactured to ensure proper performance of the test, and are used to verify the tester's ability to properly perform the test and interpret the results.

- The positive controls will produce a reactive test result and are manufactured to produce a faint line. The negative controls will produce a nonreactive test result. None of the external controls will produce an invalid result.

- Test kits shall be stored per manufacturer's standards. Both ADCT and INSTI test kits can be stored between 36-86°F, and can be operated between 59-86°F. The temperature of storage area(s) for test kits will each be checked daily and recorded on the Test Kit Storage Temperature Log (**Attachment Q**).

- External controls shall be stored per manufacturer's standards. Controls for both ADCT and INSTI can be stored between 35-46°F. The temperature of storage area(s) for external controls will be checked daily and recorded on the Test Control Storage Temperature Log (**Attachment R**).

- Agencies shall keep a log of external controls as they are performed (**Attachment S**). The test kit controls will give the expected reactive or nonreactive result or the test results are not valid. If test kit controls do not provide expected results after being repeated, contact the product manufacturer and the Community HIV Testing Coordinator.

Quality Controls for the Alere Determine Combo Test

Internal Quality Control

A procedural control line is included on the test to ensure assay validity. For a test result to be valid, a pink/red control line must be visible.

NOTE: A pink/red control line may appear even when a test sample has not been applied to the test unit.

External Quality Control

ADCT reactive and nonreactive controls are available separately for use with ADCT. The controls are specifically formulated and manufactured to ensure proper performance of the test, and are used to verify the test counselor's ability to properly perform the test and interpret the results.

The nonreactive control will produce a nonreactive test result, and a visible pink/red line will only appear in the control area of the test strip. The HIV-1 and HIV-2 reactive controls will produce a reactive test result and have been manufactured to produce both a pink/red control line as well as a visible, pink/red line in the "Ab" area of the test strip. The HIV-1 p24 Antigen

control will produce a reactive test result and has been manufactured to produce both a control line, and a visible, pink/red line in the "Ag" area of the test strip. Use of control reagents manufactured by another source may not produce the required results, and therefore, will not meet the requirements for an adequate quality assurance program for the ADCT.

The external quality controls are color-coded according to their contents, as follows:

- White Bottle: Negative Control
- Purple Bottle: HIV-1 p24 Reactive Control
- Red Bottle: HIV-1 Antibody Reactive Control
- Green Bottle: HIV-2 Antibody Reactive Control

Running ADCT External Controls

Note: <u>Do not add chase buffer when running external controls.</u>

1. Remove the desired number of test kits from the test card.
2. Remove the protective foil cover from each test and place it on a flat surface or in the disposable work tray.
3. Label the test above the green area with control reagent name or identification number.
4. Open a control vial containing the control reagent.
5. Apply 1 large drop of control reagent with the disposable pipette to the sample pad (marked by the arrow symbol). **<u>Use a new pipette with each new control reagent.</u>**
6. In a well-lit area, read the result between 20 and 30 minutes after the addition of the control reagent. If the reactive controls become reactive before 20 minutes, this result can be considered accurate. **Do not read test result after 30 minutes.**
7. Discard the used test device and any other test materials into a biohazard waste container. Reseal the control reagent vials and store them in their original container at 2-8^{o}C (35-46^{o}F).
8. Be sure to complete the control log. (**Attachment S**)

Quality Controls for the INSTI HIV-1/2 Antibody Test Kit

Internal Quality Control

An internal control is included in the test in order to confirm that the test is functioning properly. The test is valid if a blue spot appears in the control area at the top of the absorbent pad, above the test area. If no control spot appears, the test result is invalid.

External Quality Controls

External quality controls have been manufactured to determine that the test is able to properly detect the presence of HIV-1 and HIV-2 antibodies, as well as the absence of antibodies. The HIV-1 and HIV-2 controls will each produce a blue spot in the control area at the top of the

absorbent pad, as well as a blue spot in the test area at the bottom of the absorbent pad, closest to the plastic tab. The nonreactive control will produce only a blue spot in the control area.

Running INSTI External Controls

- Remove the HIV-1, HIV-2, and nonreactive controls from the refrigerated storage area.

- Open the INSTI test membrane unit by tearing at the notches on the top of each side of the foil pouch. Do not touch the center well of the membrane unit. Do not use if the foil pouch has been previously opened or if the packaging integrity is compromised in any manner. Once the membrane unit has been opened, it must be used immediately.

- Place the HIV-1 control vial and membrane unit on the absorbent pad with the tab of the membrane unit facing the test counselor.

- Remove the vials of Sample Diluent (Solution 1), Color Developer (Solution 2), and Clarifying Solution (Solution 3) and place on absorbent pad. Remove one single-use control pipette and place on the absorbent pad.

- Uncap the HIV-1 control vial. Take the control pipette and lightly depress the top bulb. Insert the pipette tip into the clear liquid in the vial, slowly releasing the top bulb to completely fill the pipette stem. Ensure that the liquid in the stem reaches only to the fill line, or 50 µL. Open the Sample Diluent (Solution 1) and transfer the HIV-1 control sample held in the pipette to the Sample Diluent bottle by completely squeezing the pipette bulb. Recap the Sample Diluent bottle and mix by inversion for 5 seconds.
    - The mixed fluid can remain in the Sample Diluent bottle for up to 5 minutes. If the mixed fluid is kept in the Sample Diluent bottle for longer than 5 minutes, the sample cannot be used, and must be discarded.

- Pour the entire contents of the Sample Diluent bottle to the center of the Membrane Unit well. The mixture should be absorbed through the membrane in less than 30 seconds; however, absorption times will vary slightly.

- Open the Color Developer and add the entire contents to the center of the Membrane Unit well. The colored solution should flow through completely in about 20 seconds.

- Open the Clarifying Solution (Solution 3) and add the entire contents to the center of the Membrane Unit well. This will reduce the background color and facilitate reading of the test result. Immediately read the result once the solution is through the well.
    - **Do not read the results if more than 5 minutes have elapsed following addition of Clarifying Solution.**
    - **Note:** If, at any period during the quality control procedure, the Sample Diluent, Color Developer, or Clarifying Solution stop flowing through the Membrane Unit, the procedure must be stopped and re-started with new INSTI components.

- Interpret the result of the HIV-1 control, and repeat with the HIV-2, and nonreactive controls. The HIV-1 and HIV-2 controls will each produce a reactive test result, and the nonreactive control will produce a nonreactive result.

- The test is invalid if any of the following occurs:
    - There is no blue color on the control or the test spot
    - There is blue color on the test spot, but not the control spot ○ There is a uniform tint across the membrane, but no spots appear ○ Only blue specks appear on the membrane

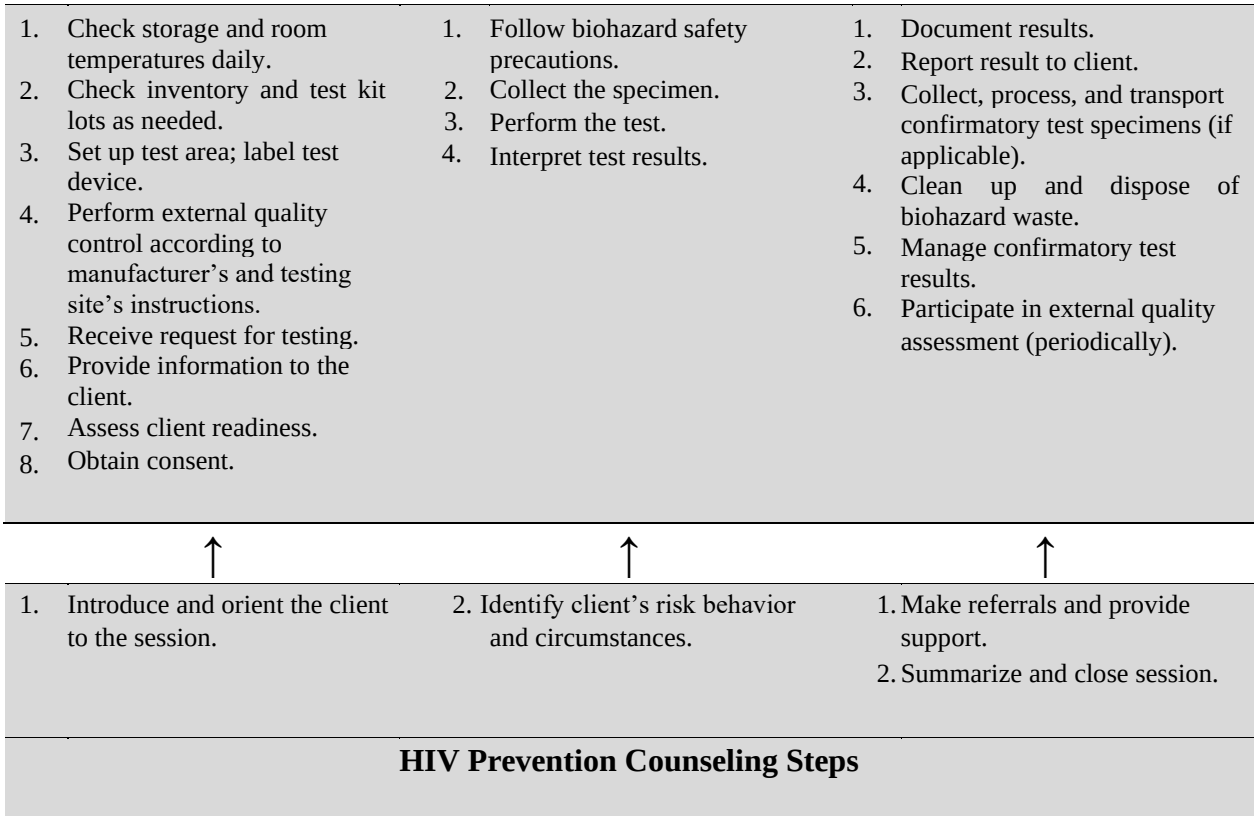
- Discard the test device, the test vials, and the control pipette, and return the control vials to their storage area.

- Be sure to complete the control log.

Quality Assurance Integration

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	**During Testing**	**After Testing**



Troubleshooting and Problem Solving Procedures

A troubleshooting log for documenting problems or unusual occurrences can be invaluable for detecting patterns and conducting after-the-fact investigations when something fails, and as a basis for discussions regarding methods to improve the process. Significant problems shall be immediately reported to the appropriate supervisory personnel, and documented in the HIV & Hepatitis Testing Team Administrative Portal (https://redcap.link/hhptestingteam). Problems and unusual events shall also be documented for the agency's records in the troubleshooting log (**Attachment T**), which contains fields for describing the problem and actions taken to resolve the problem.

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

- What to do and to whom to report when QA requirements need corrective action (e.g., temperatures are out of range, thermometer/clock is missing, etc.).

- When to discontinue testing (e.g., external controls fail, two invalid tests in a row, external controls not available on-site, etc.).

- How to document problems and actions taken (e.g., a troubleshooting log book to document problems and actions to resolve problems, including guidance regarding what

is appropriate to enter in the log book, such as any invalid test results, any out of range temperatures, temperatures not checked at the right time, unusual client reactions, etc.).

- How to report problems with rapid test kits using the HIV & Hepatitis Testing Team Administrative Portal.

Personnel Responsibilities Appendix

Agencies shall complete the Personnel Responsibilities Appendix, such that it is available for review during site visits. Although there are specific QA duties assigned to various personnel, every person involved in the testing process has the responsibility to complete the QA duties assigned to them, and bring any other QA issues to the attention of their supervisor. The Personnel Responsibilities Appendix lays out staff duties related to each specific QA activity, and describes the procedures that should be followed in the event that the normal procedure fails.

The Personnel Responsibilities Appendix should be reviewed at least once annually for accuracy and updated as needed.

