

LA Department of Health Office of Public Health
STD/HIV/Hepatitis Program
HIV, Syphilis, and Hepatitis C Prevention Counseling and Rapid Testing
Quality Assurance and Procedural Protocol for CBOs
Revised April 2024

I. DESCRIPTION OF THE INTERVENTION

A. The HIV, Syphilis, and Hepatitis C Prevention Counseling, Rapid Testing, and Referral Services (CTR) intervention involves one-on-one, client-centered, risk/harm reduction counseling sessions coupled with screening for HIV, syphilis, and hepatitis C (HCV); whereby both test results and appropriate referrals to other services are provided to clients during the same visit. The rapid (same visit results) HIV, syphilis, and HCV testing components of the intervention can only be conducted in community settings using FDA approved and CLIA-waived rapid HIV test devices. "CLIA" stands for the Clinical Laboratory Improvement Amendments, which represents federal legislation and an oversight administration that governs and classifies all diagnostic tests performed on human subjects according to each test's level of operating difficulty. Rapid syphilis and HCV testing will only take place in conjunction with HIV testing; **standalone syphilis or HCV testing should not occur** (unless the client has previously had a reactive/positive test to either).

B. The State of Louisiana standards for HIV Prevention Counseling, Rapid Testing and Referral Services (abbreviated as CTR for the remainder of this protocol) are based on the integrated National Centers for Disease Control and Prevention's (CDC) HIV prevention counseling and rapid testing models, which empower clients to assess their own behaviors and develop a realistic plan for behavior change. More information regarding the CDC guidelines for HIV rapid testing and prevention counseling can be found on the CDC's website (www.cdc.gov).

II. PREREQUISITES TO IMPLEMENTING CTR

This section covers what must be done to assure the proper functioning of the rapid test and to prepare an agency for implementing the CTR intervention. Before CTR can be performed, prerequisites related to physical testing sites, testing supplies, quality assurance and personnel training must be satisfied.

A. Prerequisites for CTR Sites

1. CTR conducted by CBOs is reserved for high-prevalence areas as outlined in the Integrated Plan and high priority zip codes. CBOs under contract with SHHP should maintain/establish CTR sites in areas that have been identified by the Regional Prevention Coordinator as priority zip codes in the area, or identified as a site of particular importance/appropriateness for HIV prevention activities (such as a site with a history of at least 1% new positivity among individuals tested, a site where high risk activities occur such as commercial sex work, etc. or a site where individuals belonging to priority populations are known to congregate).

2. All sites must be assessed and approved by the OPH STD/HIV Program Regional Prevention Coordinators (SHHP) before CTR can be conducted. Agencies conducting CTR must register

both fixed and mobile sites through the SHHP Regional Coordinator or other SHHP prevention staff using the Site Assessment and Registration Form (see Attachments RT-3.5). If not conducted virtually, SHHP staff will visit each potential site to determine if it is appropriate for rapid testing activities. Please allow up to four (4) weeks to process the Site Assessment and Registration Form. SHHP will assign a unique site number and site type code for the new site and send a notice of approval for CTR back to the requesting agency once the registration process is complete.

Requesting an expedited new site registration: Expediting a temporary approval of a testing site may be allowed on a case-by-case basis and only for short term use until fully approved by the Regional Coordinator. There is no guarantee that a conditional/temporary approval will be granted without enough notice. Please allow at least 2-3 business days to review the new site proposal. The Regional Prevention Coordinator will conduct their own assessment in-person and confirm with their approval for long term use.

The request must be accompanied by the following:

- a. Reasoning for the expedited request/urgency
- b. Testing site registration form with both a detailed description of testing site as well as a self-evaluation of the following components for a site that attests for the acceptability of the following:
 - Work space to process test
 - Confidentiality of setting
 - Cleanliness
 - Lighting
 - Temperature control
 - Supply storage
 - Hand washing station
 - Record keeping
 - Waiting area
- c. Ample photos of proposed testing site

3. Agencies conducting CTR must yield at least a one-percent (1%) newly identified positivity rate annually for HIV. The percent positivity is defined as the total number of newly identified reactive HIV tests, divided by the total number of tests conducted by the agency and multiplied by one hundred.

