



**VIRGINIA DEPARTMENT OF HEALTH
DIVISION OF DISEASE PREVENTION**

Policies & Procedures for HIV Testing

and

Quality Assurance in HIV Testing Programs

2016 Edition

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INTRODUCTION

This document is comprised of two manuals which outline 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 which receive support (financial or material) from the Division of Disease Prevention (DDP).

HIV testing programs which 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 procedures for three HIV test technologies that have been approved for use in HIV testing programs supported by DDP:

- OraQuick Advance Rapid HIV-1/2 Antibody Test.
- Clearview HIV 1/2 Stat-Pak
- Clearview Complete HIV 1/2

The first section in this document is *Policies & Procedures for HIV Testing*. This section describes policies that DDP-supported HIV testing programs (clinical and nonclinical) are required to adopt, as well as processes used to order supplies, mail test forms, report positive test results, and enter data in e2Virginia, the data system DDP uses to record and monitor HIV testing activities.

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 nonclinical programs. Clinical sites include hospital emergency departments, urgent care clinics, inpatient services, substance abuse treatment clinics, public health clinics, community clinics, correctional health-care facilities, and primary care settings, any of which may be public or private. Nonclinical sites include community based settings that cannot offer testing through venous blood draw.

QA refers to planned, ongoing, step-by-step activities designed to ensure that: HIV testing is being performed correctly; results are accurate and reliable; and errors are found and corrected. QA activities should be in place during the entire testing process, from the time a client requests a rapid HIV test until the time the results are provided.

SECTION I

POLICIES AND PROCEDURES FOR HIV TESTING

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

After completing the three courses, staff members and volunteers are required to participate in a competency assessment (**Attachment A**). New test counselors should also review the manuals provided in this document. This ensures that the test counselors have obtained the competencies necessary for HIV testing, and also that they are familiar with VDH protocols and procedures. Staff unprepared to deliver a preliminary positive result should not conduct testing and should be given other functions during testing events.

In addition to a competency assessment, test counselors must also review and sign a confidentiality agreement that can be found at http://www.vdh.virginia.gov/content/uploads/sites/10/2016/01/DDP_Security_and_Confidentiality_Policies_and_Procedures.pdf, page 48. Signed agreements must be submitted to the Testing Specialist before performing any testing. Competency assessments and signed confidentiality agreements for each test counselor should be kept in their personnel or volunteer file. Copies may also be kept in the HIV Testing Manual for easy access during a site review. The Agency HIV Testing Coordinator must keep each testing counselor's training certificates on file.

For questions regarding the *HIV Prevention Counseling Series*, please contact your local VHARCC site using the information listed below. Training schedules can be accessed online (www.VHARCC.com).

Eastern Virginia:

Eastern Virginia Medical School

Tanya Kearney

(757) 446-6170

Kearnatk@evmes.edu

Southwest and Central Virginia:

Virginia Commonwealth University HIV/AIDS Center
Johanna McKee
(804) 828-2210
jmckee2@mcvh-vcu.edu

Northern and Northwest Virginia:

Inova Juniper Training Program
Leigh Guarinello
(703) 321-2600
Leigh.Guarinello@inova.org

For CDC guidelines for HIV testing in nonclinical settings, see [Implementing HIV Testing in Nonclinical Settings: A Guide for HIV Testing Providers](#). For CDC guidelines for effective interventions, see <https://effectiveinterventions.cdc.gov/>.

VDH Testing Requirements

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 has a variety of options available to clients to make testing a routine part of their healthcare. Our testing options reflect DDP's "No Wrong Door" philosophy. Testing options include rapid-rapid testing (see **Attachment B**), couples testing (<http://www.vdh.virginia.gov/epidemiology/DiseasePrevention/Programs/HIVPrevention/index.htm#CouplesCounseling>), testing in clinical and nonclinical settings, pharmacy-based testing, as well as strategies that target high risk populations, such as social network strategies. Oral fluid testing is no longer a recommended testing methodology by the CDC.

DDP requires that all supported HIV testing programs maintain a minimum positivity determined by the category of VDH's cooperative agreement with the CDC. The minimum positivity rate for programs supported by Category A or special funding is 1%; the minimum positivity rate for programs supported by Category B is 2%.

To meet these requirements, testing should be focused on the highest risk populations, including Men who have Sex with Men (MSM), Injection Drug Users (IDU), and transgender persons. Targeted testing should also be provided to populations disproportionately impacted by HIV, including Blacks and Latinos, and persons living in low income or high prevalence areas. Clients with extremely high risk (i.e., unprotected sex with an HIV positive person in the past three months, or possible symptoms of acute infection) may be tested, but should also be referred to a health department for a lab based 4th generation HIV test. Staff should also conduct outreach (online and in the community) as a way to recruit clients for testing.

Agencies not meeting the target positivity rates should carry out additional activities to increase identification and testing of HIV positive persons, and discuss strategies with their VDH Testing Specialist. Agencies are also encouraged to review testing data against local HIV prevalence data to ensure that testing is provided to the right populations in the right geographic areas. Testing may be expanded and offered to the public for events such as: National HIV Testing Day,

National Black HIV/AIDS Awareness Day, and National Latino AIDS Awareness Day. Agencies should consider how large testing events will impact the overall required 1% positivity rate of the agency and proceed accordingly. Contractors may collaborate with other organizations for special testing events; however, contractors may not give away or loan test kits to these organizations and must have staff present to provide counseling and administer tests at any collaborative event.

If contractors plan to test in correctional facilities, a Letter of Agreement must be obtained 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 Susan Carr at (804) 864-8023.

Rapid testing must be conducted in a controlled, stable environment so as to assure basic minimum QA standards. Clients must be tested in a confidential manner, and in a location that provides privacy.

Agencies offering incentives for HIV testing must track the incentives and retain a log that can be accessed during site visits. Agencies offering incentives for testing must obtain prior approval from VDH.

All DDP-supported HIV testing programs must conduct supplemental testing or have an approved written protocol for linking clients to supplemental testing at a local health department.

Competency Assessment

Before someone is permitted to perform testing alone for the first time, his or her ability to conduct the test needs to be demonstrated and documented by a person competent in testing procedures. A supervisor's signature on the training form is required and the form needs to be kept in a personnel file and available on site for review. New staff must perform proficiency testing six months after the initial test and yearly after that (see **Attachment A**). The assessment can be carried out in many ways, but regardless of the method, every task a tester is responsible for needs to be evaluated.

A supervisor or trainer performs the assessment and may use a combination of methods to determine competency. Examples of these methods are presented below.

To assess task performance before testing, staff should be able to:

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

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

- Observe how the test is performed for a client. Explain to the client that the tester is being observed by someone in the agency for quality review. In the event that the client declines, have the staff observed through role play.

- Observe the staff member performing the fingerstick, collecting the blood on a test loop and placing it into the testing vial, or assess their instructions to the client on collecting the oral specimen.
- Evaluate the use of universal or standard precautions and procedures for biohazard and sharps (e.g., lancets, needles) disposal.
- Review results obtained on a panel of referenced specimens that show a range of results, such as five specimens that include nonreactive, weakly reactive, and reactive results. Use the controls supplied by the manufacturer as a source of the specimens in the panel.
- Appraise the individual's ability to interpret results. This might include using previously used test devices or pictures of devices that show nonreactive, weakly reactive, reactive, and invalid results.

To assess task performance after testing:

- Review test records and quality control results documentation.
- Observe giving the test results to the client (if trainee's responsibility).
- Observe venous blood and/or oral fluid specimen collection. If an agency does not test frequently, the trainee can be observed collecting blood and/or oral fluid from a staff volunteer. Verify that confidentiality is maintained.

Additional Requirements

If a client requests written test results, the approved VDH form must be used (**Attachment C**). Written results may not be routinely offered but may be provided upon request.

Staff must offer the client the appropriate manufacturer's rapid HIV test subject information pamphlet. Staff that provides testing needs to read and understand the manufacturer's instruction booklet.

A testing site will evaluate the physical space and client flow on a periodic basis. This evaluation can identify potential problems like privacy concerns, cleanliness, and client comfort before becoming barriers to successful testing.

Each testing program will: have a completed Agency QA Standards Document, including a written Rapid HIV Test Exposure Control Plan; hold new employee training within one month of hire; offer HAV/HBV vaccination, and; will ensure that all testing staff receive annual OSHA updates (**Attachment D**).

Staff will offer the appropriate level of prevention counseling to all clients receiving testing (please reference "[Implementing HIV Testing in Nonclinical Settings: A Guide for HIV Testing Providers](#)" for specific information).

Each site shall have a method to detect and document problems that occur at any point in the testing process, especially those that will affect the accuracy of the test results.

Conflict of Interest

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”. An HIV test form must be completed for all tests.

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

Age Requirements

HIV testing sites supported by DDP may provide 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 VDH Testing Specialist.

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 local health department for a blood draw.

Refusing Service

Agencies should not provide testing to anyone who meets the following criteria*:

- Children under the age of 13.
- 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 delayed and cannot give informed consent.
- Persons who are employed by the agency providing testing.

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 Heather Bronson (804) 864-8020 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 confirmatory test need not be conducted. In such a case, agencies will contact their VDH Testing Specialist to advise that the client is already aware of their status and should not be contacted by health department representatives.

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

Location Requirements

Venues appropriate for testing vary according to the program funding category. Programs receiving Category B funding may provide testing at clinical sites, see page one for clinical site examples. Programs receiving Category A or special funding may not provide testing at clinical sites, especially those already offering HIV testing, without expressed permission from the Community HIV Testing (CHT) Coordinator. Special exceptions may be made for sites that partner with local health departments to offer after-hours testing opportunities to marginalized groups (i.e., MSM, IDU, or transgender risk categories).

All testing sites must have a copy of the original CLIA Certificate of Waiver. The most current/valid CLIA certificate must be displayed at the agency's main headquarters. Copies must be available at satellite sites (including one-time or temporary sites) in case of a surprise inspection.

All on and off-site testing areas must be climate controlled and ensure privacy and confidentiality for all clients presenting for services.

Anonymous Testing

Name based reporting is required in Virginia; therefore, anonymous testing is not permitted. Names and identifying information must be collected.

HIV Testing Procedures

Ensuring Confidentiality

To ensure confidentiality, follow the "three lock" rule by placing 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 needs to be available for use by the testing staff <http://www.pssl.com/Vaultz-VZ01045-Locking-Cd-Media-Binder-Holds-128>. If staff does not immediately return to the office, documents must remain in the physical presence of the responsible staff at all times. Confidential forms should never be left in a personal car or left unattended at any time.

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

Informed Consent

Community-based (nonclinical tests) sites should get written informed consent from each client before conducting an HIV test. Getting written consent in nonclinical test sites provides protection for both the client and the testing agency. While the Code of Virginia does not require separate written consent for HIV testing, clinical sites already obtain written consent for overall medical care and do not need separate written consent for HIV testing. To give informed consent, the client must (in both clinical and nonclinical settings) understand the purpose of the test, the meaning of a nonreactive or a reactive result, and be informed that they have the right to refuse testing.