Quality Assurance Review by DDP

DDP will conduct periodic on-site review of every agency's HIV testing program to ensure that DDP policies and procedures are followed and implemented, and that the minimum QA standards for HIV testing programs are upheld. Items to be reviewed by DDP staff during a QA check will, at a minimum, include:

- Physical inspection of the agency's testing area(s) and kit/control storage area(s);
- Physical inspection of the area(s) where HIV testing data is stored;
- Observation of staff conducting testing;
- Documentation of HIV test events (consent forms, CTR parts 1 and 2, TTH forms, Epi-1 forms, internal agency testing logs, etc.)
- Documentation of partner elicitation training, and final sign-off and annual observation by RSPC for staff who conduct interviews (if applicable)
- External control logs;
- Test kit and control storage temperature logs;
- Incentive tracking log (if applicable);
- Couples Counseling log (if applicable);
- Completed/accurate Personnel Responsibilities Appendix;
- Relevant documentation for staff and volunteers who conduct testing, including:
    - Training certificates; ○ Testing observation logs; ○ Hepatitis B vaccination records; ○ Signed confidentiality agreements;
    - Signed Verification of Receipt and Assurance of Key Requirements for Non-DDP Personnel forms for the current year.

If questions or issues concerning the adequacy of QA procedures result from the review, the Community HIV Testing Coordinator will initiate immediate corrective action.

ATTACHMENTS

Attachment A

Agency:

Rapid HIV Testing and Prevention Counseling Competency Assessment

Counselor:_____

Observer:_____ Date:_____

Step 1: Pre-Test Counseling and Test Administration

Introduce/orient client. Did the counselor:

- ☐ Introduce him/herself by name
- ☐ Explain his/her role
- ☐ State duration of session
- ☐ Explain test procedure

Obtain informed consent. Did the counselor:

- ☐ Determine if client understood the written consent
- ☐ Explain difference between rapid and conventional test
- ☐ Explain difference between screening and confirmatory test
- ☐ Explain meaning of test results
- ☐ Obtain client signature

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
- ☐ Complete documentation
- ☐ Use safety precautions

Step 2: Risk Reduction Counseling and Test Interpretation

Identify current risk behaviors and safer goal behaviors.

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

- ☐ Sex partners
- ☐ Needle-sharing partner(s)
- ☐ Identify safer goal behaviors that the client is willing to adopt.

Maintain a client-centered posture. Did the counselor:

- ☐ Keep the session focused on HIV risk reduction?
- Ask ☐ open-ended questions?
- ☐ Avoid 'information overload' by clarifying only major misconceptions and giving information simply?
- ☐ Provide skills-building opportunities for the client when appropriate?

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

- ☐ Yes
- ☐ No

Report test result. Did the counselor:

- ☐ Explain the meaning of a non-reactive test and the need for further testing based on date of last risk exposure
- ☐ Explain the meaning of a reactive rapid 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

Provide support and referrals. Did the counselor:

- ☐ Assess the client's unmet social service needs
- ☐ Assess the client's need for other STI testing
- ☐ Assess the client's awareness of/interest in PrEP
- ☐ Offer any referrals
- ☐ Choose appropriate referrals
- ☐ Facilitate an active referral
- ☐ Document the referral(s)
- ☐ Make a follow-up plan

Step 3:

Summarize and close the session. Did the counselor:

- ☐ Ask the client for questions or comments
- ☐ Summarize the action plan and follow-up plan for referrals
- ☐ Offer support
- ☐ Offer his/her business card or contact information
- ☐ Offer appointment for client's next HIV test
- ☐ Distribute condoms, lubricant, and/or other latex barriers

SUPERVISOR USE

☐ This counselor is competent to provide rapid HIV testing and prevention counseling.

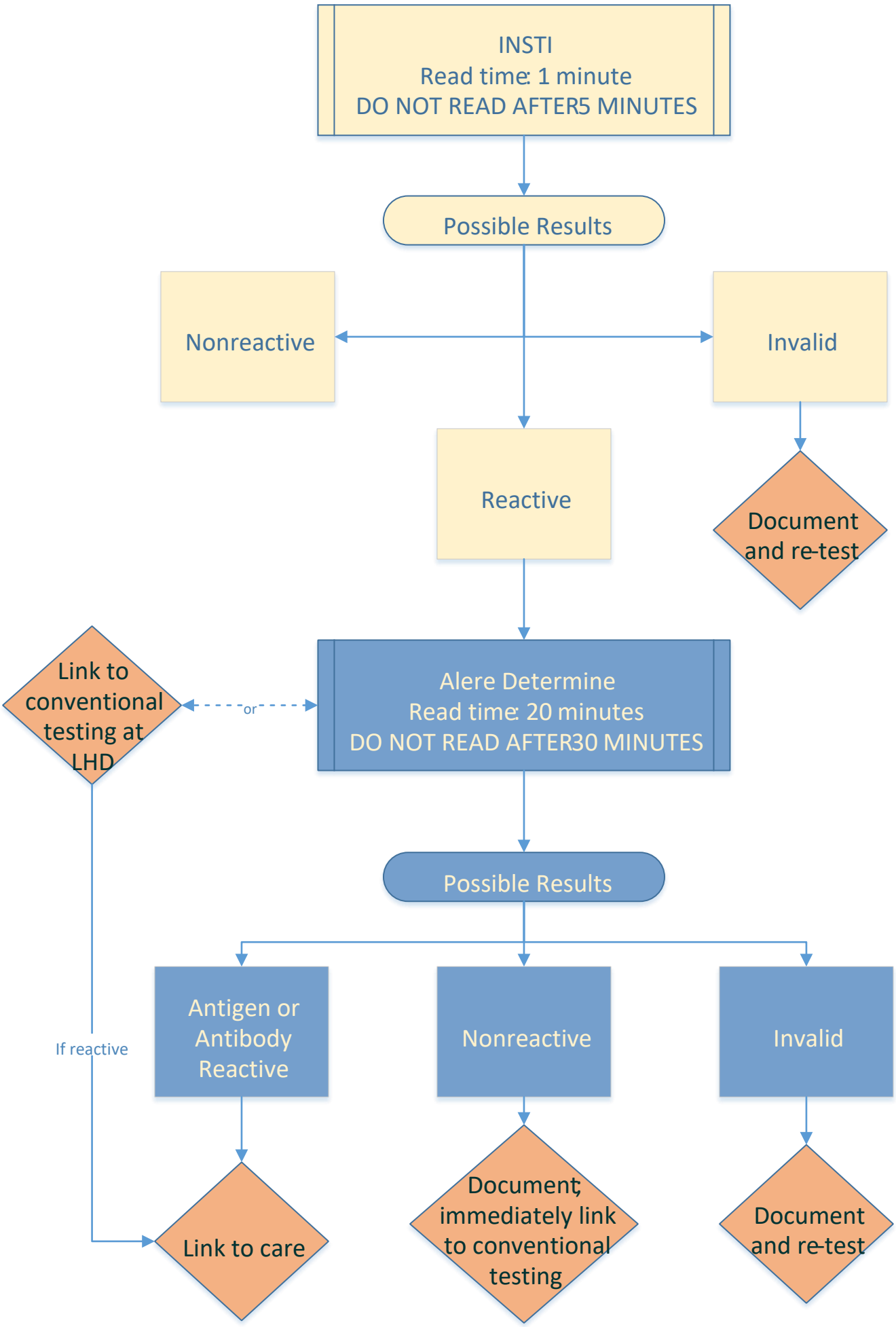
☐ This counselor is **not** competent to provide rapid HIV testing and prevention counseling.

Supervisor Name: _____

Supervisor Signature: _____ Date: _____

Attachment B

DDP HIV Rapid Testing Diagnostic Algorithm; 2020


INSTI
Read time: 1 minute
DO NOT READ AFTER5 MINUTES
Possible Results
Nonreactive
Invalid
Reactive
Document and re-test
Link to conventional testing at LHD
or
Alere Determine
Read time: 20 minutes
DO NOT READ AFTER30 MINUTES
Possible Results
If reactive
Antigen or Antibody Reactive
Nonreactive
Invalid
Link to care
Document, immediately link to conventional testing
Document and re-test

Attachment C1

GENERAL INSTRUCTIONS FOR COMPLETING PART 1 of the CTR (900) TEST FORM

900 indicates Human Immunodeficiency Virus. Do not put a name on the form.

- The legibility of this form depends on the quality of the hand-written and selected information.
- Carefully separate the sheets at the perforations. If the form tears, it may not be readable by the operator.
- Each part has a top and bottom sheet. The top sheet (white) is the **only** sheet to be mailed to VDH Central Office**.** The bottom sheet (yellow) should be retained for record-keeping purposes.
- **Mailing Address: VDH/DDP Central Registry Unit, 109 Governor Street, 2nd Floor, Richmond, VA 23219**
- **DO NOT** use red ink. Blue or black ink is preferred.
- **DO NOT** fold, staple, wrinkle, or tear forms.
- **DO NOT** punch holes or mark on the Form ID Number; doing so may cause the wrong number to be entered.
- **DO NOT** make any stray marks on the form, particularly in the fields where answers will appear.
- **DO NOT** wrinkle or tear form(s).
- Part 1 is the only form with a pre-printed code. **You must attach a form identification sticker (barcode) located on the back of the carbonless copy (yellow) to Part 2 in order to link a client's information.**
    1) Part 1 is required for all testing events
    2) Worker ID is **required**: Write the Worker ID of the person who performed the test or obtained the specimen to be used. Worker ID is required for each test.

RESPONSE FORMATS

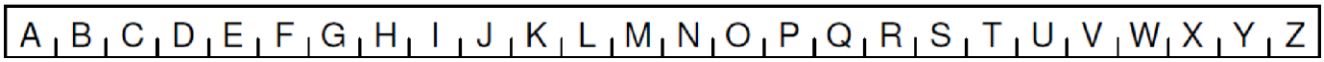
There are two ways to record data: (1) text boxes and (2) small selection boxes. Please do not use a check in the selection boxes, as these can extend and become difficult to interpret. **Please use X-marks or fill in boxes completely.**

Text boxes are used to record handwritten information (e.g., codes, dates). When writing letters or numbers in the boxes:

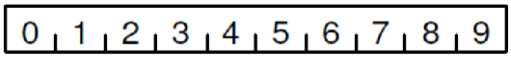
- Print neatly, using only capital letters.
- Put only one letter or number per box.

Here are examples of how to write letters and numbers:

1. LETTERS



2. NUMBERS



Selection boxes are small squares used to select only one option from among two or more options. For example, selection boxes are used to select "Current Gender ID". However, note that multiple selection boxes may be marked for "Race".

Separate the general instructions page from the form.

1. The Form ID Number is used to identify and link different parts of the 900 Test Form for a client. Stickers with the Form ID Number can be found on the back of Part 1.

Program Announcement Number and VDH Grant Program

2. Select only one Program Announcement Number that funds the 900 test being performed. If you do not know which funding number to select, please call the DDP Testing Coordinator at (804) 864-7978.
3. If applicable, select only one VDH Grant Program that this test will be credited toward. If you are unsure if the test should count toward a VDH Grant Program, contact your supervisor or agency head.

Agency

4. Session Date is the date when the test event occurred.
5. Unique Agency ID Number is a unique number for your agency. If you do not know your Unique Agency ID Number, call the DDP Testing Coordinator at (804) 864-7978.
6. Site Type is the setting where the test was performed. A list of site type codes can be found on the back of the Part 1 (yellow copy).
7. Site ZIP Code is the postal service ZIP code where the test was performed.