4. A representative from SHHP Prevention staff may be in attendance during the agency's first day of CTR implementation to monitor quality assurance and adherence to protocols.

5. All CTR sites must provide a private, confidential setting for HIV prevention counseling to occur.

Essential elements of a confidential setting include:

- i. Appropriate space for a private conversation to occur.
- ii. Private or confidential area for counseling session.

iii. All testing site staff to respect privacy and dignity of clients.

6. Agencies providing any CTR are required to post a sign in their reception area stating the age limitations for rapid testing and provide appropriate referrals to other testing sites for clients outside of the serviceable age range.

- **Failure to comply with a manufacturer's instructions is a violation of a testing site's CLIA agreement.**
- **Minors in Louisiana may consent to HIV/STD testing without parental consent.**
- **The information below is found in RS 40:1095 and 40:1065, the links below will take you to additional information:**

Summary

- Adults
 - In Louisiana, an adult who is not mentally ill or otherwise incompetent has sole right to consent to his or her care. Even if you are married, you make your own health care decisions and your spouse does not have a right to change them. Physicians and other health care providers must respect your privacy and cannot talk to others about your care without your permission, unless you are unable to consent or they are required to make a legal report of your condition. If you tell your doctor that you do not want your spouse to know about your medical care, then the doctor or hospital cannot talk to your spouse about your care.
 - If you are mentally ill or otherwise permanently incompetent, the court will appoint a person to make decisions for you. In many cases this will be your spouse.
 - If you are unable to consent to medical care because of an accident or a illness, Louisiana allows the court to appoint someone to consent for you. If the court has not appointed someone to consent for you, and you have not appointed someone yourself, then your spouse may consent to care for you. Your spouse may not consent for you if you are judicially separated. If you are not married or your spouse is not available, then your adult children, your parents, or other relatives may consent to care for you.
 - If there is a medical emergency and there is no one available who can consent to care, the doctors can take care of you without getting consent. This is called implied consent because the law assumes you would want to be treated.
- Minors
 - Louisiana allows minors to consent to their own medical care without telling their parents. This includes care for pregnancy and childbirth, and sexually transmitted infections. (There are special rules about abortion and sterilization.) The statute does not set a lower limit on the age of minor who may consent, and there is no case law that sets a minimum age of consent. Physicians are protected from liability for relying on the consent of a minor.
 - If you are a minor, the doctor is not required to tell your parents or guardian about your care, but may tell them if this is in your best interest, even if you do not want them told. If your parents disagree with you about your care, their decision is final.
 - Parents can consent to the care of their minor children, even if the parent is a minor.

Consent for Minors

[RS 40:§1095. Medical treatment \(for minors\)](#)

[La. R.S. § 40:1065.1. Minor's consent for treatment of venereal diseases](#)

Age Limitations for Rapid Testing

- i. Rapid HIV testing may be offered to individuals age 13 and older. Persons 12 and younger must be referred to an early intervention clinic or pediatrician for proper medical attention and assessment of HIV infection.
- ii. Rapid syphilis testing may be offered to individuals age 13 and older. Persons 17 and younger must be referred to a clinical site for assessment of syphilis that does not involve the Syphilis Health Check (SHC).
- iii. Rapid HCV testing is approved for people age 15 and older. Persons 14 and younger must be referred to a clinical site

7. All testing sites are required to develop and/or maintain written policies on crisis intervention and management, assessing the sobriety or mental clarity of clients to consent to services or obtain services, confidentiality, adhere to HIPAA standards, and the right to deny services.

8. Organizations are responsible for obtaining the proper liability insurance coverage for rapid HIV testing. SHHP may require proof of current and appropriate insurance prior to the approval of any rapid HIV testing activities.

9. Organizations must obtain a CLIA certificate independent of the public health laboratory for processing rapid HIV test kits. CLIA application fees are the responsibility of the organization. Instructions for completion are available through the OPH SHHP Regional Coordinator. A copy of the agency's CLIA certificate must be faxed or emailed to OPH SHHP prior to the initiation of any rapid testing activities. It is the responsibility of the organization to renew, maintain, and display this certificate on site.