When that is completed, the counselor should give the client a few minutes to review the Manufacturer's Subject Information Pamphlet and answer any questions. The counselor should then discuss with the client:

- The difference between rapid and conventional testing
- The difference between a screening and supplemental test
- The procedure for a nonreactive result and a reactive result

The client should be asked if they have any questions or concerns before continuing. If there are no questions, 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 C**).

Collect Client Information

It is critical that client information is collected for each testing event. The CDC uses the data for disease surveillance, epidemiological research, and for funding purposes.

The information that must be collected for all DDP-supported testing events is located in the section titled “Community HIV Testing Documentation” on page 12.

If the client does not identify with any of the given classes of race or ethnicity, the counselor should check “Declined” as their response.

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. 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 below.

If a client presents for testing and received a diagnosis in another state, the test counselor should collect the information listed on the “Verification of Previous Diagnosis Form” (**Attachment E**) and contact their DDP Testing Specialist.

Risk Assessment

Category A community-based testing sites and Health Department STD clinic counselors should conduct a brief risk assessment with each client who presents for testing.

Agencies should refer to the risk variables listed on the CTR test form (**Attachment F**). Risk information is vital to DDP’s ability to report accurate information regarding Virginia’s HIV epidemic.

In the event of a large-scale off-site testing event, counselors are still required to obtain risk for each client in order to complete the variables listed on the CTR test form.

Active Referral into Care for HIV Positive Clients

HIV testing sites are required to use active referral to HIV medical care for clients who receive a positive test result using the Coordination of Care and Services Agreement (CCSA) (**Attachment G**). The CCSA was developed by DDP to help testing sites facilitate referral either directly to care or, if available, to a program designed to help HIV positive individuals enter care (ARTAS, patient navigation, etc.). The CCSA should be faxed to the appropriate agency after completion, and the original should be stored with the client’s CTR test form.

Supported HIV testing programs are required to successfully link 85% of clients to care within 30 days of a presumptive diagnosis. “Linkage” is defined by the client having seen a physician who can prescribe ART, or having HIV-related lab work conducted (CD4, viral load).

When the client has successfully linked to care, the agency to which the HIV test counselor has referred their client will return the second page of the CCSA, completed to include the details of the client’s appointment. This should be stored with the original CCSA form in the client’s record.

Disease Intervention Specialists (DIS) may refer clients who receive a reactive test result 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 for record-keeping purposes.

Completing Documentation

Once the client has left, it is important to complete the test form, as well as any other documentation that may be relevant.

Counselors should review the test form, filling out information that they may have missed earlier and adding notations that could be helpful. At this time, the results of the test should be recorded on the test form.

- Agencies need to use the CTR test form 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 at 109 Governor Street, 2nd Floor, Richmond, Virginia 23219. If a client does not return for the test results or has not made an appointment for the results, the CTR test form should be mailed 30 days after the test event (see also page 13).
- A confidential morbidity report (Epi 1) should be submitted to the local health district within three days of a positive test result. The testing agency should detach and retain the bottom (pink) copy of the Epi 1 and submit the top two copies of the form. The testing agency must maintain a log or other mechanism to document that each positive test has been reported as required.
- An HIV Incidence (Testing and Treatment History or TTH) form shall be completed and submitted for all confirmed positive results within 30 days.

For information related to ordering CTR, TTH, or Epi 1 forms, see page 15.

Partner Elicitation Protocol (for participating agencies) & Partner Services

Through HIV Partner Services, individuals are confidentially informed of their possible exposure to HIV and offered testing. Partner Services, including Partner Elicitation (PE) services, is a case-finding activity conducted by a Disease Intervention Specialist at the local health department level. Partner Elicitation, as part of HIV Testing, is a one-on-one discussion conducted by DIS and participating community agencies with an HIV positive individual to identify their sex partners and needle sharing partners who may be at risk for HIV and to develop a plan for notifying those partners so they can be tested. For more information regarding Partner Services and Partner Elicitation contact Tammie Woodson at (804) 864-7979 or Tammie.Woodson@vdh.virginia.gov.

Notified partners who choose not to be tested (or are found to be uninfected), can receive counseling about reducing their risk to avoid future exposure to HIV. In addition to discussing traditional prevention methods, partners should be counseled on the possibility of taking pre-exposure prophylaxis or PrEP, a one pill a day regimen that has been proven to reduce the chances of HIV infection. If they are found to be HIV positive, they can be linked to services and be counseled on methods to prevent transmission of HIV to others and reduce the risk of becoming infected with other STDs.

Testing site staff is not, under any circumstances, to attempt to locate and contact partners. According to Virginia's Regulations for Reporting and Control, <http://www.vdh.virginia.gov/epidemiology/documents/pdf/regs.pdf> (page 18), only DIS may conduct partner location and notification activities and **only those agencies that have approval can participate in the PE process.**

Reporting & Virginia Law

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 reactive individual. A DIS 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.

Results, whether reactive or nonreactive, can legally be requested by the parent or the legal guardian of a client under the age of 18. The agency may not notify those individuals 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.

Agencies 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/>.

Laws Pertaining to HIV Testing, Consent, and Confidentiality

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/>.

And

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/>.

HIV Testing Documentation

Required Variables

Staff members are also responsible for collecting required variables, which are necessary to enter a test form into the data collection system. This data is then reported to CDC. If variables are missing, the form cannot be entered into the system. Examples of required variables include:

- Form ID
- Session Date
- Unique Agency Identification Number
- Program Announcement Number
- Site Type (system required)
- Site Zip Code (also system required)
- Year of birth (also system required)
- State (also system required)
- Ethnicity (also system required)
- Race (also system required)
- Current Gender ID (also system required)
- Assigned Sex at Birth
- Previous (900) Test
- Self-Reported Result
- Sample Date
- Test Election
- Test Technology
- Test Result
- Results Provided
- Date Results Provided
- If results not provided, why?
- Risk Factors
- Session Activity (Risk reduction plan only)
- CDC Use Fields
- Referrals

The form ID number from the CTR test form may be peeled off and placed onto all interagency forms for proper tracking before separating the two copies of the CDC form. The original (white copy) of the CTR test form is sent to VDH's CENTRAL REGISTRY UNIT at 109 Governor Street, 2nd Floor, Richmond, Virginia 23219 following the mailing requirement below. The carbon copy is retained by the agency.

Policy for Mailing Confidential Patient Information

VDH DPP programmatic forms [HIV Counseling, Testing and Referral (CTR test forms, Interview Records, Field Records), HIV Incidence, TTH forms] containing confidential patient information may be received through a secure mail system, provided the mailing is done in a confidential manner that meets or exceeds the following guidelines:

*Note: Use **two** envelopes when mailing any HIV/STD test related forms:*

- Forms should be placed inside the “first” or inner envelope and securely sealed with packaging tape. The envelope must protect contents from being read or viewed (a regular manila envelope will meet this requirement). The number of forms placed within the envelope may not exceed 1 inch stacked. The total number of forms being sent must be documented in the upper right corner on the outside of the inner envelope.
- The “second” or outer envelope must be made of a material that is tear, puncture, and moisture-resistant, such as Tyvek. DDP will provide these envelopes for use by HIV testing sites, STD Surveillance Network (SSuN) sites, and staff performing disease intervention activities.
- The recipient and sender name and address need to be placed on the inner envelope. DDP will provide local health districts, HIV testing sites, and SSuN sites with United Parcel Service (UPS) mailing labels for “return service.” The UPS label must be placed on the “second” or outer envelope. Double addressing gives an additional level of security that the envelope will reach the intended person/address.
- The frequency of mailing should be at least weekly, provided forms are complete. It is suggested that mailings be combined when activities are occurring in multiple clinics at the same location as long as the volume is less than 25 forms or 1 inch stacked. **HOWEVER, HIV COUNSELING, TESTING, AND REFERRAL FORMS MUST ALWAYS BE MAILED SEPARATELY.** If UPS service has not been established, you can call 1- 800-PICK-UPS® (1-800-742-5877). A fee may be charged.
- Protected health information including any of the following: client name, address, demographics, test results, etc., must not be communicated by email.

Documenting Positive Clients in e2Virginia

All clients who receive a preliminary positive result or presumptive HIV diagnosis must be entered in e2Virginia. The following information is required to enter a new client into the “Prevention” screen:

- Date of test
- Test result (preliminary, previous, confirmed)
- CTR test form number
- Client full name
- Client date of birth
- Client gender
- Client ethnicity
- Client race

If a client is entered as “Preliminary Positive”, the agency must update the client’s test result once their status is confirmed and a presumptive diagnosis is established.

System Access:

- To gain access you must complete the following forms to access the system:
 - e2Virginia System Access Request Form for Non-DDP Employees (**Attachment H**).
 - Verification of Receipt and Assurance of Key Requirements for Non-DDP Personnel (**Attachment I**).
- After completion and submission of the Verification and e2Virginia access request forms, you will receive an email from e2Virginia with instructions for logging into the system and creating a password.
- **Agencies must inform VDH about a user’s employment change within 24 hours so that access can be suspended. E-mail notification must be sent to VDH at support@e2virginia.com.**

Questions and Technical Assistance:

- For any questions related to e2Virginia, please email support@e2virginia.com or call 973-773-0244.
- For LKM and password reset assistance, please email VDH at support@e2virginia.com.

Record Storage and Retention Requirements

CHT documentation must be kept under VDH’s three lock rule, i.e., there must be three locks between the entrance of an agency and where confidential identifying information is stored (example: locked agency door, locked office, locked cabinet).

Contractors must retain original CTR test forms and other testing information containing patient identifiers for two years for negative results and ten years for positive results, after which the contractor may destroy 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 2016 would be kept for two years (January 1, 2017 through 2018) and can be shredded after

January 1, 2019. 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 shredding, pulping, burning, and overwriting or physically destroying media. Deletion of confidential or privacy-protected information in computer files or other electronic storage media is not acceptable. Records containing Social Security numbers must be destroyed in compliance with 17 VAC 15-120-30, follow link for full code:

<http://law.lis.virginia.gov/admincode/title17/agency15/chapter120/section30/>.

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 ten-year 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.

Ordering Forms, Supplies, and HIV Test Kits

When ordering forms, supplies, test kits or controls, please allow 7-9 business days for delivery. For a copy of the CTR order form, see **Attachment J**.