Client

8. Client ID is a unique number used for the identification of the client. The Client ID Number can be the medical record number, the Web Vision number, or the Part 1 printed Form ID Number. Local Health Departments using Web Vision must use the Web Vision number.
9. Year of birth is the year the client was born.
10. Client state, ZIP code, and county refer to where the client was currently living at the time the test took place. **For Client City/County please write the city or county where the client lives (not the FIPS code).**
11. Mark **both** the client's Ethnicity and Race. Ethnicity is the client's self-reported indication whether or not they are of Hispanic or Latino origin. Race is a client's self-reported classification of the biological heritage with which they most closely identify. Multiple races may be selected. "Don't Know" should only be used when the client does not identify with any of the available options, or indicates no knowledge of their race. "Not Specified" should only be used if the test counselor, for whatever reason, is not able to obtain a self-report from the client.
12. Assigned Sex at Birth is the biological sex the client was assigned at birth.
13. Current Gender is the client's current self-reported gender.
14. Previous 900 Test is the client's self-report of having had at least one prior test.

900 and Other Test Information

15. Sample Date is the date on which the specimen was collected.
16. Worker ID is a code used to identify the person who delivered services to the client. This can be an employee number, or simply the test counselor's initials.
17. Test Technology is a description of the type of test used, including the brand of the rapid test, if applicable.
18. Test Result indicates the outcome of the test conducted. **Only use "Prelim Positive" if the client received just 1 rapid test, and was not confirmed by another rapid or conventional test.** Definitions of test results are available on the back of the Part 1 (yellow copy).
19. Result Provided indicates whether the client was given their test result.
20. Test 2 and Test 3 columns are provided to complete information on subsequent tests.
21. "This was the last test performed" should only be marked in the column of the last test performed on the client.
22. Other Tests provides selection boxes for co-infections that the client may also have tested for **at the time of the test event**.

PrEP Awareness and Referral

23. Indicate whether the client self-reports that they are at risk of HIV infection. The definition of "at risk" can be found on the back of the Part 1 (yellow copy). "Risk not known" should only be used if the test counselor is not able to obtain a self-report from the client.
24. Indicate whether the client was screened for PrEP eligibility, and if they are eligible by either CDC or DDP criteria. Both criteria for PrEP eligibility can be found on the back of the Part 1 (yellow copy).
25. Indicate if the client was referred to a PrEP provider for additional screening and/or prescription of PrEP.
26. Indicate if the client was provided navigation services to link to a PrEP provider.
27. Indicate if the client has ever heard of PrEP, if they are currently taking daily PrEP, and if they took daily PrEP any time in the 12 months prior to the test event.

Priority Populations

28. The client had sex (oral/vaginal/anal) with a male in the last five years.
29. The client had sex (oral/vaginal/anal) with a female in the last five years.
30. The client recreationally injected drugs or other substances in the last five years.
31. The client had sex (oral/vaginal/anal) with a person they knew was HIV-positive in the last five years.
32. Indicate if the client participated in sex work in the last five years. The definition of sex work can be found on the back of the Part 1 (yellow copy).

Other Service Needs

33. Indicate whether the client was screened for need, had an identified need, and/or was referred to or provided health benefits (insurance) enrollment.
34. Indicate whether the client was screened for need, had an identified need, and/or was referred to or provided an evidence-based risk-reduction intervention.
35. Indicate whether the client was screened for need, had an identified need, and/or was referred to or provided behavioral health services (mental health or substance abuse treatment). The definition of behavioral health services can also be found on the back of the Part 1 (yellow copy).

36. Indicate whether the client was screened for need, had an identified need, and/or was referred to or provided other social services. The definition of other social services can be found on the back of the Part 1 (yellow copy).

Local Use Fields

37. Local Use Fields can be used for any additional information the agency wants to capture.

Imprint Barcode (Form ID) Here

CTR (900) FORM
PART 1

Date Modified: 9/13/18

VDH VIRGINIA DEPARTMENT OF HEALTH

PROGRAM ANNOUNCEMENT NUMBER (Select Only One)

- ☐ PS18-1802
- ☐ PS17-1711
- ☐ PS15-1509
- ☐ PS19-1901 CDC STD
- ☐ PS15-1502-Category B
- ☐ Other:_____

VDH GRANT PROGRAM (Select One if Applicable)

- ☐ CHT
- ☐ CHARLI
- ☐ Other:_____
- ☐ Clinical Testing
- ☐ EC4Life
- ☐ Pharmacy Testing
- ☐ MSM

AGENCY

Session Date (MMDDYYYY) ☐☐/☐☐/☐☐☐☐

Unique Agency ID Number ☐☐☐☐☐☐☐☐☐☐

Site Zip Code ☐☐☐☐☐

Site Type F ☐☐.☐☐ (See codes on reverse)

If Site Type is Other, please specify:

- ☐ Family Planning
- ☐ General Medical
- ☐ Maternal/OB
- ☐ Refugee
- ☐ Other: _____

CLIENT

Client ID ☐☐☐☐☐☐☐☐☐☐☐☐

Year of Birth (YYYY) ____

State ☐☐

Zip Code ☐☐☐☐☐

Client County (or Independent City) _____

Ethnicity

- ☐ Hispanic or Latino
- ☐ Not Hispanic or Latino
- ☐ Don't know
- ☐ Declined

Race –Check all that apply

- ☐ American Ind./AK Native
- ☐ Asian
- ☐ Black/African American
- ☐ Native HI/Pac. Islander
- ☐ White
- ☐ Declined
- ☐ Don't know
- ☐ Not Specified

Sex At Birth

- ☐ Male
- ☐ Female
- ☐ Declined

Current Gender ID

- ☐ Male
- ☐ Female
- ☐ Declined
- ☐ Transgender-F2M
- ☐ Transgender-M2F
- ☐ Trans - unspecified
- ☐ Another gender:_____

Previous Test

- ☐ Yes
- ☐ No
- ☐ Don't know

TEST INFORMATION

	TEST 1	TEST 2	TEST 3
Sample Date (MMDDYYYY)	☐☐/☐☐/☐☐☐☐	☐☐/☐☐/☐☐☐☐	☐☐/☐☐/☐☐☐☐
Worker ID	_____	_____	_____
Test Technology	☐ Fingerstick Rapid ☐ Determine ☐ INSTI ☐ Other ☐ Lab-Based Test	☐ Fingerstick Rapid ☐ Determine ☐ INSTI ☐ Other ☐ Lab-Based Test	☐ Fingerstick Rapid ☐ Determine ☐ INSTI ☐ Other ☐ Lab-Based Test
Test Result	**Rapid:** ☐ Prelim Positive ☐ Positive ☐ Negative ☐ Discordant ☐ Invalid **Lab-Based:** ☐ HIV Negative ☐ HIV-1 Positive ☐ HIV-2 Positive ☐ Inconclusive	**Rapid:** ☐ Prelim Positive ☐ Positive ☐ Negative ☐ Discordant ☐ Invalid **Lab-Based:** ☐ HIV-Negative ☐ HIV-1 Positive ☐ HIV-2 Positive ☐ Inconclusive	**Rapid:** ☐ Prelim Positive ☐ Positive ☐ Negative ☐ Discordant ☐ Invalid **Lab-Based:** ☐ HIV Negative ☐ HIV-1 Positive ☐ HIV-2 Positive ☐ Inconclusive
Result Provided	☐ Yes ☐ No ☐ Yes, client obtained result from another agency	☐ Yes ☐ No ☐ Yes, client obtained result from another agency	☐ Yes ☐ No ☐ Yes, client obtained result from another agency
Was this the last test?	☐ This was the last test performed	☐ This was the last test performed	☐ This was the last test performed

OTHER TESTS

Client tested for co-infections? ☐ Yes ☐ No

If yes, mark the co-infections for which the client was tested:

- *Syphilis* ☐
- *Chlamydia* ☐
- *Gonorrhea* ☐
- *Hepatitis C* ☐

BELOW THIS LINE REQUIRED ONLY FOR STI CLINIC & NON-CLINICAL TESTING

RISK PROFILE AND SERVICE NEEDS

Client Received Risk Assessment ☐ No ☐ Yes

Client is at risk for HIV: ☐ No ☐ Yes ☐ Risk Not Known

Was client screened for PrEP Eligibility? ☐ No ☐ Yes

Is client eligible for PrEP referral?

☐ No ☐ Yes, by CDC criteria ☐ Yes, by DDP criteria

Was client referred to PrEP provider? ☐ No ☐ Yes

Was client provided PrEP navigation? ☐ No ☐ Yes

PrEP Awareness and Use: *(check all that apply)*

- Client has ever heard of PrEP ☐
- Client currently taking daily PrEP ☐
- Client used PrEP in past 12 months ☐

In the last 5 years, client has: *(check all that apply)*

- Had sex with a male ☐
- Had sex with a female ☐
- Injected drugs/substances ☐
- Had sex with an HIV+ person ☐
- Participated in sex work ☐

OTHER SERVICE NEEDS	Screened	Need Identified	Referred or Provided
Health Benefits Enrollment	☐	☐	☐
Risk-Reduction Intervention	☐	☐	☐
Behavioral Health Services	☐	☐	☐
Other Social Services	☐	☐	☐

Local Use Fields (32 characters max)

L6:_____

L7:_____

Notes

Mail form to: VDH, Division of Disease Prevention, Central Registry Unit, 109 Governor St. Rm 228-E, Richmond, VA 23219

Codes for Site Types: CLINICAL	Codes for Site Types: NON CLINICAL
F01.01 Clinical - Inpatient hospital	F04.05 Non-clinical - HIV testing site
F02.12 Clinical - TB clinic	F06.02 Non-clinical - Community setting- School/educational facility
F02.19 Clinical - Substance abuse treatment facility	F06.03 Non-clinical - Community setting- Church/mosque/synagogue/temple
F02.51 Clinical - Community health center	F06.04 Non-clinical - Community Setting- Shelter/transitional housing
F03 Clinical - Emergency department	F06.05 Non-clinical - Community setting - Commercial facility
F08 Clinical - Primary care clinic (other than CHC)	F06.07 Non-clinical - Community setting - Bar/club/adult entertainment
F09 Clinical - Pharmacy or other retail-based clinic	F06.08 Non-clinical - Community setting - Public area
F10 Clinical - STD clinic	F06.12 Non-clinical – Community setting – Individual residence
F11 Clinical - Dental clinic	F06.88 Non-clinical - Community setting – Other
F12 Clinical - Correctional facility clinic	F07 Non-clinical - Correctional facility - Non-healthcare
F13 Clinical – Other	F14 Non-clinical - Health department - field visit
	F15 Non-clinical - Community Setting - Syringe exchange program
	F40 Non-clinical – Mobile Unit
	F88 Non-clinical – Other

DEFINITIONS

VALUE DEFINITIONS FOR RAPID TEST RESULTS

Preliminary Positive: One or more of the same rapid tests were reactive, **and no confirmatory testing was done at your agency**.
Positive: Two or more (orthogonal) rapid tests were reactive.
Negative: One or more rapid tests were nonreactive, and none were reactive.
Discordant: One rapid test was reactive, and another (orthogonal) rapid test was nonreactive, and no lab-based testing was done.
Invalid: The rapid test did not give a result, and no repeat testing was done.

VALUE DEFINITIONS FOR LAB-BASED TEST RESULTS

HIV Negative: The final test run on the collected sample was nonreactive.
HIV-1 Positive: The final test run on the collected sample was conclusively reactive for HIV-1 RNA.
HIV-2 Positive: The final test run on the collected sample was conclusively reactive for HIV-2 RNA.
Inconclusive: HIV antibodies were detected, but the presence of HIV 1/2 RNA was not confirmed. Further testing is needed.

VALUE DEFINITIONS FOR RISK & PrEP VARIABLES

At Risk for HIV: Since their last HIV test, the client:
(a) Was not taking daily PrEP; and
(b) Had unprotected vaginal or anal sex, **or**
(c) Shared injection drug use equipment with
(d) A person of unknown HIV status or an HIV-positive person with a detectable viral load

Sex Work: Client gave or received sexual favors in exchange for something they wanted or needed (money, housing, drugs, etc.).