10. Agencies conducting CTR must arrange for the proper disposal of biohazardous waste materials resulting from CTR activities. All used rapid testing devices and other testing materials that have come into contact with bodily fluids must be disposed of in biohazard waste material bags in accordance with local regulations for infectious waste disposal. Shipping and/or transporting of processed devices/vials outside approved testing areas is prohibited, unless stored in a sealed and clearly marked biohazard waste container and placed in a trunk or impermeable container to ensure no contact with personnel or other individuals in the event of an accident, etc.

11. Agencies interested in conducting SHC and rapid HCV but do not have onsite follow up testing and/or treatment available must submit documentation of their plan for linkage to follow up testing and treatment. This written plan must include:

- A. The agency they are partnered with for confirmatory testing and treatment.

B. Documentation of the agreement (MOU) with the testing agency and the agency or clinic patients are being referred to for follow up testing and treatment. This should include check marks for the agency to confirm the following for syphilis:

___ Confirmatory (non-treponemal AND treponemal) Testing Available

___ Laboratory used: _____

___ Bicillin and Doxycycline available (Doxycycline for patients with penicillin allergy)

___ Basic Emergency Treatment for Anaphylaxis available on site (Epinephrine IV and Benadryl IV with 911 call)

C. The process for reporting syphilis and HCV treatment confirmation back to SHHP, including how the CBO will obtain confirmatory test results and/or confirmation of treatment from the referral agency

D. Identification and contact information for the agency staff responsible for ensuring client follow up, etc.

E. The SHHP Regional Coordinator will review and approve the written plan.

B. Prerequisites for Testing Supplies

1. Unless otherwise approved by SHHP staff, testing sites contracted or approved to conduct rapid HIV testing will use Determine and INSTI rapid testing devices – all technologies are CLIA waived, single-use, qualitative immunoassays to detect antibodies to HIV. Determine also detects the HIV p24 antigen. The processing time for Determine is 20-30 minutes and one minute for INSTI.

On a case-by-case basis, agencies may request a temporary change in the testing algorithm of leading with Determine and confirming with INSTI, especially for high volume testing events and other special occasions. Prior approval must be obtained by SHHP's Statewide Testing and/or Prevention Program Manager before proceeding.

The Determine HIV-1/2 Antigen/Antibody Combo Test consists of:

- o A single-use testing device
- o A disposable workstation to place the testing device in
- o Disposable single use specimen collection pipette (50µl)
- o Chase buffer solution

The INSTI Rapid HIV-1/2 Antibody Test consists of:

- o A single use testing device
- o 3 solution vials
- o Disposable single use specimen collection pipette (50µl)
- o Sterile safety lancet
- o Alcohol prep pad

2. Testing sites contracted or approved to conduct rapid syphilis testing will use the Syphilis Health Check (SHC) rapid testing device. It is a CLIA waived, single-use, qualitative immunoassay technology to detect treponema pallidum (syphilis) antibodies. The processing time for SHC is 10-15 minutes.

The Syphilis Health Check (SHC) test consists of:

- o A single use testing device
- o Disposable single use specimen collection pipette (50µl)
- o Diluent bottle

3. Testing sites contracted or approved to conduct rapid HCV testing will use the OraQuick HCV rapid testing device. It is a CLIA waived, single-use, qualitative immunoassay technology to detect HCV antibodies. The processing time for OraQuick HCV is 20 minutes.

The OraQuick HCV rapid test consists of:

- o A single use testing device
- o A single use developer vial
- o Disposable single use specimen collection loop
- o A reusable test stand

4. In addition, testing sites will also need:

- o Sterile gauze
- o Alcohol prep pads
- o Adhesive bandages
- o Determine, INSTI, Syphilis Health Check, and HCV controls
- o Disposable absorbent workspace covers
- o Biohazard waste disposal bags
- o Latex/polyurethane/nitrile gloves
- o Sharps container
- o Disposable lancets
- o Thermometers (one for the area where test is processing, one for the storage area, one for the refrigerator/freezer, one for mobile sites)
- o Freezer
- o Timers
- o 10% bleach solution or FDA approved disinfectant
- o HIV test forms
- o Informed consent forms

5. Approved supplies will be provided by SHHP for SHHP funded CTR sites. Agencies may be required to obtain certain items at their own expense. CTR sites will not be provided additional funds for supplies or phlebotomy services. Up to date documentation of testing (including HIV test forms) must be submitted to SHHP before any additional supplies will be sent to a site.