Epi 1 Forms	Kevin Jones	Kevin.Jones@vdh.virginia.gov	804-864-7994
TTH Forms	Phyllis Morris	Phyllis.Morris@vdh.virginia.gov	804-864-8000
CTR test forms and HIV Testing Supplies	Micah Daingerfield	Micah.Daingerfield@vdh.virginia.gov	804-864-8002
OraSure Test Kits/Controls	Heather Bronson	Heather.Bronson@vdh.virginia.gov	804-864-8020
Rapid Test Kits/Controls other than OraSure	Felencia McGee or Micah Daingerfield	Felencia.McGee@vdh.virginia.gov Micah.Daingerfield@vdh.virginia.gov	804-864-7987

SECTION II

QUALITY ASSURANCE IN HIV TESTING PROGRAMS

Quality Assurance Introduction

Quality Assurance guidelines contained in this document focus on the three rapid HIV testing technologies approved for use in DDP supported testing programs. This document provides procedures for the Federal Drug Administration CLIA waived rapid HIV tests: OraQuick Advance Rapid HIV-1/2 Antibody Test, Clearview Complete HIV-1/2 Antibody Test, Clearview HIV-1/2 Stat-Pak.

The OraQuick Advance Rapid HIV-1/2 Antibody Test is manufactured by OraSure Technologies, Inc. It is a single-use, qualitative, immunoassay used to detect antibodies to HIV-1 and HIV-2 in oral fluid, whole blood, and plasma specimens. Test results can be read between 20 and 40 minutes.

The Clearview Complete HIV-1/2 and the Clearview HIV-1/2 Stat-Pak are manufactured by Alere. The assay is a single-use immunochromatographic test for the detection of antibodies to HIV-1 and HIV-2 in whole blood, and serum or plasma specimens. Read test results between 15 and 20 minutes.

Waived tests are simple and accurate when performed at point-of-care by personnel trained to follow 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. One of the most important procedures in obtaining accurate and reliable results every time a test is given is validating test kit performance by running controls. Below is a list of external quality control procedures common to OraQuick and the Clearview tests.

External Quality Control Procedures Common to OraQuick and the Clearview Tests

- Always wear gloves when performing test kit control procedures.

- Each rapid HIV test kit has a test kit control available separately from the rapid HIV test device.
- The test kit controls are specifically formulated and manufactured to ensure performance of the test, and are used to verify the tester's ability to properly perform the test and interpret the results.
- The positive controls will produce a reactive test result and are manufactured to produce a faint line. The negative controls will produce a nonreactive test result.
- Controls need be refrigerated per manufacturer's standards. Temperature of the control storage area will be checked daily and recorded on the Test Kit Control Storage Temperature Log (**Attachment K**)
- Test kits shall be stored per manufacturer standards. Temperature of the test kit storage area will be checked daily and recorded on the Test Kit Storage Temperature Log (**Attachment L**)
- 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 VDH Testing Specialist.

Quality Control Procedures for OraQuick

Internal Quality Control

The rapid HIV test has a built-in procedural control that demonstrates assay validity. A control line will appear on all valid tests, whether or not the sample is reactive or nonreactive. For OraQuick tests, a reddish-purple line in the control area of the result window indicates that the test is running correctly.

Run Controls under the following circumstances:

- With each new operator, prior to performing testing on a patient specimen.
- When opening a new test kit lot.
- Whenever a new shipment of test kits is received.
- If the temperature of the test kit storage area falls outside of 35-80°F (2-27°C).
- If temperature of the testing area falls outside of 59–99°F (15-37°C).
- At a new site that is going to be an ongoing testing venue.
- Whenever there is reason to suspect test kits are not functioning properly (e.g., two invalid test results in a row or an excessive number of unexpected results).
- At regular intervals determined by the testing site or contract agency.

Test Kit Control Storage

- Store the OraQuick Advance test kit controls at 35-46°F (2-8°C).
- Do not use test kit controls beyond the expiration date printed on the outer carton.
- Open the test kit control vials only when you are performing tests. Staff should initial and date control vials when opened and document a **new** expiration date 60 days after the control vials are opened.
- After use, recap and store the vials in their original container at 35–46°F (2–8°C). Dispose of unused portion of opened test kit control after 60 days.

Test Kit Control Procedures for OraQuick

1. Set up your workspace.
2. Always wear gloves when conducting test kit control procedures.
3. Open three (3) OraQuick test kits and place the three developer solution vials in the reusable test stand. Label each pouch, developer solution vial, and test device as HIV-1, HIV-2, and Nonreactive, respectively. The developer and test device should come from the same pouch.

4. Open a test kit control vial containing the control agent.
5. Insert the round end of an unused specimen loop into the vial of control reagent. Visually inspect the loop to make sure that it is completely filled with the control reagent. Use separate unused specimen collection loops for each control reagent. NOTE: Test kit control reagents are clear to straw-colored. Do not use if the reagent appears visually cloudy or discolored.
6. Immediately immerse the control reagent-filled specimen loop in the developer solution inside the developer solution vial of the corresponding control reagent (e.g., HIV-1 control agent into developer solution vial labeled HIV-1). Use the specimen collection loop to stir the specimen in the developer solution. Remove the specimen collection loop from the developer solution vial and discard the used loop in a biohazard waste container.
7. Remove the test device from the divided pouch without touching the flat pad. Insert the test device, flat pad first, into the developer solution vial containing the specimen. Be sure that the result window faces forward and the flat pad touches the bottom of the developer solution vial.
8. Set the timer for 20 minutes. Do not touch or remove the test device from the vial until the results have been read. Read the results after 20 minutes, but no more than 40 minutes, in a fully lighted area.
9. Dispose of the used developer solution vial and the test device in a biohazard waste container.
10. Reseal the test kit control reagent vials and store them in their original container at 35-46°F (2-8°C).
11. Deviations from the procedures outlined in the test kit control or rapid HIV test pack insert will produce unreliable results. Test kit controls are intended for use in undiluted form. Adverse shipping and storage conditions or use of expired reagents will produce erroneous results.

Interpreting Test Results

1. The **CONTROL LINE** (the line closest to the top of the test strip) indicates that the specimen was adequately applied, and there was proper hydration and migration of reagents. The control line will become visible within 15 minutes after starting the test, regardless of the HIV antibody status of the specimen.
2. The **TEST LINE** (the line closest to the bottom of the test strip, below the control line) indicates the presence of HIV specific antibodies. The test line will only become visible within 15 minutes after starting a valid test when HIV specific antibodies are present at detectable levels in the specimen.

3. **INVALID** - A pink/purple line will always appear in the CONTROL area, whether or not a line appears in the TEST area. If there is no distinct pink/purple line visible in the CONTROL area, then the test is INVALID. If any of the lines appear outside of the Control or Test areas, then the test is an INVALID test. An INVALID test cannot be interpreted. It is recommended that the test be repeated with a new device.

Expected Results for OraQuick Advance

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

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

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

All results are recorded on the “External Kit Control Log” (see **Attachment M**).

Material Requirements for OraQuick Advance

Each HIV Rapid Test Kit Contains:

- Test device (including an absorbent packet)
- Developer solution vial (containing 1 microliter)
- Reusable test stand
- Manufacturer’s Subject Information Pamphlet
- Customer letter
- Specimen collection loop (5 microliter)
- Package insert

Other Materials Required:

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

Additional Items Required for Fingerstick Specimens:

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

General Test Preparation for OraQuick Advance

Escort client to the test location and have client sit in a stationary chair at the workspace. Record client identification, room temperature, date the specimen collected, divided pouch lot#, and divided pouch expiration date on the “Rapid HIV Test Result Log” sheet (**Attachment N**). For agencies using names on log sheets, be mindful of client confidentiality.

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

Fingerstick Whole Blood Specimen Collection and Testing for OraQuick Advance

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

- Put the rounded end of the loop on the drop of blood. Make sure that the loop is completely filled with blood.
- Specimen Preparation
 - Immediately insert the blood-filled end of the loop all the way into the vial. Use the loop to stir the blood sample in the developer solution.
 - Remove the used loop from the solution. Throw the used loop away in the biohazard waste container.
 - Check the solution to make sure that it appears pink. This means that the blood was correctly mixed into the solution. If the solution is not pink, discard all the test materials in a biohazard waste container. Start the test over. Use a new pouch and a new blood sample.
- Specimen Testing
 - Remove the device from the pouch. DO NOT touch the flat pad.
 - Check to make sure that an absorbent packet is included with the device. If no absorbent packet is present, discard the device and obtain a new pouch for testing.
 - Insert the flat pad of the device all the way into the vial containing the blood sample. Make sure that the flat pad touches the bottom of the vial. The result window on the device should be facing the tester.
 - Start timing the test. Record the time the specimen was collected on the “Rapid HIV Test Result Log” (**Attachment N**). Look at time specimen is collected versus when test starts running. DO NOT remove the device from the vial while test is running. Pink fluid will appear and travel up the results window. The pink fluid will gradually disappear as the test develops.
 - While the test is developing, conduct prevention counseling to include in-depth risk assessment and the identification of safer behavioral goals and action step(s).
 - Read the test results after 20 minutes, but no more than 40 minutes, in a fully lighted area. A flashlight may be used to read test results; however, the flashlight must not be used behind the paddle to read test results.

Reading Test Results for OraQuick Advance

Nonreactive: The test is nonreactive if a reddish-purple line appears next to the triangle labeled “C” and no line appears next to the triangle labeled “T.”

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

Invalid: Test is invalid if:

- No reddish-purple line appears next to the triangle labeled “C,” or

- A red background in the results window makes it difficult to read the result after 20 minutes, or
- If any of the lines are NOT inside the “C” or “T” triangle areas.

Quality Control Procedures for Clearview Complete

Internal Quality Control

The rapid HIV test has a built-in procedural control that demonstrates assay validity. The control line will appear on all valid tests, whether or not the sample is reactive or nonreactive. For *Clearview Complete* test kits, a pink-purple line will appear in the CONTROL area if the test has been performed correctly and the device is working properly.

Run controls under the following circumstances:

- With each new operator, prior to performing testing on a patient specimen.
- When opening a new test kit lot.
- Whenever a new shipment of test kits is received.
- If the temperature of the test storage area or the testing area falls outside of the 64 to 86°F (18 to 30°C).
- At a new site that is going to be an ongoing testing venue.
- Whenever there is reason to suspect test kits are not functioning properly (e.g., two invalid test results in a row or an excessive number of unexpected results).
- At regular intervals determined by the testing site or contract agency.

Test Kit Control Storage for Clearview Complete

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

Test Kit Control Procedures for Clearview Complete

1. Read the Product Insert completely before using this product.
2. Wear gloves when conducting test kit control procedures.
3. Follow the instructions carefully as not doing so may result in inaccurate Test Results.
4. Open a Control Vial containing the Control Reagent.
5. From the Clearview Complete, remove Buffer Vial – separate from top of Sampler and place in Disposable Rack provided with Complete HIV-1/2 Assay.
6. From one of the control vials, using a fresh pipette, collect Control from vial.