PrEP Eligibility Criteria: Client is HIV-negative, and:
(a) Had or has an HIV-positive sexual or injecting partner;
(b) Had a recent bacterial STI (gonorrhea, chlamydia, syphilis);
(c) Has a high number of sex partners;
(d) Has a history of inconsistent or no condom use;
(e) Practiced sex work;
(f) Shared injection equipment;
(g) Had sexual encounters under the influence of drugs or alcohol;
(h) Wants PrEP.

"Yes, by CDC criteria" if any are true.

"Yes, by DDP criteria" if **only** G or H is true.

VALUE DEFINITIONS FOR SCREENING & REFERRAL VARIABLES

Health Benefits Enrollment: Navigation or assistance enrolling in a health insurance or Patient Assistance Program.
Behavioral Health Services: Mental Health Treatment, Substance Abuse Treatment
Other Support Services: Housing Services, Employment Services, Transportation Services, Domestic Violence Intervention
Screening: Any formal process for determining the existence of a need for services
Need Identified: A client's need for one or more services identified as the result of Screening
Referred or Provided: Provision of service, or provision of contact information and/or appointment time and date for a service provider as a result of a Need Identified

Form ID stickers
(n=8)

Attachment C2

GENERAL INSTRUCTIONS FOR COMPLETING PART 2 of the CTR (900) TEST FORM

900 indicates Human Immunodeficiency Virus. Do not put a name on the form.

- The legibility of this form depends on the quality of the hand-written and selected information.
- Carefully separate the sheets at the perforations. If the form tears, it may not be readable by the operator.
- Each part has a top and bottom sheet. The top sheet (white) is the only sheet to be mailed to VDH Central Office. The bottom sheet (yellow) should be retained for record-keeping purposes.
- **Mailing Address: VDH/DDP Central Registry Unit, 109 Governor Street, 2nd Floor, Richmond, VA 23219**
- **DO NOT** use red ink. Blue or black ink is preferred.
- **DO NOT** fold, staple, wrinkle, or tear forms.
- **DO NOT** punch holes or mark on the Form ID Number; doing so may cause the wrong number to be entered.
- **DO NOT** make any stray marks on the form, particularly in the fields where answers will appear.
- **DO NOT** wrinkle or tear form(s).
- Part 1 is the only form with a pre-printed code. You must attach a form identification sticker (barcode) located on the back of the carbonless copy (yellow) to Part 2 in order to link a client's information.
    1) Part 1 is required for all testing events
    2) Worker ID is **required**: Write the Worker ID of the person who performed the test or obtained the specimen to be used. Worker ID is required for each test.

RESPONSE FORMATS

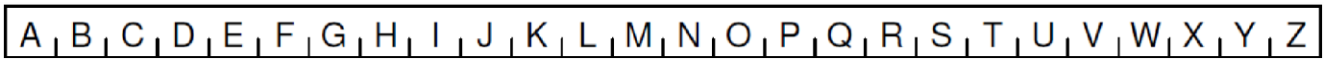
There are two ways to record data: (1) text boxes and (2) small selection boxes. Please do not use a check in the selection boxes, as these can extend and become difficult to interpret.

Text boxes are used to record handwritten information (e.g., codes, dates). When writing letters or numbers in the boxes:

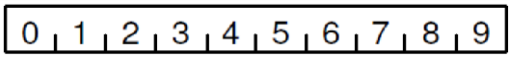
- Print neatly, using only capital letters.
- Put only one letter or number per box.

Here are examples of how to write letters and numbers:

1. LETTERS



2. NUMBERS



Selection boxes are small squares used to select only one option from among two or more options. For example, selection boxes are used to answer, "Has the client ever had a positive HIV test?"

Separate the general instructions page from the form.

1. Part 2 of the 900 Test Form is used to document additional information about **preliminary and confirmed** positive clients. Part 2 is **required** for all **preliminary and confirmed** positives.

Barcode Sticker

2. Remove a barcode sticker from the back of the Part 1 form (yellow copy) and place on the Part 2 form *in the upper left corner* for a preliminary positive or confirmed positive client in order to link the client's information with the Part 1 testing information form.

ID

3. Worker ID is used to identify the individual who provided service to the client. Worker ID can be an employee ID, or simply the test counselor's initials.
4. Client ID is a unique number used for the identification of the client. The Client ID Number can be the medical record number, the Web Vision number, or the Part 1 printed Form ID Number. Local Health Departments using Web Vision must use the Web Vision number.

5. Unique Agency ID Number is a unique code that corresponds to your agency. If you are unsure of your Unique Agency ID, call the DDP Testing Coordinator at (804) 864-7978.

6. Session Date is the date in which the information is being gathered. This is the same date as the Session Date on the Part 1 form.

Follow-Up & Reporting

7. Indicate if the client attended an HIV-related medical care appointment. If the client attended the appointment, provide the date. If the client has an appointment scheduled, but it has not yet taken place, mark "Pending". When the client attends their visit, send an amended Part 2 form by placing a sticker from the original Part 1 on a new Part 2 form, and mark the updated information for attendance at a medical visit.
8. Indicate if the client has ever had a positive HIV test prior to the current test. If the client has had a positive test prior to the current test, provide the data of first positive. If the date is unknown, use "1/1/1800". If only the month and day are unknown, use January 1st of the year indicated by the client. If only the day is unknown, use the 15th of the month.
9. Indicate if the client received individualized counseling to reduce their risk of transmitting HIV to others or avoid reinfection.
10. Indicate if the client's information was provided to the health department for reporting and/or partner services using the Confidential Morbidity Report (Epi-1) form. Clients who have received **only** a preliminary positive, and who have not been confirmed, should not be reported on an Epi-1, as they have not been officially diagnosed.

Housing

11. The client's self-reported most unstable housing status in the 12 months prior to the test event.

Prenatal Care

12. If the client was female at birth, are they pregnant?
13. If the client is pregnant, indicate if they currently self-report receiving prenatal care.
14. Indicate if the client received a needs assessment for perinatal service coordination.
15. If the client was screened for perinatal service coordination need, was a need identified?
16. If a perinatal service coordination need was identified, indicate if the client was given a referral for service.

Partner & Other Services

17. Indicate if the client was screened for need, had an identified need, and/or was provided or referred to **another agency** for help linking to medical care.
18. Indicate if the client was screened for need, had an identified need, and/or was provided help linking to medical care **by your agency**.
19. Indicate if the client was screened for need, had an identified need, and/or was provided or referred for assistance maintaining adherence to antiretroviral medication.
20. Indicate if the client was interviewed for Partner Services. If the client was interviewed, provide the date of the interview, and the Field Record Number. If the date is unknown, use "1/1/1800". If only the month and day are unknown, use January 1st of the year indicated by the client. If only the day is unknown, use the 15th of the month.
21. The Field Record number is a unique number that corresponds to a partner services investigation. The Field Record Number can be found on the front page of the Field Record form.

Local Use Field

22. Local Use Fields can be used for any additional information the agency wants to capture.

Place Barcode Sticker Here

CTR (900) FORM
PART 2

VDH VIRGINIA DEPARTMENT OF HEALTH

Date Modified: 08/10/18

CDC requires the following information on all preliminary and confirmed positive clients:

ID

Worker ID: _____

Client ID	Unique Agency ID Number	Session Date (MMDDYYYY)
		/ /

FOLLOW-UP & REPORTING

Did the client attend a medical care appointment after this positive test?

☐ No
☐ Don't know
☐ Pending
☐ Yes, confirmed → **Date of first appointment client attended** ___/___/____ (MMDDYYYY)
☐ Yes, client self-report → **Date of first appointment client attended** ___/___/____ (MMDDYYYY)

	Don't Know	No	Yes	
Has the client ever had a positive HIV test?	☐	☐	☐ →	**Date of first positive test** ___/___/____ (MMDDYYYY)
Did client receive individualized risk-reduction counseling?		☐	☐	
Was client's information provided to the Health Department for Reporting and Partner Services using the Epi-1?		☐	☐	

HOUSING

What was the client's most unstable housing status in the past 12 months?

☐ Literally Homeless
☐ Unstably Housed or at Risk of Losing Housing
☐ Stably Housed
☐ Not Asked
☐ Declined to Answer
☐ Don't Know

PRENATAL CARE

If born female, is client pregnant?

☐ Yes → If yes, in prenatal care?
- ☐ Yes
- ☐ No
- ☐ Don't know
- ☐ Declined
- ☐ Not asked

☐ No
☐ Don't know
☐ Declined

Was client screened for perinatal service coordination needs?

☐ Yes → If yes, did client need perinatal service coordination? ☐ Yes → If yes, did client receive a referral? ☐ Yes ☐ No
☐ No

PARTNER & OTHER SERVICES

Indicate if the client was screened for or provided the following services:	Screened	Need Identified	Referred/ Provided Service
Navigation for Linkage to Care	☐	☐	☐
Linkage to Medical Care	☐	☐	☐
Medication Adherence Support	☐	☐	☐

Was the client interviewed for Partner Services?

☐ No
☐ Don't know
☐ Yes, by the health department → **Date of Interview** ___/___/____ (MMDDYYYY)
☐ Yes, by non-health department staff → **Date of Interview** ___/___/____ (MMDDYYYY)

Field Record Number

DDP USE ONLY

New or Previous Diagnosis?

☐ New, verified
☐ New, not verified
☐ Previous
☐ Unable to determine

Did client see a medical provider for HIV treatment in the past 6 months?

☐ No
☐ Yes
☐ Declined to answer
☐ Don't know

eHARS NUMBER

Local Use Field (32 characters max)

L8: _____

Notes (Print Only)

Mail form to: VDH, Division of Disease Prevention, Central Registry Unit, 109 Governor St. Rm 228-E, Richmond, VA 23219

Attachment D

Revised: April 2014

Division of Disease Prevention (DDP) Security and Confidentiality Policies and Procedures Verification of Receipt and Assurance of Key Requirements for Non-DDP Personnel[1] (External contractors, service providers and data recipients)

If you handle, use, enter, or analyze DDP's confidential paper or electronic records or data, you must follow these requirements:

- Always protect and maintain security of state property you use (such as paper and electronic records, computers, flash drives, cell phones).
- Do not connect personal storage devices (such as non-state issued cameras, phones, MP3 players, flash drives) to state IT equipment/computers.
- Obtain DDP approval before removing or transporting confidential information from agreed upon locations/offices.
- Transport confidential information in a locked briefcase or similar secure container.
- Use an approved IronKey™ flash drive if you must transport confidential electronic data. ○ Ensure data is encrypted or flash drive is stored under lock and key when not in use, ○ Keep flash drive in a separate location from your computer, and ○ Delete all data immediately after use.
- Store all confidential information in specified, locked filing locations.
- Return all confidential information to locked file locations at end of workday.
- Do not store confidential DDP information on the hard drive of your computer.
- Collect, share, and transport the minimum confidential information necessary to conduct your work.
- Whenever possible, code information to avoid use of disease specific or client identifying information.
- Immediately report any known or suspected confidentiality breach to your immediate supervisor, DDP contract monitor and the DDP director.
- No confidential information should be transmitted via email.
- Send mail in manner that does not allow confidential contents to be revealed.
- Faxes containing confidential information must only be sent to, or received at secure locations.
- Do not disclose confidential information over the telephone without first confirming the recipient is allowed access to the information.
- Make every effort to ensure that confidential data is removed from PCs prior to surplus.
- Avoid photography or video in office locations that involve DDP confidential data, unless it is absolutely necessary for business purposes and approved by your supervisor(s).
- If you are a recipient of data from DDP, you will ensure that all data stewardship activities are handled according to the signed Data Request and Data Recipient Agreement forms.

Your signature below indicates that:

- You have read the Security and Confidentiality Policies and Procedures in its entirety,
- You have read and understand these key requirements, and
- You have discussed any content you do not understand with your supervisor.