C. Prerequisites for Quality Assurance of Test Kits

1. Running and documenting the results of external controls is the primary method to ensure the accuracy of rapid test devices. The respective controls verify that the rapid tests are working properly and that users are able to properly administer and interpret the test.

2. CTR sites should run controls at least once each week before the start of testing that week – controls should additionally be run under any of the following conditions:

- i. Prior to a newly trained counselor conducting CTR with a patient/client
- ii. When opening a new test kit lot (lot numbers are printed on each box and device)
- iii. When a new shipment of test kits is received
- iv. If the temperature of the test kit storage area falls outside the acceptable storage temperature range
- v. If the temperature of the testing area falls outside of the acceptable storage temperature range
- vi. Prior to using test kits at remote locations (when the test kits are used outside of the area where they are stored), e.g., mobile vans, outreach testing, prisons/jails, drug treatment centers, etc.

3. If the results of any one of the control tests do not match the expected result, re-run all controls. If the repeated control test run produces unexpected results, do not use any tests from that entire lot number and notify the SHHP Capacity Building Supervisor, Regional Prevention Coordinator, or Statewide Testing Supervisor immediately.

4. Each rapid test device contains a built in control feature that demonstrates whether or not the test was conducted correctly. A control line or dot should appear in the control area (may be labeled “C” or “Control” depending on the specific device being used) of the test strip. The control line/dot must appear in order for the respective test to be valid, whether or not there is a line/dot present in the test area of the test strip. The rapid test must be considered “invalid” when:

- i. No control line/dot appears in the control area of the testing device
- ii. A colored or flecked background in the result window makes it too difficult to read the result after the required processing time has elapsed
- iii. If any of the lines are not inside the appropriate control or test line areas (does not apply to INSTI)

D. Prerequisites for CTR Staff/Personnel

**In light of the COVID-19 pandemic, some of the certification steps have been adapted to mitigate risk of exposure. Temporary guidance is included below:*

HIV, Syphilis, & Hepatitis C Prevention Counseling, Rapid Testing and Referral Services (CTRS) Certification Process

*Due to the global COVID-19 pandemic and being unable to conduct in person trainings that are normally 2.5 days, SHHP is releasing some **temporary** guidance for this training and the certification process. To help meet the needs of our CBOs, SHHP will be providing the CTRS training virtually through the zoom learning platform until a new normal is established that allows for in person trainings and observations. Please be patient with us during these uncertain times as guidance is subject to change. For the time being, the training will be **four** days long, with a two-hour session in the morning (10am-12pm) and a two-hour session in the afternoon (1pm-3pm) each day. We are suggesting that participants be essential testing staff/volunteers at this time, however if individuals or agencies are interested in other types of educational trainings, including but not limited to HIV/STD/HCV 101 they can reach out to SHHP’s [Capacity Building](#)*

Supervisor directly. Below you will find the process for CTRS certification and the new responsibilities of the QA coordinator at the agencies for the time being:

1. Prospective counselors can register for one of the training below by emailing their preferred date to the [Capacity Building Supervisor](#). The schedule may adjust as COVID-19 measures and social distancing guidance changes. Once in person trainings are safe to conduct, SHHP will resume providing those across the state. Confirmation emails with the zoom link will be sent to registered participants.
2. **Prior** to the training, prospective counselors need to learn how to conduct each rapid test at the agency AND run controls at the agency including all necessary information on PPE and quality assurance guidance for safety. This will include reviewing the COVID-19 mitigation plan the agency has put in place. All prospective counselors should learn what a non-reactive/negative, reactive/positive, and invalid test results look like and be able to interpret them correctly within a week before the training. The testing technologies should include Determine, Insti, Syphilis Health, OraQuick HCV, and if applicable SureCheck. Agencies that don't offer rapid syphilis or hepatitis screening will not need to cover those tests. Additionally, the QA coordinator needs to show each prospective counselor how to properly conduct a fingerstick puncture and blood collection procedure. The QA coordinator will email the [Capacity Building Supervisor](#), confirming the names of all prospective counselors who completed these tasks along with the dates of completion prior to the training. SHHP staff will also send out informational videos about each testing technology after registration and prior to the training to be viewed before the virtual training. All of the information will be reviewed during the virtual training to answer questions.
3. Prospective counselors will attend and participate in the virtual CTR training. It is required that all participants have the connectivity and technology to participate with both video (webcam) and audio functions. If a participant cannot ensure this feature will be available to them, they will not be able to complete the virtual training.
4. After the training, a survey monkey link will be sent to the QA coordinator who can open the link at the agency where the prospective counselor can take the test. The QA coordinator must be in the room to proctor the test to ensure test integrity, such as not using the internet during the test or referring to the training materials, slides, etc . After receiving and scoring the test, SHHP staff will then email the results indicating a pass or fail. As a reminder, if an individual fails the test two times, they will need to retake the training before moving on.
5. Prospective counselors will still need to practice the fingerstick collection process at least two times at the agency and observe at least two CTRS sessions with already certified counselors. When they are ready for their own counselor observation, SHHP will email the QA coordinator a copy of the grading rubric and have the QA coordinator conduct the observation with a client. The results from that observation will be sent to the [Capacity Building Supervisor](#). As a reminder, if an individual fails the observation two times they will need to retake the training. If you are interested in attending a zoom virtual meeting on reviewing the counselor observation form and to ask questions, please email the [Capacity Building Supervisor](#).
6. After SHHP receives the completed observation form and the counselor meets those requirements, an email will be sent to the individual counselor and the QA coordinator that they can begin CTRS using the QA coordinator's worker/counselor ID number. This will be a temporary procedure until SHHP staff can conduct in person observations. As social distancing guidance are updated, and SHHP staff can physically come to the agency in person, the prospective counselor will then need to be re-observed by SHHP staff. Currently, we do not know when this will be possible but will send out additional information as we have it. After SHHP staff have observed and passed the prospective counselor, then they will be emailed their own worker/counselor ID number along with a certificate to the agency.

If COVID-19 restrictions are not in place, please follow the guidance below. If you are unsure of which process to follow please contact your Regional Prevention Coordinator for clarity.

1. All persons certified to conduct CTR must first attend the combined HIV, Syphilis, and HCV Prevention Counseling and Rapid Testing training (CT training). Applications must be submitted online at www.louisianahealthhub.org. Any person who is confirmed to attend CT training but does not show up or cancel within 24 hours prior to the start of training, will not be given priority in future CT training. If this occurs twice within a 12 month period, then the person will not be allowed to attend any CT training for 2 years after the second missed training.

2. After completing the CT training and receiving a certificate of completion, these additional steps must be taken.

- o An online test covering prevention counseling, rapid testing skills, and protocol/paperwork must be passed. The dates, locations, and method of signing up for a class are outlined on www.louisianahealthhub.org.
- o All persons must practice the finger stick blood collection process at their respective agencies a minimum of two times prior to testing clients. This will entail properly using a lancet and pipette to collect 50µl of blood. This blood will NOT be used to run any testing device.
- o All persons must watch a certified CTR counselor conduct at least two sessions. The client must consent and agree to allow the observer in the room.
- o After all of these previous steps have been completed, persons conducting CTR must successfully complete an observation session with the Regional Prevention Coordinator or other SHHP Prevention staff as arranged by the Prevention Coordinator (see attachment RT-3.9).

Note: Each person has two opportunities to pass the written test and the counselor observation. If the person fails either the test or the observation twice, they must go through the entire process again, beginning with training. The written test must be passed before the observation can be scheduled. If more than two lancets are required for the finger stick procedure that will result in automatic failure of the observation. Once the SHHP Training Coordinator assigns a unique counselor number to the counselor, they are fully certified and may conduct CTR.

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

4. Clients should only see one counselor – this includes giving test results and for any follow-up visits if possible. Consistency of the client and counselor relationship helps the client feel secure, reduces misunderstanding, and promotes the likelihood of effective risk reduction and/or linkage to care.