7. Transfer Control to a fresh weight boat.
8. Collect Control from weight boat using sampling tip of Device.
9. With Buffer Vial in disposable rack, firmly press the Sampler tip through foil cover.
10. Continue pushing to the bottom of the Buffer Vial until Sampler and Buffer Vial snap together tightly.
11. Start timing – wait for 15 minutes. NOTE: the Sampler/Buffer Vial should be kept upright.
12. Read the Test Result between 15 and 20 minutes. In some cases a test line may appear in less than 15 minutes (if the test is reactive); however, 15 minutes are needed to report a Nonreactive Test Result. Read Test Results in a well-lit area (a faint line is reactive). Do not read Test Results after 20 minutes.
13. Discard the used pipette tips, Test Device and any other test materials into a biohazard waste container.
14. Reseal the Control reagent vials and store them in their original container at 36 to 46°F (2 to 8°C).
15. Deviations from the procedures outlined in the test kit control or rapid HIV test pack insert will produce unreliable results. Test kit controls are intended for use in undiluted form. Adverse shipping and storage conditions or use of expired reagents will produce erroneous results.

Interpretation of Test Results for Clearview Complete

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

Expected Results for Clearview Complete

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

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

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

All results shall be recorded on the “External Kit Control Log” (see **Attachment M**).

Material Requirements for Clearview Complete

Each HIV Rapid Test Kit contains the components to perform 25 tests:

- 1 Product Insert for the Complete HIV 1/2 assay
- 25 Copies of Subject Information Notice
- 25 Disposable Test Stands
- 25 Pouches, each containing:
 - Sampler with a Test Strip inside
 - Buffer Vial attached to the Sampler (~350µL)
 - Sterile Safety Lancet
 - Bandage
 - Desiccant Packet

Other Materials Required:

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

Additional Items Required for Fingerstick Specimens:

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

General Test Preparation for Clearview Complete

Escort client to the test location and have client sit in a stationary chair at the workspace. Record client identification, room temperature, date specimen collected, divided pouch lot#, and divided pouch expiration date on the “Rapid HIV Test Result Log” sheet (**Attachment N**). For agencies using names on log sheets, be mindful of client confidentiality.

- Open Pouch, Remove and Identify Components.
- Identify Test Device, Buffer Cap and Test Stand.
 - *Note: If Desiccant Packet is missing or if absorbent pad (at top of Sampler) is missing or if sample filter (at bottom of Sampler) is missing, DO NOT USE. Discard device and use a new device.*
- Write Patient ID on Stand.
- Separate Buffer Cap from Test Device.
- On a firm surface, drop the Buffer Cap in the Test Stand.
- For fingerstick whole blood, touch blood drop with Sampler tip until the tip is full
- Start the Test:
 - With Buffer Cap in Stand, firmly press the Device tip through foil cover.
 - Push hard until Device is fully seated in the Buffer Cap. It will “snap” 3 times when properly seated.
 - Snap 1: through foil
 - Snap 2: into cap
 - Snap 3: fully seated
- Confirm Device is Fully Seated:
 - The blue line directly above the arrows must line up with the clear line in the Stand.
 - You will see pink/purple buffer solution begin to flow upward.
- Start Timing – Wait for 15 Minutes.
 - If you do not see pink/purple flow within 3 minutes, push again and then restart timer.
 - *NOTE: the Sampler/ Buffer Vial should be kept upright in the Test Stand.*

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

Fingerstick Whole Blood Specimen Collection and Testing for Clearview Complete

- Specimen Collection
 - Using an antiseptic wipe, clean the client's finger. Allow the finger to dry thoroughly or wipe dry with a sterile gauze pad.
 - Using a sterile, retractable safety lancet, puncture the skin just off the center of the finger pad.
 - Hold the finger downward. Apply gentle pressure beside the point of the puncture.
 - Wipe away this first drop of blood with a sterile gauze pad. Allow a new drop of blood to form.
 - Pick up an unused specimen collection loop by the thick-handled end.
- Specimen Testing
 - Point the sample loop down and touch it to the sample pad in the center of the sample well of the device.
 - The blood sample will flow onto the sample pad. Add only one loop full of sample.
 - Remove the developer solution vial from the box. Hold the buffer bottle vial firmly in your hand. Carefully remove the cap from the vial.
 - Set the cap on the workspace cover.
 - Hold the running buffer bottle vertically (not at an angle) above the sample well and squeeze three free falling drops into the sample well.
 - Start timer.
 - Read the test results after 15 minutes. Do not read results after 20 minutes.

Reading Test Results for Clearview Complete

Nonreactive: The test is nonreactive if a pink-purple line appears in control area, with no line in the test area.

Reactive: The test is reactive if two pink-purple lines appear: one in the test area and one in the control area. The line in the test area may look different from the line in the control area. Intensities of the test and control lines may vary. A test result with visible lines in both control and test areas, regardless of the intensity is considered reactive.

Invalid: The test is invalid if there is no distinct pink-purple line visible in the control area.

Quality Control Procedures for Clearview Stat-Pak

Internal Quality Control

The rapid HIV test has a built-in procedural control that demonstrates assay validity. The control line will appear on all valid tests, whether or not the sample is reactive or nonreactive. For Clearview Stat-Pak, A pink-purple line will appear in the CONTROL area if the test has been performed correctly and the device is working properly.

External Quality Control

- Each rapid HIV test kit has a test kit control available separately from the rapid HIV test device.
- The test kit controls are specifically formulated and manufactured to ensure performance of the test, and are used to verify the tester's ability to properly perform the test and interpret the results.
- The positive controls will produce a reactive test result and are manufactured to produce a faint line. The negative controls will produce a nonreactive test result.
- Controls will be refrigerated and/or frozen per manufacturer's standards. Temperature of the control storage area will be checked daily and recorded on the Test Kit Control Storage Temperature Log (**Attachment K**)
- Test kits need to be stored per manufacturer standards. Temperature of the test kit storage area will be checked daily and recorded on the Test Kit Storage Temperature Log (**Attachment L**)
- **The test kit controls 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 VDH Testing Specialist.**

Run controls under the following circumstances:

- With each new operator, prior to performing testing on a patient specimen.
- When opening a new test kit lot.
- Whenever a new shipment of test kits is received.
- If the temperature of the test kit storage area or testing area falls outside of the 64 to 86°F (18 to 30°C).
- At a new site that is going to be an ongoing testing venue.
- Whenever there is reason to suspect test kits are not functioning properly (e.g., two invalid test results in a row or an excessive number of unexpected results).
- At regular intervals determined by the testing site or contract agency.

Test Kit Control Storage for Clearview Stat-Pak

- The Clearview HIV Reactive/Nonreactive Controls should be stored at 36 to 46°F (2 to 8°C).
- Do not use beyond the indicated expiration date.

- Open the Control Vials only when you are performing tests.
- Recap and store the Control Vials in their original container at 36° to 46°F (2° to 8°C) after use.

Test Kit Control Procedures for Clearview Stat-Pak

1. Wear gloves when performing test kit control procedures.
2. Open a Control vial containing the Control Reagent.
3. Remove the Clearview HIV-1/2 Stat-Pak Test Device from its pouch and place it on a flat surface. (It is not necessary to remove the desiccant from the pouch).
4. Label the Test Device with Control Reagent name or identification number.
5. Touch the 5 uL Sample Loop provided to the Control Reagent, allowing the opening of the Sample Loop to fill with the liquid. Use separate unused specimen Sample Loops for each control Reagent.
6. Holding the Sample Loop vertically, touch it to the sample pad in the center of the Sample (S) well of the Test Device to dispense ~5 uL of Control Reagent onto the sample pad.
7. Invert the Running Buffer bottle and hold it vertically (not at an angle) over the sample well. Add 3 drops (~105 uL) of Buffer slowly, drop-wise, into the SAMPLE(S) well.
8. Read the Test Result between 15 and 20 minutes after the addition of the Running Buffer. In some cases a test line may appear in less than 15 minutes (if the test is reactive) however, 15 minutes are needed to report a Nonreactive Test Result. Read Test Results in a well-lit area. Do not read Test Results after 20 minutes.
9. Discard the used Sample Loop, Test Device and any other test materials into a biohazard waste container.
10. Reseal the Control Reagent Vials and store them in the original container at 2 to 8°C (36 to 46°F).
11. Deviations from the procedures outlined in the test kit control or rapid HIV test pack insert will produce unreliable results. Test kit controls are intended for use in undiluted form. Adverse shipping and storage conditions or use of expired reagents will produce erroneous results.

Interpretation of Test Results for Clearview Stat-Pak

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

Expected Results for Clearview Stat-Pak

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

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

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

All results shall be recorded on the “External Kit Control Log” (see **Attachment M**).

Material Requirements for Clearview Stat-Pak

Each Kit contains the components to perform 20 tests:

- 20 Stat-Pak Individually Pouched Test Devices
- 20 Copies of Subject Information Notice
- 20 Disposable 5µL Sample Loops
- 1 HIV Running Buffer (3.5mL)
- 1 Product Insert for the HIV 1/2 Stat-Pak Assay

Other Materials Required:

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

Additional Items Required for Fingerstick Specimens:

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

General Test Preparation for Clearview Stat-Pak

Escort client to the test location and have client sit in a stationary chair at the workspace. Record client identification, room temperature, date specimen collected, divided pouch lot#, and divided pouch expiration date on the “Rapid HIV Test Result Log” sheet (**Attachment N**). For agencies using names on log sheets, be mindful of client confidentiality.

- Remove the Clearview Stat-Pak test device from its pouch and place it on a flat surface. (It is not necessary to remove the desiccant from the pouch).
 - *Note: If Desiccant Packet is missing, DO NOT USE, discard test device and a new test device should be used.*
- Label the test device with patient name or ID number.
- Touch the 5 uL sample loop provided to the specimen, allowing the opening of the loop to fill with the liquid.
- Holding the sample loop vertically, touch it to the sample pad in the center of the SAMPLE(S) well of the device to dispense ~5 uL of sample (serum, plasma or whole blood) onto the sample pad.
- Invert the Running Buffer bottle and hold it vertically (not at an angle) over the sample well. Add 3 drops (~ 105 uL) of buffer slowly, drop-wise, into the SAMPLE(S) well.

- Read the Test Result between 15 and 20 minutes after the addition of the Running Buffer. Reactive Test Results (See Interpretation of Test Results section) may be observed and read earlier than 15 minutes. To verify a Nonreactive Test Result, wait the entire 15 minutes after starting the test. Do not read results after 20 minutes.