Name *(print)*:_____Signature:_____Date:_____

Supervisor's Signature: _____ Date: _____

If employed external to DDP, identify your employer or affiliation: _____

[1] This one-page document summarizes key attributes of the Security and Confidentiality Policies and Procedures. It is not inclusive of all Security and Confidentiality Policies and Procedures requirements.

Attachment E

[insert agency logo]

Waiver of Hepatitis B Vaccination

I understand that due to my occupational exposure to blood or other potentially infectious materials I may be at risk of acquiring hepatitis B virus (HBV) infection. I have been given the opportunity to be vaccinated with hepatitis B vaccine, at no charge to myself. However, I decline hepatitis B vaccination at this time. I understand that by declining this vaccine, I continue to be at risk of acquiring hepatitis B, a serious disease. If in the future I continue to have occupational exposure to blood or other potentially infectious materials and I want to be vaccinated with hepatitis B vaccine, I can receive the vaccination series at no charge to me.

I have read the above information and I agree to comply with this policy. If I have any questions or concerns I will address them with _____
(supervisor name)

Print Name _____

Sign Name: _____

Date: _____

Attachment F1

CTR Form ID Number_____

HIV Information and Testing Agreement

Testing provided by [Agency] is voluntary. By signing this form, you agree to take a test that will show if you have antibodies for HIV, the virus that causes AIDS. Your body reacts to the presence of HIV by making antibodies, which this test can detect. If you have antibodies for HIV, you are likely infected.

People get HIV most often by having unprotected sex or sharing needles/syringes with an infected person. It can take up to three months for your body to make HIV antibodies after infection, though most people will test positive on our current antibody tests about one month after infection. If your test today is negative but you have had unprotected sex or shared injection equipment in the past month, it is recommended that you test again

in one month. People who often engage in high-risk behavior should test every three months and consider taking Pre-Exposure Prophylaxis, a daily pill that can prevent HIV.

Like a number of other communicable diseases, HIV is a reportable condition in the state of Virginia. This means that if you are diagnosed with HIV, your name and contact information will be reported to the Virginia Department of Health. The health department will protect your identity and your records.

If you are diagnosed with HIV, [Agency] or the health department will help you access medical care. Receiving HIV-specific treatment is important to protecting your health. With medical care, most people with HIV can have a normal lifespan. Proper HIV medical treatment can also make it impossible for an infected person to pass the virus to someone else.

What Kind of Test Will Be Done?

You are receiving a **rapid test**. Rapid tests are simple and accurate when performed at point-of-care by personnel trained to follow manufacturer's instructions. Your test counselor has been specially trained to conduct your HIV test, and will use a lancet to collect a fingerstick blood specimen. The results of your rapid test will be ready in about 60 seconds.

What does my Test Result Mean?

If your rapid HIV test is negative, no antibodies for HIV were found. However if you had unprotected sex or shared needles/syringes in the past three months, there is a chance that you may be in the "**window period"**. This means that you may be infected, but it may be too early for the test to detect any antibodies in your blood, and you should be tested again in one month.

If your rapid test is reactive for HIV antibodies, you will need a confirmatory, or follow-up test, to verify the result of the first HIV test. By signing this form, you consent to have confirmatory testing done in order to establish an HIV diagnosis. Confirmatory testing will be provided by this agency, and will involve a different rapid test.

Signature: _____ Date: _____

Printed Name: _____

Date of Birth: _____

Attachment F2

CTR Form ID Number _____

Acuerdo de prueba e información del VIH

La prueba que proporciona [Agency] es voluntaria. Al firmar este formulario, acepta realizarse una prueba que mostrará si tiene anticuerpos contra el VIH, el virus que causa el SIDA. El cuerpo reacciona a la presencia del VIH produciendo anticuerpos, que esta prueba puede detectar. Si usted tiene anticuerpos contra el VIH, es probable que esté infectado.

Las personas contraen el VIH con mayor frecuencia al tener relaciones sexuales sin protección o al compartir agujas/jeringas con una persona infectada. Puede tardar hasta tres meses para que el cuerpo produzca anticuerpos contra el VIH después de la infección, aunque la mayoría de las personas obtendrán un resultado positivo en nuestras pruebas actuales de anticuerpos aproximadamente un mes después de la infección. Si el resultado de su prueba de hoy es negativo, pero ha tenido relaciones sexuales sin protección o ha compartido materiales de inyección en el último mes, se recomienda que se vuelva a realizar la prueba en un mes. Las personas que suelen participar en conductas de alto riesgo deben hacerse la prueba cada tres meses y considerar la posibilidad de tomar profilaxis de preexposición, una píldora diaria que puede prevenir el VIH.

Al igual que muchas otras enfermedades contagiosas, el VIH es una enfermedad de declaración obligatoria en el estado de Virginia. Esto significa que, si se le diagnostica VIH, se comunicará su nombre e información de contacto al Departamento de Salud de Virginia. El Departamento de Salud protegerá su identidad y sus registros.

Si se le diagnostica VIH, [Agency] o el Departamento de Salud le ayudará a obtener acceso a atención médica. Recibir tratamiento específico para el VIH es importante para proteger su salud. Con atención médica, la mayoría de las personas con VIH tienen una esperanza de vida normal. El tratamiento médico adecuado para el VIH también puede lograr que sea imposible que una persona infectada le pase el virus a otra persona.

¿Qué tipo de prueba se realizará?

Recibirá una **prueba rápida**. Las pruebas rápidas son sencillas y precisas cuando el personal capacitado para seguir las instrucciones del fabricante las realiza en el lugar de atención. Su consejero de pruebas ha sido especialmente capacitado para realizarle la prueba de VIH y usará una lanceta para tomar una muestra de sangre por punción digital. Los resultados de la prueba rápida estarán listos en alrededor de 60 segundos.

¿Qué significa el resultado de mi prueba?

Si el resultado de su prueba rápida de VIH es negativo, significa que no se encontraron anticuerpos contra el VIH. Sin embargo, si tuvo relaciones sexuales sin protección o compartió agujas/jeringas en los últimos tres meses, existe la posibilidad de que se encuentre en el **"período ventana"**. Esto significa que puede estar infectado, pero puede ser demasiado pronto para que la prueba detecte anticuerpos en la sangre. Debe volver a hacerse la prueba en un mes.

Si el resultado de su prueba rápida es reactivo para los anticuerpos contra el VIH, necesitará una prueba confirmatoria o de seguimiento para verificar el resultado de la primera prueba de VIH. Al firmar este formulario, da su consentimiento para que se le realice una prueba confirmatoria a fin de establecer un diagnóstico de VIH. Esta agencia proporcionará la prueba confirmatoria, que implicará una prueba rápida diferente.

Firma: _____ Fecha: _____

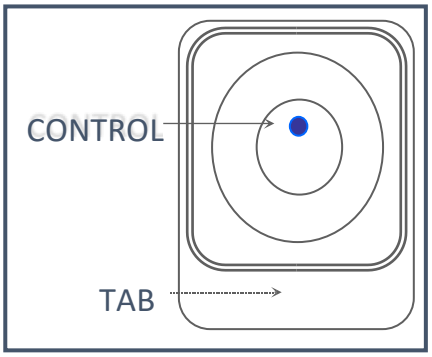
Nombre en letra de imprenta: _____

Fecha de nacimiento: _____

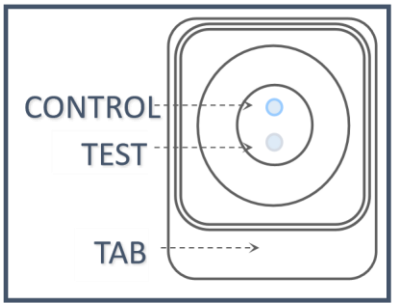
Attachment G

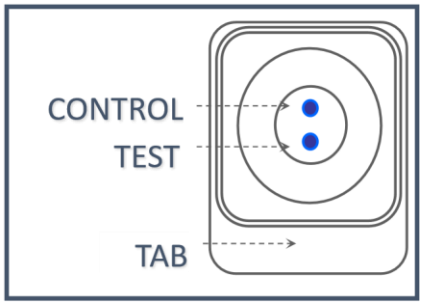
bioLytical INSTI Interpretation Guide

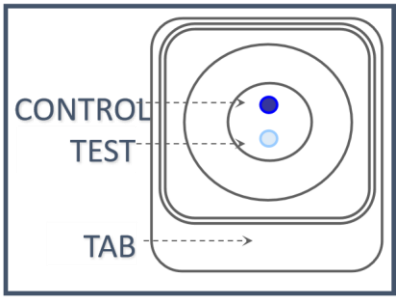
Non-Reactive



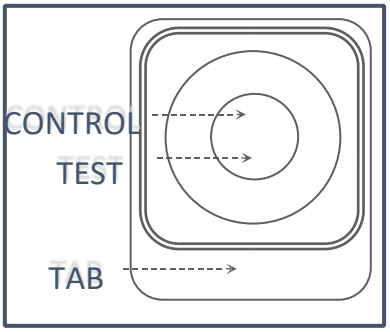
Reactive

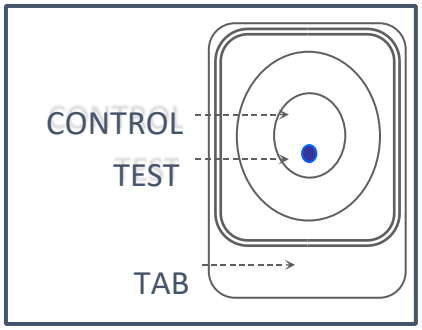






Invalid

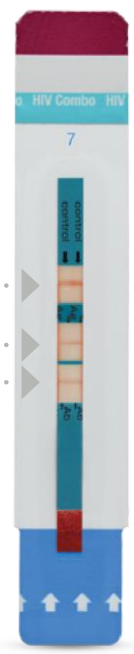




Attachment H

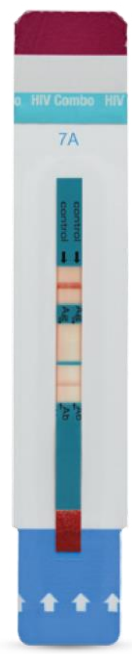
Alere Determine™ HIV-1/2 Ag/Ab Combo
Interpretation Guide

Reactive/Preliminary Positive Results

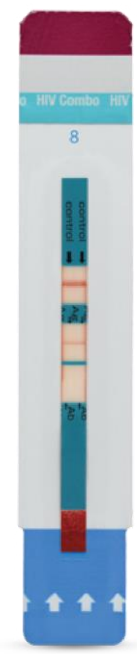


Control line
Ag test line
Ab test line

Reactive/Preliminary Positive for HIV-1 and/or HIV-2 antibodies and HIV-1 p24 antigen
Control line present
Ag and Ab test lines present

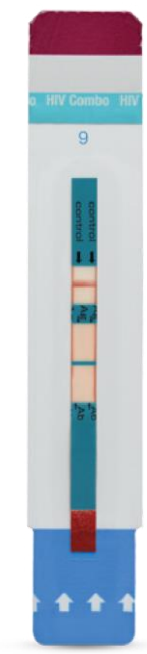


Reactive/Preliminary Positive for HIV-1 and/or HIV-2 antibodies
Control line present
Ab test line present



Reactive/Preliminary Positive for HIV-1 p24 antigen*
Control line present
Ag test line present

Nonreactive Result



Nonreactive
Control line present
No test lines present

Invalid Results

Invalid
No control line present

Invalid
No control line present
Ag and Ab test lines present

Invalid
No control line present
Ag test line present

Invalid
No control line present
Ab test line present

*NOTE: A test result that is REACTIVE/PRELIMINARY POSITIVE for HIV-1 p24 antigen in the absence of reactivity for HIV-1 or HIV-2 antibodies may indicate an acute HIV-1 infection in the test subject. In this case the acute HIV-1 infection is distinguished from an established HIV-1 infection in which antibodies to HIV-1 are present.