5. All agencies must identify, in writing, a designated Quality Assurance Coordinator (QAC) (typically the same person identified to CLIA as the laboratory director – this could be the Counseling and Testing Supervisor/Coordinator, Head Nurse, Prevention Manager, etc.). The Agency’s rapid testing Quality Assurance Coordinator will be responsible for informing other staff on updates and/or revisions to the State of Louisiana Rapid HIV, Syphilis, and HCV Testing and Prevention Counseling Quality Assurance Protocol as needed. The Quality Assurance Coordinator is also responsible for ensuring their agency is in 100% compliance with the quality assurance protocol including the proper use, storage and documentation of rapid testing devices/activities. This includes ensuring that all rapid testing logs are checked at least once per month. Quality Assurance Coordinators must be fully trained on the rapid testing device(s) being used at their agency and have sufficient experience with rapid testing (Ideally they also have at least 6 months of experience rapid testing and at least 200 tests conducted for staff at established agencies – agencies not new to conducting rapid testing).

When designating a new QA Coordinator, notification should be sent (via email) to both SHHP’s Statewide Testing Coordinator and your agency’s Regional Prevention Coordinator with the following information:

1. The testing agency
2. The testing location (if agency has multiple locations)
3. Reason for changing QA
4. New QAC Name, title, counselor number, phone number, work email, months/years of experience with testing

III. REQUIRED ACTIVITIES DURING CTR SESSIONS

A. General Requirements for Conducting CTR Sessions

1. All agencies conducting CTR in Louisiana must model sessions with clients according to the format and guidelines that follow. The Regional Prevention Coordinator and the Testing and Capacity Building Supervisor must approve any alternate model/process of conducting the CTR intervention. Agencies that want to use an alternate model/process of conducting CTR must submit detailed proposals along with any supporting evidence, in writing, to the Regional Prevention Coordinator. Agencies will be notified by SHHP in writing whether or not it is acceptable for an alternate model/process of conducting the intervention (see Attachment RT-3.7 for one-page model).

2. Universal precautions for the prevention of occupational exposure to blood borne pathogens must be strictly adhered to at all times during CTR sessions.

B. Required Activities Before the Rapid Test Begins Processing (Before Testing)

1. Introduce yourself to the client. Give the client your name and welcome them to the agency.

2. Assess client's readiness to receive the results on the same day. Ask the client open-ended questions to determine their motivation for getting tested and what, if any, support system is in place.
3. Offer options for testing that are available including confidential and anonymous testing. Anonymous testing is not an option with SHC; clients will have to give their full name and contact information if they want to receive SHC. If syphilis follow-up testing cannot be performed at the time of a positive SHC, a full name and contact information must be given when the client arrives at the office for follow up testing and entered on the new Part 1 form. Conventional syphilis test will also be marked on this Part 1 form.
4. Offer anonymous and confidential options for HIV and HCV, and explain what each means. Clients must be offered the option of anonymous or confidential HIV testing in accordance with Louisiana law 1300.12 HIV –related testing; consent; exceptions, element E. Anonymous testing involves the use of no personal identifiers (i.e. last name, first name, or social security number) that would link an individual to their test result. Confidential testing indicates a client is willing to provide personal identifiers (including a first and last name and at least one of the following: mailing address, e-mail address, or phone number) that can be used to link the individual to their rapid test result. Confidential testing is strongly encouraged to facilitate the entry into follow-up medical services for tests that are reactive/positive for HIV, syphilis, and/or HCV and should be encouraged for all confirmatory testing. Persons testing anonymously cannot be contacted – they can only receive test results by keeping track of and presenting their "P" number, which corresponds to their HIV test form. See B3 above for guidance on confidential testing for syphilis.
5. If a client tests anonymously with the rapid HCV test, they will have to give their name and contact information after a reactive HCV rapid in order to be connected to confirmatory testing and curative treatment.
6. Describe the testing process, what type of specimen will be collected, how long the whole process will take, and what each of the three possible results mean. It is a part of informed consent for clients to understand what type of specimen will be taken from them, how long the rapid testing session will take, and that the three possible results from any rapid test are preliminary (reactive/positive, non-reactive/negative, and invalid). Clients should also be informed what actions will take place after each of the results.
7. Explain to client that if a preliminary reactive result for HIV is received, a second rapid test should be conducted (unless it is an antigen only reactive). According to the CDC, a very important part of counseling persons who have a reactive rapid HIV test result is to make sure they understand that the test result is preliminary, and further testing must be done before referring to medical care. Clients must be asked how they would react to getting a preliminary reactive result in a rapid time frame in order to determine if testing is beneficial at that time.
8. Explain to client that if a positive rapid test result for syphilis is received, lab based follow up tests should be conducted. Follow up testing will include both non-treponemal tests (i.e. RPR or