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

Fingerstick Whole Blood Specimen Collection and Testing for Clearview Stat-Pak

- Specimen Collection
 - Using an antiseptic wipe, clean the client's finger. Allow the finger to dry thoroughly or wipe dry with a sterile gauze pad.
 - Using a sterile, retractable safety lancet, puncture the skin just off the center of the finger pad.
 - Hold the finger downward. Apply gentle pressure beside the point of the puncture.
 - Wipe away this first drop of blood with a sterile gauze pad. Allow a new drop of blood to form.
 - Pick up an unused specimen collection loop by the thick-handled end.
- Specimen Testing
 - Point the sample loop down and touch it to the sample pad in the center of the sample well of the device.
 - The blood sample will flow onto the sample pad. Add only one loop full of sample.
 - Remove the developer solution vial from the box. Hold the buffer bottle vial firmly in your hand. Carefully remove the cap from the vial.
 - Set the cap on the workspace cover.
 - Hold the running buffer bottle vertically (not at an angle) above the sample well and squeeze three free falling drops into the sample well.
 - Start timer.
 - Read the test results after 15 minutes. Do not read results after 20 minutes.

Reading Test Results for Clearview Stat-Pak

Nonreactive: The test is nonreactive if a pink-purple line appears in control area, with no line in the test area.

Reactive: The test is reactive if two pink-purple lines appear: One in the test area and one in the control area. The line in the test area may look different from the line in the control area. Intensities of the test and control lines may vary. A test result with visible lines in both control and test areas, regardless of the intensity, is considered reactive.

Invalid: The test is invalid if there is no distinct pink-purple line visible in the control area.

Interpretation of Test Results

- A nonreactive test result means that HIV-1 and HIV-2 antibodies were not detected in the specimen. The test result is interpreted as negative for HIV-1 and HIV-2 antibodies. However, this did not exclude possible infection with HIV. Follow CDC guidelines to inform the test subject of the test result and its interpretation.
- A reactive test result means that HIV-1 or HIV-2 antibodies have been detected in the specimen. The test result is interpreted as reactive/positive for HIV-1 and/or HIV-2 antibodies. The test result is interpreted as preliminary positive for HIV-1 and HIV-2 antibodies. Follow CDC guidelines to inform the test subject of the test result and its interpretation.
- An invalid test result means that there was a problem running the test, related either to the specimen or to the device. An invalid test cannot be interpreted. Repeat the test with a new pouch and a new oral fluid or fingerstick.

Supplemental Testing Procedures

All DDP-supported HIV testing programs are required to provide additional testing to clients who receive a preliminary positive test result. Testing programs shall adhere to the VDH-approved rapid-rapid testing algorithm (**Attachment B**)—this algorithm indicates that clients who receive a preliminary positive result using a rapid HIV test should have their result confirmed through the administration of a second, orthogonal rapid HIV test technology.

Orthogonal means that the two HIV test technologies must test for different HIV-specific antibodies. Agencies shall not confirm a preliminary result by re-testing the client with the same test technology—another brand must be used. Two successive reactive test results shall be considered a presumptive diagnosis of HIV, and the test counselor shall complete the required documentation and referral to HIV medical care indicated in “Policies and Procedures for HIV Testing – Active Referral into Care for HIV Positive Clients”.

If the confirmatory testing yields a discordant result, a third test shall be conducted to confirm the client’s reactive or nonreactive status, and the discordant test will be documented using the Rapid Test Discordant Test Case Report (**Attachment O**).

HIV Prevention Counseling

Fundamentals of HIV prevention counseling with rapid HIV tests include:

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

- Seek flexibility in the counseling technique and process, avoiding a “one-size-fits- all” approach.

Pre-Test Counseling

- Provide information about the HIV test, its benefits and its consequences. This can be done by face-to-face communication, video, brochure, or pamphlet.
- Assess client readiness to test and receive results on the same session.
- Inform the client that confirmatory testing is needed if the first rapid test result is reactive.
- Obtain consent.
- Prior to specimen collection, provide the client with the Subject Information Notice from the test manufacturer.
- Conduct test.

Post-Test Counseling

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

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

Nonreactive Rapid HIV Test Results

During the initial visit, the provider can definitively tell a client whose rapid HIV test result is nonreactive that he or she is not infected, unless the client has had a recent (within three months) known or possible exposure to HIV. Retesting should be recommended for those clients with recent risks because sufficient time needs to elapse before antibodies develop that can be detected by the test. Explore risks and step(s) clients can take to avoid infection in the future. Clients who describe recent symptoms (fever, malaise, diarrhea, etc.) and/or very recent risk (within 2 weeks) should be referred to a local health department for a 4th generation conventional blood draw.

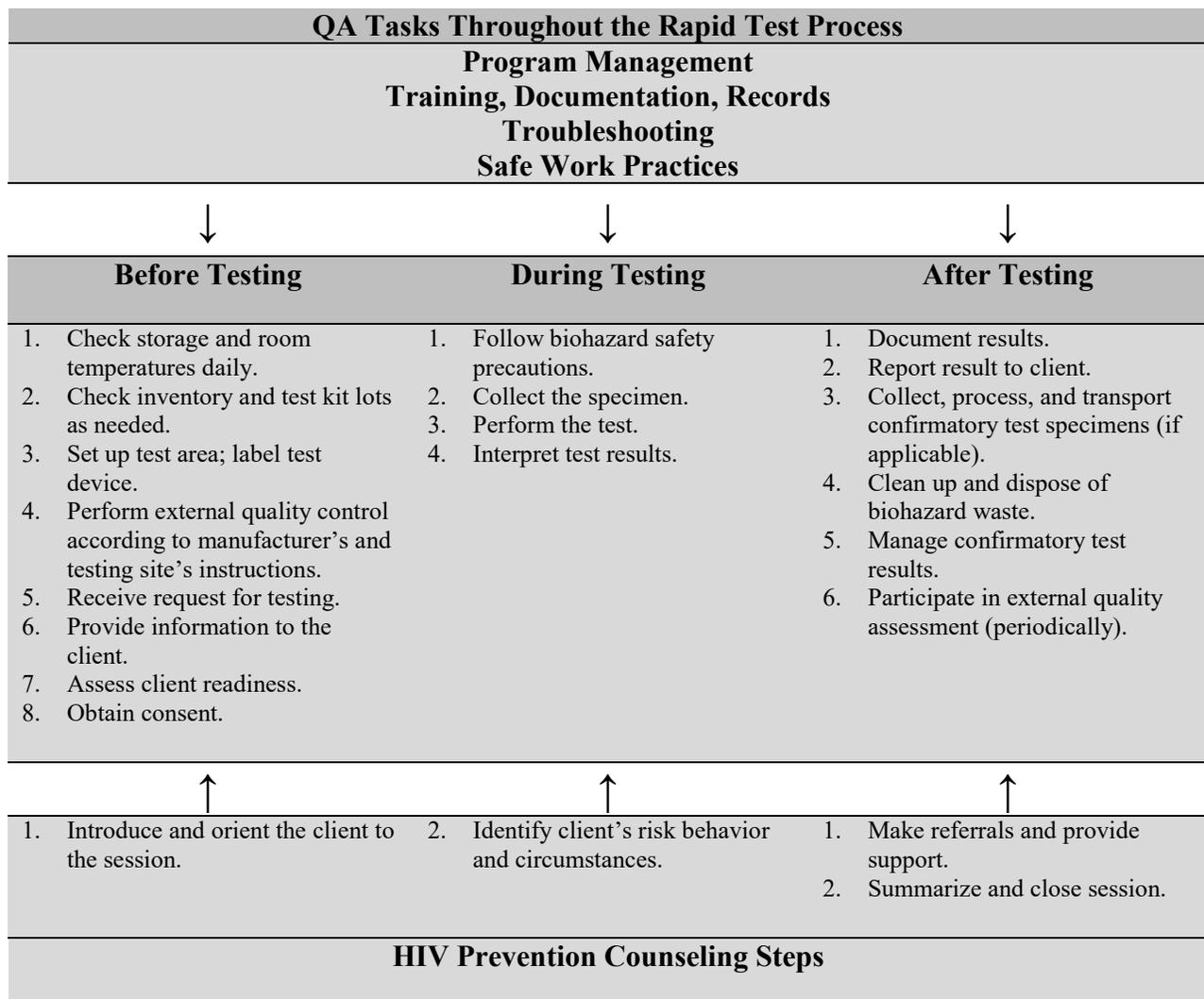
Reactive Rapid HIV Test Results in sites without Rapid-Rapid Protocols

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

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

Quality Assurance Integration

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



Documentation for review shall, at a minimum, include:

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

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

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

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

Troubleshooting and Problem Solving Procedures

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

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

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

Problem and Action Chart

Problem	Action
Control testing fails to yield accurate results.	Retest with a new control unit to determine whether failure was a result of test kits or units. (Do not test client specimens until proper functioning of the test kits has been verified.)
Second attempt at control testing fails with new control unit.	Do not test client specimens until problem is resolved. Notify supervisor, VDH, and manufacturer. Consult troubleshooting log to identify possible reason for failure. Begin preparations to notify clients, who tested since last successful external control test, previous HIV test result may not be reliable.
Invalid test result occurs while testing a client specimen	Offer the client the option of retesting with a rapid HIV test from a different lot or referral for a conventional test.
Two invalid test results occur in a row while testing client specimen kits. If control fails, see above.	Offer clients referral for a conventional test. Do not test further client specimens until problem is resolved. Run controls to determine if invalid results are due to client sample or rapid HIV test kits.
Test kit storage area temperature exceeds recommended range.	Run external controls to verify that kits continue to function properly.

Quality Assurance Duties and Activities

Agencies need to have a completed “Personnel Responsibilities Form” (**Attachment Q**) available for review during site visits. Although there are specific quality assurance 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. Each funded and/or partner agency must have a plan that details the QA duties and activities for all testing staff. A sample has been attached to this document that can be adapted to meet the needs of each agency (**Attachment Q**).

Attachment A

Agency:

Site:

Rapid HIV Testing and Prevention Counseling Observation Form

Counselor: _____ Observer: _____ Date: _____

Step 1:

Introduce/orient client. Did the counselor:

- Introduce him/herself by name
- Explain 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:**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.