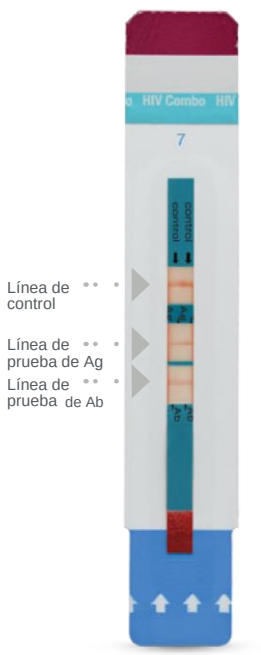
For technical assistance, please call 1.877.866.9335 or email ts.scr@alere.com

FOR INFORMATIONAL USE ONLY. Not to be used for performing the assay. Please refer to the package insert for more information.

Alere Determine™ HIV-1/2 Ag/Ab Combo

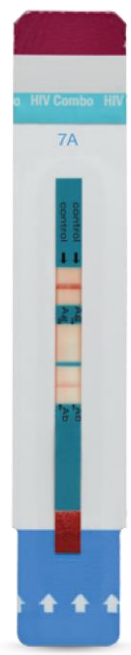
Guía de interpretación

Resultados Reactivos/Positivos Preliminares



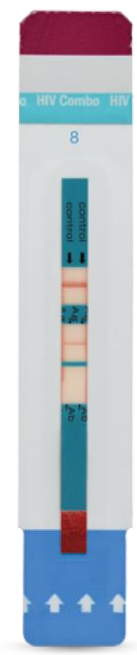
Reactivo/Positivo Preliminar a anticuerpos (Ab) contra VIH-1 y/o VIH-2 y al antígeno (Ag) p24 de VIH-1

Hay línea de control
Hay líneas de prueba de Ag y Ab



Reactivo/Positivo Preliminar a anticuerpos contra VIH-1 y/o VIH-2

Hay línea de control
Hay línea de prueba de Ab



Reactivo/Positivo Preliminar al antígeno p24 de VIH-1*

Hay línea de control
Hay línea de prueba de Ag

Resultado Sin Reacción

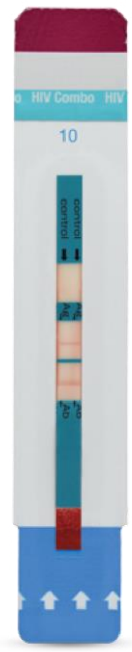
Sin Reacción

Hay línea de control
No hay líneas de prueba

Resultados No Válidos

No Válido

No hay línea de control



No Válido

No hay línea de control
Hay líneas de prueba de Ag y Ab

No Válido

No hay línea de control
Hay línea de prueba de Ag

No Válido

No hay línea de control
Hay línea de prueba de Ab

*NOTA: Un resultado de prueba que es REACTIVO/POSITIVO PRELIMINAR al antígeno p24 de VIH-1, junto a una falta de reacción a los anticuerpos contra VIH-1 o VIH-2, puede indicar infección aguda por VIH-1 en la persona examinada. En ese caso la infección aguda por VIH-1 se distingue de una infección establecida por VIH-1, en la cual están presentes anticuerpos contra VIH-1.

Para obtener asistencia técnica, llame al 1.877.866.9335 o email ts.scr@alere.com

SOLO PARA USO INFORMATIVO. No debe utilizarse para realizar el ensayo. Consulte el prospecto del envase para obtener más información.

Attachment I

COORDINATION OF CARE AND SERVICES AGREEMENT (CCSA)

PURPOSE:

Coordination of care and services involves organizing client care activities and information sharing among all participants involved with a client's care, in order to achieve safer and more effective care. The main goal of coordinating care and services is to meet the client's needs and preferences in the delivery of high-quality, high-value medical care. This means that the client's needs and preferences are known and communicated to the appropriate people. Health care providers will work together to keep the client informed and to ensure that effective referrals and transitions take place.

The purpose of the Coordination of Care and Services Agreement is to allow the client and the agency that provides linkage services to identify and select available medical and community resources that align with the client's needs and preferences. This form provides the opportunity for the client to consent to allow confidential information to be shared among services providers to help coordinate services, assist with closing the referral loop and allow for easier linkages to care. This form is not intended to be a blanket consent form and information will only be shared among agencies the client selects or approves.

INSTRUCTIONS:

REQUIRED--For the agency that originates the form:

- Provide the agency name, name of the agency personnel completing the form, phone number, secure fax number and field record number (Local Health Departments only).

If the client DECLINES Coordination of Care and Services Agreement:

- **For PrEP Services only:** do NOT complete a form for that client.
- Complete **Section A** ONLY, then STOP.
  - Fill in the client's first name, middle initial, last name and date of birth.
  - Check the box for Client DECLINES Coordination of Care and Services.
  - Check the box for the reasons the client refused.
  - Sign and date (agency personnel that is completing the form).
  - **ACTION: Fax to form to VDH Central Office at (804-864-7970)**

If the client ACCEPTS Coordination of Care and Services Agreement:

- **Complete Section A**:
  - Fill in the client's first name, middle initial, last name and date of birth.
  - Check the box for Client ACCEPTS Coordination of Care and Services. ▪ Go to **Section B**.
- **Complete Sections B-C**
  - Fill in the information that the client permits to be shared for the services selected
- **Complete Section D:**
  - Provide the agency name, name of the agency personnel who is providing linkage services, phone number, and secure fax number. Check the box if the client is already in medical care but wants coordination of other services.
- **ACTION: Fax entire form to the agency listed in section D if referring to an external agency for linkage services**
- **Complete Section E**: Complete this section if your agency has received a referral for linkage services OR if you are the original agency who will also be providing linkage services for the client.
  - ***REQUIRED:*** Medical Care Referral- provide the name of the agency and provider that the client is referred to for medical care. Include the date of referral, the date of the client's first appointment, and the date that the client's attendance of the appointment is verified.
  - If the client is already in medical care, but would like coordination of other services then provide the name of the agency and medical provider that the client is currently in care at.
  - *The client's date of appointment attendance **MUST** be verified.*
  - Other Types of Service Referrals- If the client has requested referrals for additional services then complete this for all additional service referrals.

REQUIRED: If the linkage agency received a referral for linkage services, then send a copy of the completed form to the originating agency. Also, please fax ALL completed forms to the Virginia Department of Health at the secure fax number: (804) 864-7970.

For all exchanges, please be sure to use a fax cover sheet and ensure all fax lines are secure.

COORDINATION OF CARE AND SERVICES AGREEMENT

Agency Name: _____ **Agency Staff/Personnel:**

Phone Number:_____ **Secure Fax Number:**

Field Record # (DIS only):

Section A: Acceptance of Care and Coordination of Services

Client Name:

First ***MI*** ***Last***

DOB: __/__/__
(MM/DD/YYYY)

☐ Client **ACCEPTS** Coordination of Care and Services Agreement **(Go to Section B)**

☐ Client **DECLINES** Coordination of Care and Services Agreement **(Complete the Rest of Section A)**

Reason(s) Client Refused:

☐ Client is already in care and does not need coordination of care and services.

☐ Medical Provider Name:

☐ Client is unable to be located or contacted.

☐ Client did not provide a reason.

☐ Other, please specify:

Agency Personnel Signature: _____ **Date Refused:** __/__/__

STOP HERE IF CLIENT DECLINES COORDINATION OF CARE AND SERVICES, AND FAX FORM TO VDH AT (804) 864-7970

Section B: Consent of Care and Coordination of Services Agreement

I, _____ consent to receiving coordination of my care and
(Print Full Name)

services, including linkage to medical care.

I understand that different agencies provide different services and benefits, and that each agency must have specific information to provide services and benefits. By signing this form, I allow agencies to use and exchange certain information about me so it will be easier for them to work together efficiently to provide or coordinate these services or benefits.

It is understood that this agreement for the coordination of my care services is valid for 24 months from the agreement date. In addition, it is understood that in order to assist in the coordination of my care, a health system navigator (HSN), or patient navigator (PN), or other type of linkage to care staff or personnel can attempt to contact me by the aboveapproved methods, in the event that I miss a scheduled medical or other type of appointment related to my HIV care.

I can withdraw this agreement at any time by informing all referred agencies. I have the right to know what information has been shared, why, when and with whom it was shared. If I ask, each agency will show me this information. All agencies selected can accept a copy of this form as a valid consent to share information. If I do not sign this form, information will not be shared and I will have to contact each agency individually to provide my information. However, I understand that treatment and services cannot be conditioned upon whether I sign this agreement.

Client Signature: _____ **Agreement Date:** __/__/__

Section C: Client Information

Current Gender:

☐ Male
☐ Female
☐ Transgender-M to F
☐ Transgender-F to M
☐ Other, Specify: _____
☐ Declined

Race:

☐ Black/African American
☐ White
☐ Asian/Hawaiian/Pacific Islander
☐ American Indian/Alaska Native
☐ Other, Specify: _____
☐ Declined

Ethnicity:

☐ Hispanic
☐ Non-Hispanic
☐ Declined

Testing/Diagnosis Information:

HIV ☐ Negative **Negative Test Date**: __/__/__
☐ HIV Positive **First Diagnosis Date**: __/__/__
☐ Hepatitis C (HCV) **Diagnosis Date**: __/__/__

COORDINATION OF CARE AND SERVICES AGREEMENT

Confidential Information *(Check all that Apply)*

Allowed to be Shared:

☐ Contact Information
☐ Medical Diagnoses
☐ Demographic Information
☐ Medical Appointments
☐ Testing Information
☐ Financial Information
☐ Individual Services Plan
☐ Mental Health Diagnosis/Treatment
☐ Diagnosis/ Pre-Exposure Prophylaxis (PrEP)
☐ Medical Care
☐ Other Core
☐ Mental
☐ Substance Abuse
☐ Other Services, Specify:
Treatment Non-occupational Post-Exposure Prophylaxis (nPEP)

May be Released to:

☐ Providers
☐ Medical Services
☐ Health/Substance Abuse Services
☐ Medication Access

Approved Contact Methods *(Check all that apply)*:

☐ In Person *(at the address below)*

Street Address **City** **State** **Zip Code**

☐ Postal Mail/Letter *(at the address below, if different than above)*

Street Address **City** **State** **Zip Code**

☐	Home Phone: _____	May we leave a message?	Yes	No	☐	☐
☐	Cell Phone: _____	May we leave a message/text message?	Yes	No	☐	☐
☐	Work Phone: _____	May we leave a message?	Yes	No	☐	☐
☐	Email:					

Section D: Linkage to Care and Services

Agency Linking Client to Care and Services *(may be the same as the originating agency):*

Linkage Agency Name: _____ **Phone Number:**

Personnel Name: _____ **Secure Fax Number:**

☐ Client is already in medical care but would like coordination of other services

ACTION: FAX ENTIRE FORM TO THE AGENCY ABOVE IF REFERRING TO AN EXTERNAL AGENCY FOR LINKAGE SERVICES

Section E: Referrals to Care and Services and Confirmation of Linkage

*If your agency has received a referral for linkage services **OR** if you are the original agency who will also be providing linkage services for the client, please complete this section:*

(REQUIRED) Medical Care Referral: *(If client is already in medical care then list current medical provider)*

Medical Agency: _____ Date of Referral: __/__/

Medical Provider:_____ Appointment Date: __/__/

Date Attendance Verified: __/__/

Other Service Referrals:

Type of Referral: _____ Date of Referral: __/__/

Agency Referred to: _____ Appointment Date: __/__/

Type of Referral: _____ Date of Referral: __/__/

Agency Referred to: _____ Appointment Date: __/__/

Type of Referral: _____ Date of Referral: __/__/

Agency Referred to: _____ Appointment Date: __/__/

ACTION: PLEASE SECURELY FAX ALL COMPLETED FORMS TO THE ORIGINATING AGENCY (IF APPLICABLE) AND TO THE VDH CENTRAL OFFICE AT (804) 864-7970