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

- Yes
- No

Report test result. Did the counselor:

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

Step 3:

Provide support and referrals. Did the counselor:

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

Step 4:

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

General Questions:

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

Yes No

Did the counselor ask open-ended questions? Yes No

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

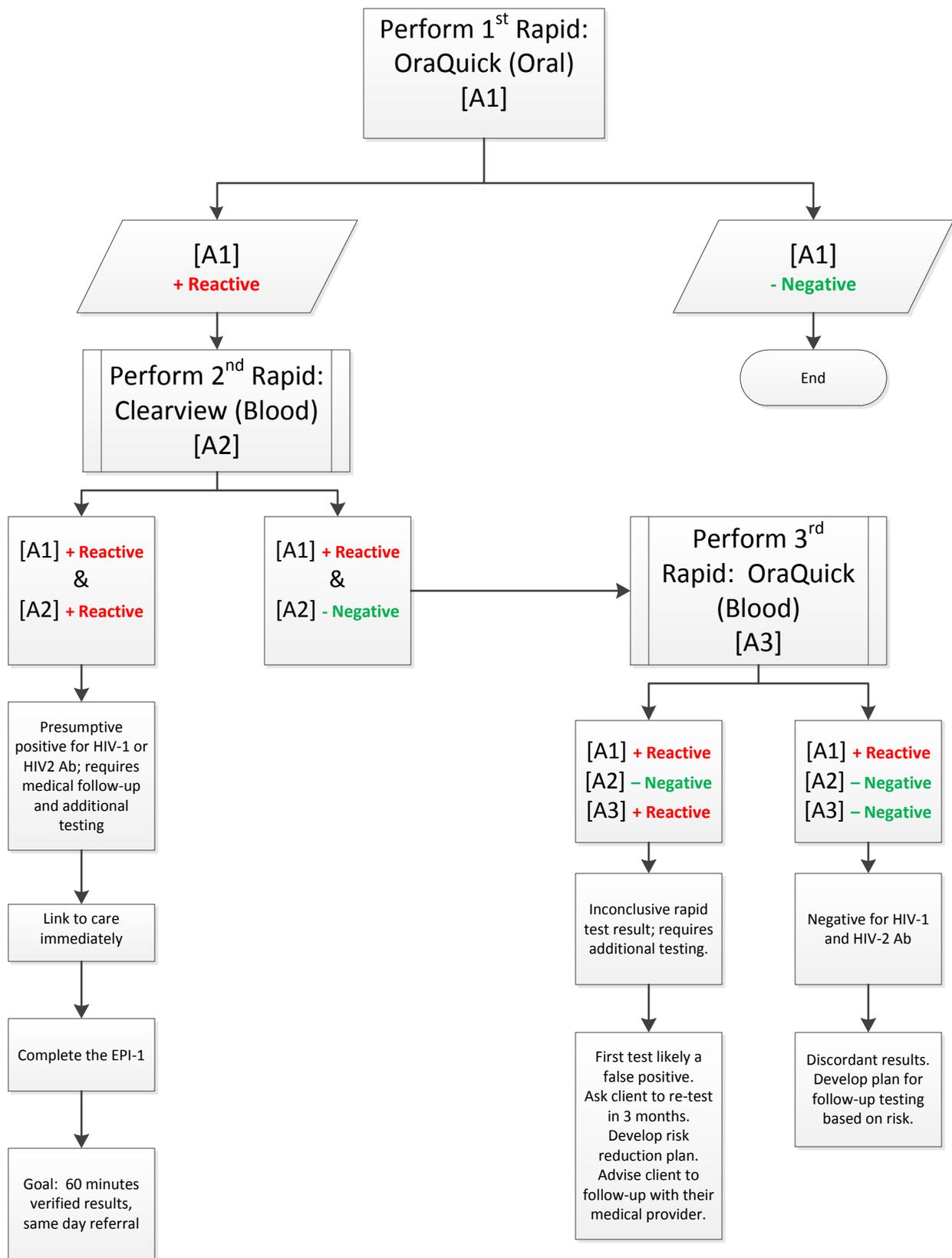
Did the counselor provide skills-building opportunities for the client when appropriate?

Yes No

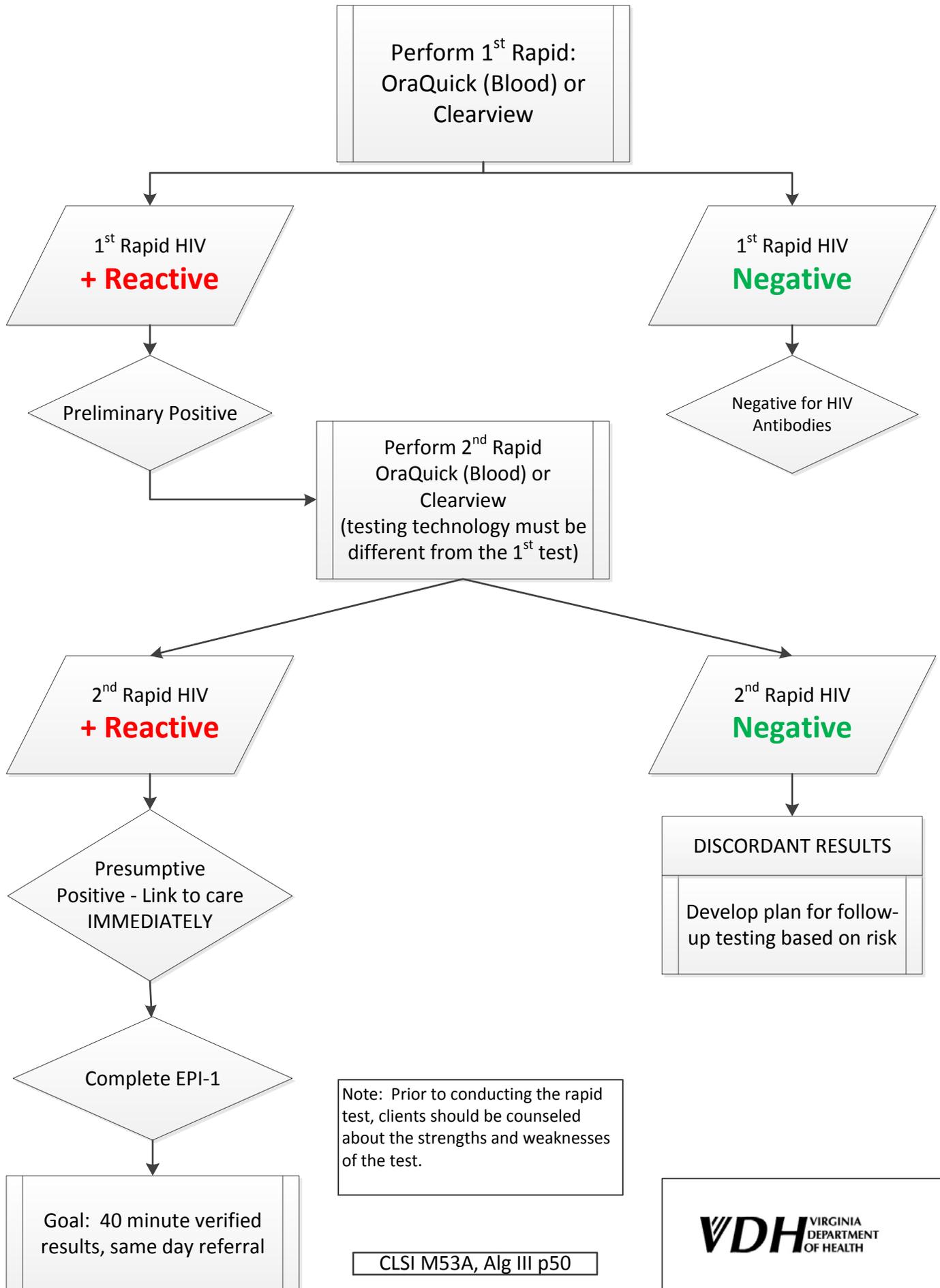
Did the counselor provide information on home test kits? Yes No

Did the counselor distribute condoms, lubricant, and/or other latex barriers? Yes No

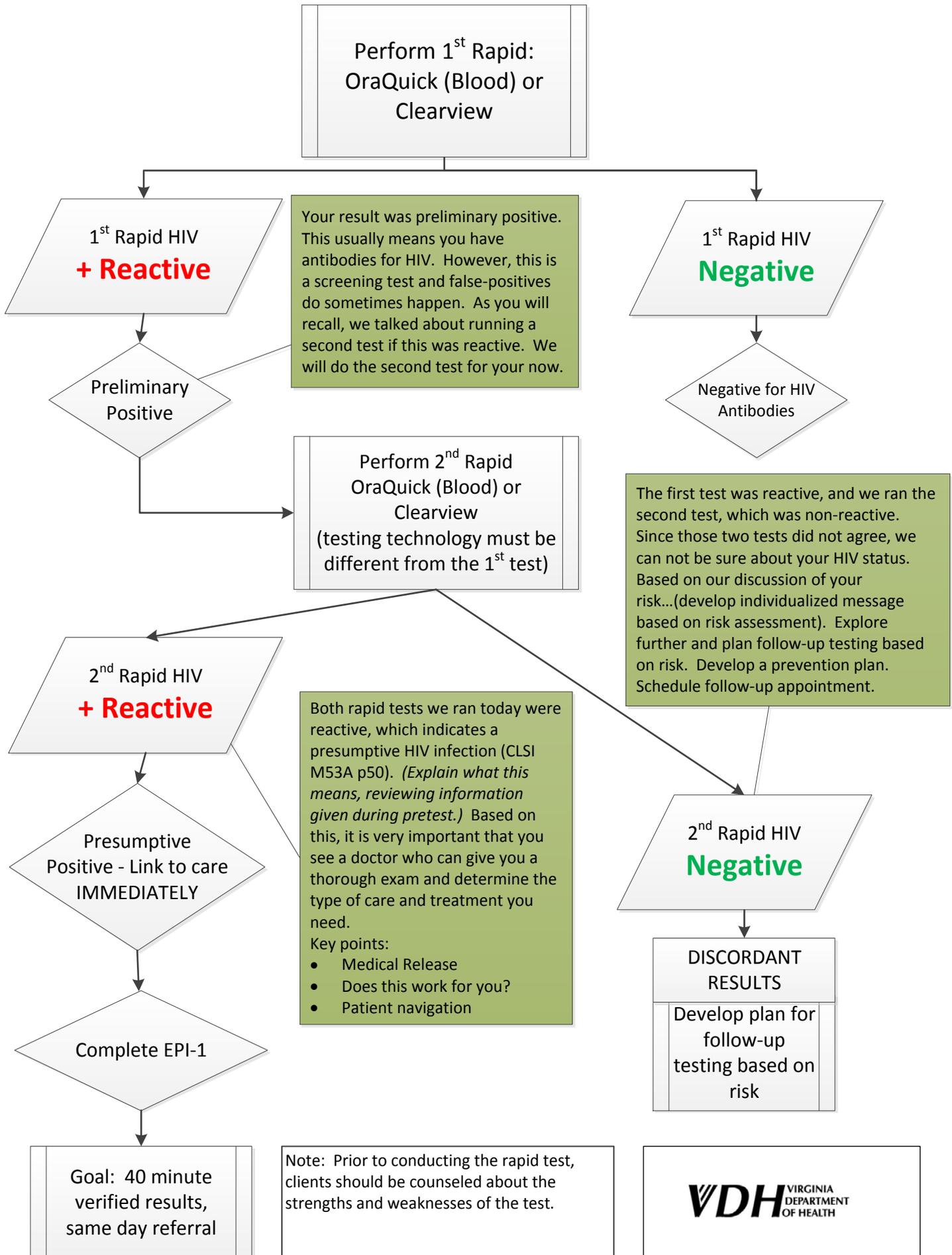
Rapid Rapid HIV Testing Algorithm With Oral Testing (1st)



Rapid Rapid HIV Testing Algorithm



Rapid Rapid HIV Testing Algorithm



Attachment C

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. Antibodies are generated by your immune system every time it comes in contact with a new disease, which means that if you have antibodies for HIV, you are likely HIV-infected. Your body does not immediately develop antibodies, but produces them over the first 90 days of a new infection.

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, who will help you get access to medical care. The health department will protect your identity and your records.

People get HIV most often by having unprotected sex or sharing needles/syringes with an infected person. If you get HIV, it can take up to 90 days to develop antibodies. If you may have been exposed to HIV in the past 90 days, it is recommended that you test again in three months regardless of your test result. People who often engage in high-risk behavior should test every three months.

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

What Kind of Test Will Be Done?

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 fingerstick lancet to collect a blood specimen. The results of your rapid test will be ready in 20 minutes or less.

What does my Test Result Mean?

If your rapid HIV test is negative, no antibodies for HIV were found. However if you recently (within last 90 days) had unprotected sex or shared needles/syringes, there is a chance that you may be in the "**window period**". This means that you may be infected, but have not yet developed the antibodies that will allow your test to yield an accurate result.

If your rapid test is reactive or preliminary positive, 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 the event of a reactive result in order to establish a presumptive HIV diagnosis. Confirmatory testing will be provided by this agency, and will involve another rapid test of a different brand.

Signature: _____

Date: _____

Printed Name: _____

Date of Birth: _____

**NEGATIVE HIV TEST RESULT TEMPLATE. PRINT ON YOUR
AGENCY LETTERHEAD**

Print Client Name: _____

Date of HIV Test: _____

Your Human Immunodeficiency Virus (HIV) test result was negative. A negative test result means one of the following:

- 1) The person tested is not infected with HIV, the virus that causes AIDS, OR
- 2) The person may have been recently infected with HIV and the test does not show it yet. If you had sex without a condom or shared needles or other items used for injection recently, you may need to take another test.

This test does NOT mean you are cannot get HIV in the future. For further information on HIV/AIDS and other sexually transmitted diseases, call the Virginia Disease Prevention Hotline at 1-800-533-4148.

My signature means I understand this form is provided to me at my request and that I may be required to complete additional medical records release forms.

Client Signature: _____ Date: _____

Print Agency, Test Site or Clinic Name: _____

Print Name of Staff Person Providing Result: _____

Staff Person Signature: _____ Date: _____

Valid only if signatures are original and form is on agency letterhead

Recommendations for Responding to Clients' Requests for Negative HIV Test Results

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. Review appropriate use of test results documentation with the client.
4. The format of documentation provided to clients should reduce its use for unintended purposes by requiring original signatures in blue ink, use of watermarks, letterhead or other mechanisms that discourage photocopying.
5. The HIV Counseling, Testing, and Referral (CTR) form is a data collection tool and should not be provided to clients as proof of HIV test results due to the following:
 - The CTR form does not have the client's name; therefore, it does not provide proof that the person presenting the form has been tested for HIV.
 - The form contains confidential information (such as risk behavior) that is not needed to document HIV test results.
 - The CTR form does not provide an explanation of what a negative test result means.

If you have questions on this issue, please contact Caroline Campbell, HIV Testing Program Coordinator at (804) 864-7978 or via email at: Caroline.Campbell@vdh.virginia.gov. A sample template for use can be found at [here](#).

Attachment D

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 color-coded. During use, containers for contaminated sharps shall be easily accessible to personnel and located as close as is feasible to the immediate area where sharps are to be used. The containers shall be maintained upright throughout use and replaced routinely and not be allowed to overfill. When moving containers of contaminated sharps from the area of use, the containers shall be closed immediately before removal during handling, storage, transport, or shipping. The container shall be placed in a secondary container if leakage of the primary container is possible. The second container shall be capable of being sealed, constructed to contain all contents, and prevent leakage during handling, storage and transport, or shipping. The second container shall be labeled to identify its contents. 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 E

Verification of Previous Diagnosis Form

Client Information

Client Full Name

Date of Encounter

Client Date of Birth

Client Social Security Number

Sex (At Birth)

Race/Ethnicity

Date of Diagnosis

State Of Diagnosis

Current Address

Date time Phone Number

Notes

Attachment F

CTR (900) FORM PART 1



Form ID Number Here

Date Modified: 09/15/15

PROGRAM ANNOUNCEMENT NUMBER												
Select only one	<input type="checkbox"/> PS12-1201-Category A	<input type="checkbox"/> PS12-1201-Category B	<input type="checkbox"/> PS12-1201-Category C	<input type="checkbox"/> PS08-803	<input type="checkbox"/> PS10-1003	<input type="checkbox"/> PS11-1113	<input type="checkbox"/> MSM Testing Initiative	<input type="checkbox"/> Other: _____				
AGENCY	Session Date (MMDDYYYY)			Unique Agency ID Number			Site Zip Code					
	[][]/[][]/[][][][][][]			[][][][][][][][][][]			[][][][][]					
	Site Type: <input type="checkbox"/> F [][][][] <small>(See codes on reverse)</small>			If Site Type is Other, please specify: _____			<input type="checkbox"/> Family Planning <input type="checkbox"/> General Medical <input type="checkbox"/> Maternal/OB <input type="checkbox"/> Refugee <input type="checkbox"/> Other: _____					
CLIENT												
Client ID			Year of Birth		State	Zip Code		Client City/County				
[][][][][][][][][][]			[][][]		[][]	[][][][][]		[][][][][][][][]				
Ethnicity		Race—Check all that apply			Assigned Sex At Birth		Current Gender ID		Previous 900 Test?	Self Reported Result		
<input type="checkbox"/> Hispanic or Latino <input type="checkbox"/> Not Hispanic or Latino <input type="checkbox"/> Don't know <input type="checkbox"/> Declined <input type="checkbox"/> Not Asked		<input type="checkbox"/> American Ind./ AK Native <input type="checkbox"/> Asian <input type="checkbox"/> Black/African American <input type="checkbox"/> Native HI/ Pac. Islander <input type="checkbox"/> White <input type="checkbox"/> Don't know <input type="checkbox"/> Declined <input type="checkbox"/> Not Asked			<input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Declined <input type="checkbox"/> Not Asked		<input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Transgender - M2F <input type="checkbox"/> Transgender - F2M <input type="checkbox"/> Transgender - unspecified <input type="checkbox"/> Declined <input type="checkbox"/> Not Asked		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know <input type="checkbox"/> Declined <input type="checkbox"/> Not asked	<input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Prelim. Pos. <input type="checkbox"/> Indeterminate <input type="checkbox"/> Don't know <input type="checkbox"/> Declined <input type="checkbox"/> Not asked		
Additional specify: _____												
900 TEST INFORMATION	TEST 1			TEST 2			TEST 3					
	Sample Date (MMDDYYYY)			[][][][][][][][][][]			[][][][][][][][][][]					
	Worker ID			[][][][][][][][][][]			[][][][][][][][][][]					
	Test Election			<input type="checkbox"/> Tested anonymously <input type="checkbox"/> Declined testing <input type="checkbox"/> Tested confidentially			<input type="checkbox"/> Tested anonymously <input type="checkbox"/> Declined testing <input type="checkbox"/> Tested confidentially					
	Test Technology			<input type="checkbox"/> Conventional <input type="checkbox"/> Fingerstick Rapid <input type="checkbox"/> Oral Rapid <input type="checkbox"/> Clearview <input type="checkbox"/> Oraquick <input type="checkbox"/> Other <input type="checkbox"/> NAAT/RNA Testing <input type="checkbox"/> Other			<input type="checkbox"/> Conventional <input type="checkbox"/> Fingerstick Rapid <input type="checkbox"/> Oral Rapid <input type="checkbox"/> Clearview <input type="checkbox"/> Oraquick <input type="checkbox"/> Other <input type="checkbox"/> NAAT/RNA Testing <input type="checkbox"/> Other					
	Test Result			<input type="checkbox"/> Positive/Reactive <input type="checkbox"/> Invalid <input type="checkbox"/> Negative <input type="checkbox"/> No result <input type="checkbox"/> Indeterminate			<input type="checkbox"/> Positive/Reactive <input type="checkbox"/> Invalid <input type="checkbox"/> Negative <input type="checkbox"/> No result <input type="checkbox"/> Indeterminate					
Result Provided			<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes, client obtained result from another agency			<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes, client obtained result from another agency						
If results not provided, why?			<input type="checkbox"/> Declined notification <input type="checkbox"/> Did not return/Could not locate <input type="checkbox"/> Other			<input type="checkbox"/> Declined notification <input type="checkbox"/> Did not return/Could not locate <input type="checkbox"/> Other						
Choose one: <input type="checkbox"/> Client completed a behavioral risk profile <input type="checkbox"/> Client was not asked about behavioral risk factors <input type="checkbox"/> Client was asked, but no behavioral risks identified <input type="checkbox"/> Client declined to discuss behavioral risk factors												
For clients completing a risk profile, did the client report the following behaviors in the past 12 months? <small>(select all that apply)</small>												
RISK FACTORS				No	Yes	Don't Know				No	Yes	Don't Know
	Vaginal or anal sex with a male			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Vaginal or anal sex with a transgender person			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	With a male without using a condom			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	With a transgender without using a condom			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	With a male who is an IDU			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	With a transgender who is an IDU			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	With a male who is 900 positive			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	With a transgender who is 900 positive			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Vaginal or anal sex with a female			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Injection drug use			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	With a female without using a condom			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Share drug injection equipment?			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	With a female who is an IDU			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Vaginal or Anal Sex with MSM? (female only)			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	With a female who is 900 positive			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>						
	Other risk factors: [][][][][][][][][][]						Have you ever been, or are you currently in, an abusive romantic/sexual relationship? Yes <input type="checkbox"/> No <input type="checkbox"/>			Referral needed? Yes <input type="checkbox"/> No <input type="checkbox"/>		
Other Session Activities (see codes on reverse)												
[][][][][][][][][][]			[][][][][][][][][][]			Local Use Fields			Notes			
[][][][][][][][][][]			[][][][][][][][][][]			L4 [][][][][][][][][][]						

Codes for Site Types: CLINICAL

F01.01 Clinical - Inpatient hospital
 F02.12 Clinical - TB clinic
 F02.19 Clinical - Substance abuse treatment facility
 F02.51 Clinical - Community health center
 F03 Clinical - Emergency department
 F08 Clinical - Primary care clinic (other than CHC)
 F09 Clinical - Pharmacy or other retail-based clinic
 F10 Clinical - STD clinic
 F11 Clinical - Dental clinic
 F12 Clinical - Correctional facility clinic
 F13 Clinical - Other