Notes/Comments:

Virginia Department of Health, Division of Disease Prevention Testing and Treatment History

(Circle one): Interview / Medical Chart Review **Health District** _____ **Worker #** _____

Internal Use Only-Source: 1-Provider Report;4-NHM&E; 5-Other

DDP Internal Use Only: eHARS State No:

Please print clearly

1. Today's Date: /____/____ Patient Name_____DOB: _____/____/____

~~Testing History~~ ~~2.~~

Have you ever had a positive HIV test before this test? (Circle one)

a) No b) Yes c) Unknown

3. What is the date of your **FIRST** positive HIV test? (List when you got tested, not when you got your results)

_____/ (month/year)

For DDP Internal Use Only
Doc Source Code: A0_____
Report Medium: _____

4. Have you ever had a **negative** HIV test? (Circle one)

a) No b) Yes c) Unknown

If yes**,** when was your last negative HIV test _____/_____(month/year)

*Test Type: □ Rapid □ HIV-1/2 IA □ HIV Ag/Ab □ HIV-1/2 Ab Differentiation □ HIV-1 NAT, Qualitative

**Facility Type / Location (City / State): _____

□

5. How many **negative** HIV tests did you have in the 24 months prior to your **FIRST** positive test (refer to date in question 3)

(*Exclude any Indeterminate, Inconclusive or Unknown tests; Exclude undetectable viral load tests)

Medication/Treatment History

6. Have you ever taken any antiretroviral medicines to treat or prevent HIV or Hepatitis? (Circle one)

a) No b) Yes c) Unknown

If NO, STOP. You are done with the questionnaire. If YES, please answer reason for ARV use (select all that apply):

❑HIV Tx ARV Meds: _____ Date Began: _____ Date of last use: _____
❑PrEP ARV Meds: _____ Date Began: _____ Date of last use: _____
❑PEP ARV Meds: _____ Date Began: _____ Date of last use: _____
❑PMTCT ARV Meds: _____ Date Began: _____ Date of last use: _____
❑HBV Tx ARV Meds: _____ Date Began: _____ Date of last use: _____
❑Other (e.g., HCV Tx):
_____ ARV Meds:
_____ Date Began: _____ Date of last use: _____

**PrEP = Pre-exposure prophylaxis; PEP = Post exposure prophylaxis; PMTCT = Prevention of Mother to Child Transmission; HBV Tx = Hepatitis B treatment; HCV Tx =Hepatitis C Tx*

*Facility Types:

STD	ATS	Jail/Prison	FP	GYN	Peds
Outreach	Field	Job Corp	Private MD	Hospital	Refugee
Immigration	Other:	Student HC	Drug Tx Ctr	OB/Prenatal	Teen Hlt Ctr	Blood donor

_____

Any Additional Pertinent Information (patient unable to locate, tested in another state, etc.):

Please mail white copy to the Central Registry Unit and file yellow copy with local records.

Virginia Department of Health
ATTN: HIV Incidence Program
PO Box 2448
Richmond, Virginia 23218

Place Barcode Sticker Here (if applicable):

Revised January 2018

MAIL THE TOP TWO COPIES TO YOUR LOCAL HEALTH DEPARTMENT

VIRGINIA DEPARTMENT OF HEALTH
Confidential Morbidity Report

Patient's Name (Last, First, Middle Initial):

SSN: _____-_____-_____

Home #: ( ) _____-_____

Patient's Address (Street, City or Town, State, Zip Code):

Work #: ( ) _____-_____

City or County of Residence

Date of Birth: (mm/dd/yyyy) | Age: | Race: ☐ American Indian/Alaskan Native ☐ Asian ☐ Black/African American ☐ Hawaiian/Pacific Islander ☐ White ☐ Unknown | Hispanic: ☐ Yes ☐ No | Sex: ☐ F ☐ M

DISEASE OR CONDITION:

Pregnant: ☐ Yes ☐ No ☐ Unknown

Death: ☐ Yes ☐ No

Death Date:

Date of Onset: | Date of Diagnosis: | Influenza: (Report # and type only. No patient identification) Number of Cases: Type, if Known:

Physician's Name: Phone #: ( ) _____-_____

Address:

Hospital Admission: ☐ Yes ☐ No Hospital Name:

Date of Admission: Medical Record Number:

Laboratory Information and Results

Source of Specimen: | Date Collected:

Laboratory Test(s) and Finding(s):

Name/Address of Lab:

CLIA Number:

Other Information

Comments: (e.g., Risk situation [food handling, patient care, day care], Treatment [including dates], Immunization status [including dates], Signs/Symptoms, Exposure, Outbreak-associated, etc.)

Name, Address, and Phone Number of Person Completing this Form:

Date Reported:

Check here if you need more of these forms, or call your local health department. (Be sure your address is complete.) ☐

For Health Department Use

Date Received:

VEDSS Patient ID:

Please complete as much of this form as possible Form Epi-1, 10/2011 **MAIL THE TOP TWO COPIES TO YOUR LOCAL HEALTH DEPARTMENT**

Please report the following diseases (and any other disease or outbreak of public health importance) in the manner required by Sections 32.1-36 and 32.1-37 of the *Code of Virginia* and 12 VAC 5-90-80 and 12 VAC 590-90 of the Board of Health *Regulations for Disease Reporting and Control*. Enter as much information as possible on the reporting form.

Acquired immunodeficiency syndrome (AIDS)
Amebiasis *

ANTHRAX * I
Arboviral infection (e.g., dengue, EEE, LAC, SLE, WNV) *
BOTULISM *

BRUCELLOSIS * I
Campylobacteriosis *
Chancroid *
Chickenpox (Varicella) *
Chlamydia trachomatis infection *

CHOLERA * I
Creutzfeldt-Jakob disease if <55 years of age *
Cryptosporidiosis *
Cyclosporiasis *

DIPHTHERIA * I
DISEASE CAUSED BY AN AGENT THAT MAY HAVE
BEEN USED AS A WEAPON
Ehrlichiosis/Anaplasmosis *
Escherichia coli infection, Shiga toxin-producing *

I ^
Giardiasis *
Gonorrhea *
Granuloma inguinale
HAEMOPHILUS INFLUENZAE INFECTION,

INVASIVE * I
Hantavirus pulmonary syndrome *
Hemolytic uremic syndrome (HUS)
HEPATITIS A *
Hepatitis B (acute and chronic) *
Hepatitis C (acute and chronic) *
Hepatitis, other acute viral
Human immunodeficiency virus (HIV) infection *
Influenza * #
(report INFLUENZA A, NOVEL VIRUS

immediately) I
INFLUENZA-ASSOCIATED DEATHS IN CHILDREN <18
YEARS OF AGE
Lead, elevated blood levels *
Legionellosis *
Leprosy (Hansen disease)

Listeriosis * I
Lyme disease *

Lymphogranuloma venereum
Malaria *
MEASLES (RUBEOLA) *

MENINGOCOCCAL DISEASE * I

MONKEYPOX *
Mumps *
MYCOBACTERIAL DISEASES (INCLUDING AFB),

I (IDENTIFICATION OF ORGANISM) AND DRUG SUSCEPTIBILITY
Ophthalmia neonatorum
OUTBREAKS, ALL (including, but not limited to, foodborne, healthcare-associated, occupational, toxic substance-related and waterborne)
PERTUSSIS I*
PLAGUE I
POLIOVIRUS INFECTION, INCLUDING

POLIOMYELITIS * I
PSITTACOSIS *

Q FEVER * I
RABIES, HUMAN AND ANIMAL *
Rabies treatment, post-exposure
RUBELLA, INCLUDING CONGENITAL RUBELLA SYNDROME *

Salmonellosis * I
SEVERE ACUTE RESPIRATORY SYNDROME (SARS) *

Shigellosis * I
SMALLPOX (VARIOLA) *
Spotted fever rickettsiosis * *Staphylococcus aureus* infection invasive methicillin-resistant (MRSA) * and vancomycin-intermediate or vancomycin-resistant * Streptococcal disease, Group A, invasive I or toxic shock * *Streptococcus pneumoniae* infection, invasive, in children <5 years of age *
Syphilis (report PRIMARY and SECONDARY immediately) *
Tetanus
Toxic substance-related illness *
Trichinosis (Trichinellosis) *

TUBERCULOSIS (TB), ACTIVE DISEASE * I
Tuberculosis infection in children <4 years of age
TULAREMIA *

TYPHOID/PARATYPHOID FEVER * I
UNUSUAL OCCURRENCE OF DISEASE OF PUBLIC HEALTH CONCERN

VACCINIA, DISEASE OR ADVERSE EVENT *
VIBRIO INFECTION *
VIRAL HEMORRHAGIC FEVER *
YELLOW FEVER *
Yersiniosis * ¶

Report all conditions to your local health department when suspected or confirmed. Those in UPPER CASE must be reported immediately by the most rapid means available. All others must be reported within 3 days.

* These conditions are reportable by directors of laboratories. In addition, these and all other conditions except mycobacterial disease (other than TB) and invasive MRSA infection are reportable by physicians and directors of medical care facilities. Reports may be by computergenerated printout, Epi-1 form, CDC surveillance form, or upon agreement with VDH, by means of secure electronic transmission.

¶ A laboratory identifying evidence of these conditions shall notify the health department of the positive culture and submit the initial isolate to the Virginia Division of Consolidated Laboratory Services (DCLS) or, for TB, to DCLS or other laboratory designated by the Board.

^ Laboratories that use a Shiga toxin EIA methodology but do not perform simultaneous culture for Shiga toxin-producing *E. coli* should forward all positive stool specimens or positive enrichment broths to DCLS for confirmation and further characterization.

Physicians and directors of medical care facilities should report influenza by number of cases only (report total number per week and by type of influenza, if known); however, individual cases of influenza A novel virus must be reported immediately by the most rapid means available.

Note: 1. Some healthcare-associated infections are reportable. Contact the VDH Healthcare-Associated Infections Program at (804) 864-8141 or see 12 VAC 5-90-370 for more information.

2. Cancers are also reportable. Contact the VDH Virginia Cancer Registry at (804) 864-7866 or see 12 VAC 5-90-150-180 for more information.

Virginia Department of Health
Office of Epidemiology
P. O. Box 2448, Suite 516-East
Richmond, Virginia 23218-2448

VDH VIRGINIA DEPARTMENT OF HEALTH
Protecting You and Your Environment
www.vdh.virginia.gov

Attachment L

PARTNER ELICITATION INTERVIEWING SKILLS INVENTORY

Interviewing Skills Individual Feedback Record

Observation Date _____

Name of Test Counselor _____

Name of Observer _____

How did the Test Counselor perform in the following areas?

Write N/O (not observed) in the satisfactory column if the interview did not present an opportunity to observe the skill.

Communication	Needs Improvement	Satisfactory	Excellent
1. Demonstrates professionalism			
2. Establishes rapport			
3. Listens effectively			
4. Uses open-ended questions			
5. Communicates at the patient's level of understanding			
6. Gives factual information			
7. Solicits patient feedback			
8. Uses reinforcement			
9. Uses appropriate nonverbal communication			

Observations: _____

_____

_____

_____

Recommendations: _____

_____

_____

_____

INTERVIEWING SKILLS INVENTORY (*continued*)

Problem Solving	Needs Improvement	Satisfactory	Excellent
10. Recognizes verbal problem indicators			
11. Recognizes nonverbal problem indicators			
12. Verifies the meaning of recognized problem indicators			
13. Assertively confronts problems communicated by patients			
14. Resolves patient problems			
15. Uses STD motivations			
16. Motivates clearly and convincingly			
17. Emphasizes confidentiality			

Analytical Capabilities	Needs Improvement	Satisfactory	Excellent
18. Computes and uses interview periods			
19. Recognizes exposure gaps			
20. Determines investigative priorities			
21. Recognizes discrepancies in patient responses			

Observations: _____

_____

_____

_____

Recommendations: _____

_____

_____

_____

Disease Intervention Behaviors	Needs Improvement	Satisfactory	Excellent
22. Emphasizes sex partner referral			
23. Tactfully persists to identify all at-risk sex partners			
24. Pursues detailed locating/identifying information on sex partners			
25. Emphasizes appropriate risk reduction behaviors			
26. Conveys a sense of urgency			
27. Establishes specific contracts and coaches patients			
28. Pursues timely reinterviews with a plan			
29. Follows interview format			

Observations: _____

_____

_____

_____

_____

_____

Recommendations: _____

_____

_____

_____

_____

_____

Final Determination

☐ This counselor is competent to conduct partner elicitation interviews.