Codes for Site Types: NON CLINICAL

F04.05 Non-clinical - HIV testing site
 F06.02 Non-clinical - Community setting - School/educational facility
 F06.03 Non-clinical - Community setting - Church/mosque/synagogue/temple
 F06.04 Non-clinical - Community Setting - Shelter/transitional housing
 F06.05 Non-clinical - Community setting - Commercial facility
 F06.07 Non-clinical - Community setting - Bar/club/adult entertainment
 F06.08 Non-clinical - Community setting - Public area
 F06.12 Non-clinical - Community setting - Individual residence
 F06.88 Non-clinical - Community setting - Other
 F07 Non-clinical - Correctional facility - Non-healthcare
 F14 Non-clinical - Health department - field visit
 F15 Non-clinical - Community Setting - Syringe exchange program
 F88 Non-clinical - Other

Codes for Other Risk Factor(s)

01 Exchange sex for drugs/money/or something they needed	13 Sex with multiple partners
02 While intoxicated and/or high on drugs	14 Oral sex
05 With person of unknown HIV status	15 Unprotected vaginal/anal sex with a person who is an IDU
06 With person who exchanges sex for drugs/money	16 Unprotected vaginal/anal sex with a person who is HIV positive
08 With anonymous partner	17 Unprotected vaginal/anal sex in exchange for drugs/money/or something they needed
12 Diagnosed with a sexually transmitted disease (STD)	18 Unprotected vaginal/anal sex with person who exchanges sex for drugs/money
	19 Unprotected sex with multiple partners

Codes for Other Session Activities

04.00 Referral	09.01 Demonstration - Condom/barrier use	11.14 Discussion - Availability of partner notification and referral services
05.00 Personalized Risk assessment	09.02 Demonstration - IDU risk reduction	11.15 Discussion - Availability of social services
06.00 Elicit Partners	09.03 Demonstration - Negotiation/Communication	11.16 Discussion - Availability of medical services
07.00 Notification of exposure	09.04 Demonstration - Decision making	11.17 Discussion - Condom/barrier use
08.01 Information - HIV/AIDS transmission	09.05 Demonstration - Disclosure of HIV status	11.18 Discussion - Negotiation/Communication
08.02 Information-Abstinence/postpone sexual activity	09.06 Demonstration - Providing prevention services	11.19 Discussion - Decision making
08.03 Information-Other sexually transmitted diseases	09.07 Demonstration - Partner notification	11.20 Discussion - Providing prevention services
08.04 Information-Viral hepatitis	09.66 Demonstration - Other	11.21 Discussion - Alcohol and drug use prevention
08.05 Information - Availability of HIV/STD counseling and testing	10.01 Practice - Condom/barrier use	11.22 Discussion - Sexual health
08.06 Information-Availability of partner notification and referral services	10.02 Practice - IDU risk reduction	11.23 Discussion - TB testing
08.07 Information - Living with HIV/AIDS	10.03 Practice - Negotiation/Communication	11.66 Discussion - Other
08.08 Information - Availability of social services	10.04 Practice - Decision making	12.01 Other testing - Pregnancy
08.09 Information - Availability of medical services	10.05 Practice - Disclosure of HIV status	12.02 Other testing - STD
08.10 Information - Sexual risk reduction	10.06 Practice - Providing prevention services	12.03 Other testing - Viral hepatitis
08.11 Information - IDU risk reduction	10.07 Practice - Partner notification	12.04 Other testing - TB
08.12 Information - IDU risk free behavior	10.66 Practice - Other	13.01 Distribution - Male condoms
08.13 Information - Condom/barrier use	11.01 Discussion - Sexual risk reduction	13.02 Distribution - Female condoms
08.14 Information - Negotiation / Communication	11.02 Discussion - IDU risk reduction	13.03 Distribution - Safe sex kits
08.15 Information - Decision making	11.03 Discussion - HIV testing	13.04 Distribution - Safer injection/bleach kits
08.16 Information - Disclosure of HIV status	11.04 Discussion - Other sexually transmitted diseases	13.05 Distribution - Lubricants
08.17 Information - Providing prevention services	11.05 Discussion - Disclosure of HIV status	13.06 Distribution - Education materials
08.18 Information - HIV testing	11.06 Discussion - Partner notification	13.07 Distribution - Referral lists
08.19 Information - Partner notification	11.07 Discussion - HIV medication therapy adherence	13.08 Distribution - Role model stories
08.20 Information - HIV medication therapy adherence	11.08 Discussion - Abstinence/postpone sexual activity	13.66 Distribution - Other
08.21 Information - Alcohol and drug use prevention	11.09 Discussion - IDU risk free behavior	14.01 Post-intervention follow up
08.22 Information - Sexual health	11.10 Discussion - HIV/AIDS transmission	14.02 Post-intervention booster session
08.23 Information - TB testing	11.11 Discussion - Viral hepatitis	15.00 HIV Testing History Survey
08.66 Information - Other	11.12 Discussion - Living with HIV/AIDS	16.00 Risk Reduction Counseling
	11.13 Discussion - Availability of HIV/AIDS counseling & testing	17.00 Personalized Cognitive Counseling
		88 Other

Form ID Number Here

COORDINATION OF CARE AND SERVICES AGREEMENT

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:

- 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 these services. I allow the selected agencies listed on page 2 to use and exchange the information I approve to be shared in order for the selected agencies to work together more efficiently to provide or coordinate these services or benefits.

I understand that this coordination of care and services agreement is valid for 2 years from the Agreement Date below. In addition, it is understood that in order to assist in the coordination of my care, a health systems navigator, patient navigator, medical provider, clinical staff or other linkage personnel can attempt to contact me by the approved methods on page 2, 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

Diagnosis: HIV
 Hepatitis C (HCV)

First Diagnosis Date: ____/____/____
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
- Substance Abuse Diagnosis/
Treatment

- Testing Information
- Financial Information
- Individual Services Plan
- Mental Health Diagnosis/
Treatment

May be Released to:

- Medical Care Providers
- Other Core Medical Services
- Mental Health/Substance Abuse Services
- Medication Access
- Other Services, Specify: _____

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:

Attachment H

e2Virginia System Access Request Form

To request electronic access to the e2Virginia system, please follow the following steps:

- Complete and fax this form to VDH at (804)864-7983.
- Submit a **signed** Data Security & Confidentiality Guidelines "**Verification of Receipt and Assurance of Key**

Requirements for non-DDP Personnel". ***Your request will not be approved without a signed certificate of receipt. ***

- For a copy of the Data Security & Confidentiality Guidelines, please go to:
http://www.vdh.virginia.gov/epidemiology/DiseasePrevention/documents/pdf/DDP_Security_and_Confidentiality_Policies_and_Procedures.pdf
- Agencies are required to notify the Division of Disease Prevention at VDH of users who are no longer with the agency within one business day so access to e2Virginia can be terminated.

e2Virginia Access Request	
Action Requested:	<input type="checkbox"/> Add User <input type="checkbox"/> Remove User
Date of Request:	_____
User Name:	_____
User Title/Role:	_____
Agency Name:	_____
User Email:	_____
User Phone Number:	_____
Supervisor Name:	_____
Supervisor Signature:	_____
Check here for level of requested access:	<input type="checkbox"/> Agency User/Data Entry <input type="checkbox"/> Agency Administrator
VDH Administration Use Only:	

Action:

Add User

Remove User

Disapproved

Signature/Date: _____

Role:

Agency User

Agency Administrator

VDH User

VDH Administrator

Notes:

Division of Disease Prevention (DDP) Security and Confidentiality Policies and Procedures
Verification of Receipt and Assurance of Key Requirements for Non-DDP Personnel¹
(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: _____

¹This 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 J

VDH NEW CTR HIV TEST FORM ORDER REQUEST

DATE: _____ AGENCY PHONE _____
NAME MUST BE FULLY WRITTEN OUT. (NO ABBREVIATIONS)

ATTENTION TO:

Name of Agency and Street Address:

PLEASE NOTE: **NO POST OFFICE BOX** Give STREET ADDRESS ONLY.

REQUESTS TO: Micah Daingerfield at Michah.Daingerfield@vdh.virginia.gov
or fax to (804) 864-7970

PLEASE SPECIFY NUMBER OF HIV TEST FORMS NEEDED

Test Form Part Required - Every HIV Test

_____ Test Form Part Required - Positive Results

• Request for Tyvek envelopes – Please specify amount of envelopes here: _____.

• **Please start using the VDH 900 Test Forms NOW.**

Thank You!

VDH Division of Disease Prevention HIV CTR (900) and Tyvek Order Form for Community Based Organizations

Requestor Information

Agency Name: [Click here to choose an agency.](#) Date: [Click here to enter a date.](#)

Agency Contact Name: [Click here to enter a contact.](#) Phone: [Click here to enter phone.](#)

Agency Contact Name: [Click here to enter a contact.](#) Email: [Click here to enter email.](#)

Shipping Address: [Click here to enter shipping address.](#)

CTR (900) Forms

[Click here to enter # needed.](#) Test Form
Part 1.

Required for every HIV test.

[Click here to enter # needed.](#) Test Form
Part 2

Required for every positive result.

Tyvek Envelopes

[Click here to enter # needed.](#)

Email request to Micah.Daingerfield@vdh.virginia.gov or fax order request to 804-864-7970. Phone 804-864-8002.

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 Wait Time* (in minutes)	Test Result N = Non-reactive R = Reactive I = Invalid	Staff Initials	Report Time**

* Test Wait Time = Time from starting test to reading test results (in minutes)
 Clearview® Complete (15 minutes)
 Clearview® Stat-Pak (15 minutes)
 OraQuick (20 minutes)

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

Attachment O

Agency: _____ CLIA# _____

Rapid Test Discordant Test Case Report

This form is to be completed for ALL testing situations that involve a reactive rapid HIV test result and a nonreactive or invalid confirmatory second rapid HIV test result.

To be completed by the testing site

Site name: _____

Person completing report: _____ State: _____

Telephone: _____

Client Demographics

Client Code: _____ Age: _____

Gender: Male Female Transgender Other Unknown

Race (check all that apply):

American Indian/Alaskan Native Asian Black/African-American
 Native Hawaiian/Pacific Islander White Other Unknown

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

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

HIV Risks (check all that apply):

Heterosexual sex MSM IDU Sex with HIV-positive person Other

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

Vaccination History:

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

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

Rapid HIV-1 Test

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

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

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

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

Test Result: Reactive Non-reactive Invalid

Attachment Q

Personnel Responsibilities

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

Personnel Responsible for QA

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

Test Kit Storage

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

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

Monitoring Test Kit Inventory

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

Receive Test Kit Delivery

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

Next Inventory Process Item

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

Monitoring Test Kit Storage Area Temperature

Storage area for test kits shall be equipped with an accurate thermometer. A “Test Kit Storage Temperature Log” (see **Attachment 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 OSHA-required waiver indicating their refusal.
When	Before testing begins at each site, and counselors shall receive a copy before initiating their first rapid test.
By Whom	[Insert name and/or position here of the person responsible for this activity.]
Corrective Action(s)	[Describe corrective action here.]