☐ This counselor is **not** competent to conduct partner elicitation interviews.

RSPC Signature: _____

Supervisor Signature: _____

Attachment M

Local Health Department Referral Template

[print on agency letterhead]

To Whom It May Concern:

The purpose of this form is to document that the client listed below was served by [agency name], and is being referred to the [health department name] for further screening and/or treatment for reportable health conditions. This client should be exempted from billing requirements under referral code LDEPIR.

Date of Service at [agency name]:_____
(mm/dd/yyyy)

Client Name:_____
(print)

Client Date of Birth:_____

[agency name] Staff Name:_____
(print)

[agency name] Staff Signature:_____
(sign)

[agency name] Staff Title:_____

Date of Staff Signature:_____
(mm/dd/yyyy)

Health Department Staff: Please refer questions about this form to Caroline Campbell at 804864-7978 or caroline.campbell@vdh.virginia.gov.

Attachment N

Agency:	Site:	CLIA#

Rapid HIV Test Result Log

Client Identification	Room Temp.	Date Specimen Collected	Time Specimen Collected*	Pouch Lot#	Pouch Expiration Date	Test Result**	Staff Initials	Report Time***

* Interpret each test within the window allotted below
    Determine (read time: 20 minutes) – do not interpret test after 30 minutes
    INSTI (read time: 1 minute) – do not interpret test after 5 minutes

** Results: Nonreactive (N), Antigen-only reactive (Ag), Antibody reactive (Ab), Antigen and antibody reactive (Ag/Ab), Invalid (I)

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

Attachment O

Personnel Responsibilities

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

Personnel Responsible for QA

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

Test Kit Storage

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

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

Monitoring Test Kit Inventory

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

Receive Test Kit Delivery

Responsibilities	[Describe actions here (e.g., receives boxes, records on inventory log with initials, writes delivery date on box, stores in cabinet, etc.)]
When	[Describe when shipment arrives.]
By Whom	[Insert name and/or position here of the person responsible for this activity.]
Corrective Action(s)	[Describe problem-solving action here – e.g., if delivery doesn't match order, if units are expired, etc. – refuse delivery? Contract supervisor? Contact manufacturer?]

Next Inventory Process Item

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

Monitoring Test Kit Storage Area Temperature

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

Test Kit Temperature Monitoring

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

Monitoring Control Unit Storage Area Temperature

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

Control Unit Temperature Monitoring

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

Running External Quality Controls

External quality controls will be run according to the manufacturer's instructions. Results will be recorded on the "External Kit Control Log" (**Attachment M**).

External Controls: New Setting/Change of Conditions

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

External Controls: New Shipment/Lot

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

External Controls: Periodic Intervals

Responsibilities	Run controls every 25 tests based on Rapid Test Daily Log and record on external quality control log.
When	Every 25 rapid tests
By Whom	[Insert name and/or position here of the person responsible for this activity.]
Corrective Action(s)	[Describe corrective action here - e.g., if controls fail, discontinue client testing, report to supervisor, enter actions taken in troubleshooting log for each step to resolution, etc.]

External Controls: Suspected Test Kit Failure

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

Storage

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

Review of QA Documentation

Initial Review of QA Documentation

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

Final Review of QA Documentation

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

Updating QA Plan

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

Update QA Plan

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

Review Update QA Plan

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

Rapid HIV Test Activities Skills Inventory

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

Safety

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

OSHA Bloodborne Pathogen Training

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

HIPAA Training

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

Biohazard Waste Management Disposal

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

Exposure Control Plan at Each Testing Site

Responsibilities	Ensure that a completed copy of the Exposure Control Plan is located at each testing site and that each testing counselor signs an acknowledgement that they receive a personal copy of the Exposure Control Plan.

When	Before testing begins at each site, and counselors shall receive a copy before initiating their first rapid test.
By Whom	[Insert name and/or position here of the person responsible for this activity.]
Corrective Action(s)	[Describe corrective action here.]

Hepatitis B Vaccine

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

Attachment P

Agency Quality Assurance Standards

The following should be adapted to meet the specific needs of each agency and submitted for VDH approval.

Rapid HIV Test Exposure Control Plan

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

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

Gloves shall be worn:

- When touching blood, body fluids requiring Universal Precautions, 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 shall be changed after contact with each client. Hands and other skin surfaces shall be washed immediately with soap if contaminated with blood or body fluids. Hands shall be washed immediately after gloves are removed.
- Use gloves in situations where hands shall become contaminated with blood or other body fluids that require Universal Precautions.
- Use gloves for performing fingersticks.
- Use gloves when handling the rapid test device during testing. Masks and protective eyewear or face shields shall be worn to prevent exposure of the mucous membranes of the mouth, nose, and eyes where droplets of blood or body fluids are likely to be generated. Gowns or aprons shall be worn during procedures that are likely to generate splashes of blood or body fluids requiring Universal Precautions. General infection control practices shall further minimize the already minute risk for salivary transmission of HIV. These infection control practices include the use of gloves for contact with mucous membranes and hand washing after exposure to saliva. Hand-washing facilities shall be made available to the employees who are exposed to blood or other potentially infectious materials. OSHA requires that these hand-washing facilities be readily available after exposure. If hand-washing facilities are not feasible, (Insert 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 devices are processed, employees are not to eat, drink, apply cosmetics or lip balm, smoke, or handle contact lenses. 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.

A warning label that includes the universal biohazard symbol followed by the term "biohazard," must be included on bags/containers of contaminated laundry; on bags/containers of regulated waste; on refrigerators and freezers that are used to store blood or OPIM; and on bags/containers used to store, dispose of, transport, or ship blood or OPIM (e.g., specimen containers). In addition, contaminated equipment which is to be serviced or shipped must have a readily observable label attached which contains the biohazard symbol and the word "biohazard" along with a statement relating which portions of the equipment remain contaminated.

Implementation of Safer Medical Devices

The Needlestick Safety and Prevention Act was signed into law on November 6, 2000, in response to the advances made in technological developments that increase employee protection. Safer medical devices replace sharps with non-needle devices or incorporate safety features designed to reduce the likelihood of injury. Safer medical devices that are appropriate, commercially available, and effective shall be utilized. An effective, safer medical device is one that, based on reasonable judgment, will decrease the risk of an exposure incident involving a contaminated sharp. Since different employees may be 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. Only single-use devices may be used.

Safety Procedures

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

Personal Protective Equipment

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

Personal Protective Equipment Accessibility

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

Personal Protective Equipment Cleaning and Disposal

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

Gloves

Gloves shall be worn where it is reasonably anticipated that employees will have hand contact with blood, other potentially infectious materials, non-intact skin, and mucous membranes; when performing fingersticks; handling used rapid test devices or controls; 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 after each client, and as soon as practical when they become torn, punctured, or when their ability to function as a barrier is compromised.

Eye and Face Protection

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

Housekeeping Procedures

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

Disposal of all regulated waste shall be in accordance with applicable federal, state and local regulations, and follow the (Insert 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 colorcoded. 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. Sharps containers shall not be opened, emptied, or cleaned. Other regulated waste shall be placed in containers that are closable and constructed to contain all contents and prevent leakage of fluids during handling, storage, transportation or shipping. The waste shall be labeled or color-coded and closed before removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping. Each employee shall ensure biohazard labels are affixed to containers of regulated wastes, and refrigerators containing blood and other potentially infectious materials (including test kit controls). The universal biohazard symbol shall be fluorescent orange or orange-red. Red bags or containers shall substitute for labels; however, regulated waste shall be handled in accordance with the rules and regulations of Virginia Department of Health.

Hepatitis B Vaccination and Testing of Immunity

Hepatitis B vaccine and vaccination series shall be made available to all (Insert Agency Name) employees that provide community-based counseling and testing. (Insert Agency Name) shall ensure that the hepatitis B vaccine and vaccination series are made available at no cost to the employee. The hepatitis B vaccination will be made available: 1) after the employee has received the blood borne pathogen training; 2) within ten (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 later decides to accept the vaccination, the vaccination shall be made available. All employees who decline the hepatitis B vaccination shall sign the OSHA-required waiver, indicating refusal. If the U.S. Public Health Service recommends a routine booster dose of hepatitis B vaccine at a future date, such booster shall be made available at no cost to the employee.

Post-Vaccination Testing of Immunity

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

Post-Exposure Evaluation and Follow-Up

Following the report of an exposure incident, the exposed employee shall seek medical evaluation immediately for the post-exposure evaluation. Please see (Insert 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 shall be addressed by the licensed healthcare professional evaluating the exposure incident.

OSHA Training

All employees shall receive the OSHA blood borne pathogen exposure training annually.

Attachment Q

Agency: Site: CLIA#

Rapid HIV Test Kit Storage Temperature Log

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

Thermometer location: _____

Month/year:_____/____

Acceptable temperature ranges: Determine: 36-86°F (2-30°C)
INSTI: 59-86°F (15-30°C)

Date/Time	Temperature (Indicate C or F)	Corrective action taken when temperature is out of range	Storage Location	Initials

Initial Review _____ Final Review _____

(signature) (signature)

Attachment R

Agency: Site: CLIA#

Test Kit Control Storage Temperature Log

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

Thermometer location: _____

Month/year:_____/_____

Acceptable temperature ranges: Determine: 36-46°F (2-8°C)
INSTI: 36-46°F (2-8°C)

Date/Time	Temperature (Indicate C or F)	Corrective action taken when temperature is out of range	Storage Location	Initials
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Initial Review _____ Final Review _____

(signature) (signature)

Attachment S

Agency:

CLIA#

External Kit Control Log

Date	Brand & Lot Number	Temp (ºf/ºc)	Test Start Time	Test Read Time	Sample Validated (Circle all samples that yielded expected result)	Staff Initials
					HIV-1 Ag | HIV-1 Ab | HIV-2 Ab | NR	
					HIV-1 Ag | HIV-1 Ab | HIV-2 Ab | NR	
					HIV-1 Ag | HIV-1 Ab | HIV-2 Ab | NR	
					HIV-1 Ag | HIV-1 Ab | HIV-2 Ab | NR	
					HIV-1 Ag | HIV-1 Ab | HIV-2 Ab | NR	
					HIV-1 Ag | HIV-1 Ab | HIV-2 Ab | NR	
					HIV-1 Ag | HIV-1 Ab | HIV-2 Ab | NR	
					HIV-1 Ag | HIV-1 Ab | HIV-2 Ab | NR	
					HIV-1 Ag | HIV-1 Ab | HIV-2 Ab | NR	
					HIV-1 Ag | HIV-1 Ab | HIV-2 Ab | NR	
					HIV-1 Ag | HIV-1 Ab | HIV-2 Ab | NR	
					HIV-1 Ag | HIV-1 Ab | HIV-2 Ab | NR	
					HIV-1 Ag | HIV-1 Ab | HIV-2 Ab | NR	

					HIV-1 Ag | HIV-1 Ab | HIV-2 Ab | NR	

*****HIV-1 Ag control only run on Determine.

Attachment T

Rapid HIV Test Problem Documentation

Date	Initials	Lot #	Expiration Date	Problem	Corrective Action Taken