VDRL) as well as a treponemal test (i.e. TP-PA, FTA-ABS, or EIA). The appropriate lab code when ordering follow up syphilis testing for LabCorp is TPPA + Quant RPR. For CRL, the correct lab code for follow up testing is 3455: T. Pallidum antibody with reflex RPR. It is imperative that we receive lab results from both test types in order to confirm diagnosis and treatment or to determine whether a false positive has occurred.

9. Explain to the client that if a reactive rapid test result for HCV is received, lab based follow up tests (HCV RNA) should be conducted.

10. If agencies do not have the capability to draw blood for lab based testing, they must refer the client to one that does.

11. Persons who have identified themselves as HIV reactive should not be retested with a rapid test. Individuals with HIV-1 and/or HIV-2 who take antiretroviral medication can produce false non-reactive/negative rapid test results under some circumstances. If a person discloses that she or he is living with HIV, they should be referred to case management and/or medical care.

12. Ask the client if they have ever been diagnosed with syphilis in the past. Persons with a known prior history of syphilis should not receive the SHC. Syphilis antibodies remain in the body and the SHC cannot distinguish a previous infection versus a current infection. Those clients who have had a previous syphilis diagnosis should not be tested with the SHC. If there is a possibility that they have been re-infected, then the client should receive a non-treponemal test and consult with a physician.

13. Once a person has tested positive for HCV, they will always test positive for the HCV antibodies, even if they have received curative treatment. Therefore, each person should be asked if they have ever received a HCV diagnosis in the past and if the answer is yes, a rapid test should not be administered. If the client believes they may have a new infection, they should not use a rapid test and instead be referred to lab based confirmatory testing.

14. Inform the client, should they test reactive/positive for HIV and/or syphilis, they will be contacted by the Office of Public Health Disease Intervention Specialist (DIS) for Partner Services. Emphasize this is an optional, free, and confidential service OPH provides should the client want help notifying partners of their exposure to HIV and/or syphilis.

15. Obtain Informed Consent. It is required that written "Informed Consent" for HIV, syphilis, and/or HCV testing be obtained prior to clients receiving any testing. It is recommended that clients testing anonymously write the HIV Test Form number on the bottom of the Informed Consent Form. Clients testing confidentially must sign their name. Disclosure of HIV, syphilis, and/or HCV test results is strictly governed by the State of Louisiana as noted on the reverse side of the consent form.

16. Provide appropriate subject information pamphlet for the rapid test being conducted. The FDA requires all test subjects receive the "Subject Information" pamphlet produced by the manufacturer of the rapid test device being used prior to collecting a specimen for testing.

These pamphlets are included in each box of the various rapid testing products. Contact your SHHP Regional Coordinator for additional copies of these pamphlets.

17. Collect and run specimen. Testers must follow the instructions provided by the manufacturer of the rapid test device they will be using. In addition to manufacturer instructions, identifying stickers from the HIV Test form should be placed on the testing device workstation to ensure quality control. Not following the manufacturer's instructions may result in inaccurate test results.

C. Required Activities While the Rapid Test is Processing (During Testing)

1. Complete the Test form-Part 1 as much as possible. Each rapid test must be documented on the SHHP Test Form-Part 1 and test forms must be completed in their entirety and submitted to SHHP on a weekly basis to be entered for reimbursement and analysis. Additional CTR supplies may not be provided until STD/HIV test forms accounting for the previously shipped supplies are received by SHHP.

2. Conduct Step 2 (Identify personal risk behavior) of the counseling process. Step 2 should explore previous risk-reduction efforts and identify successes and challenges in those efforts. SHHP takes a person first approach, meeting clients where they are and encouraging them to expand upon sexual health promotion skills that they already use or wish to use. Factors associated with continued behaviors that might be important to explore include: using drugs or alcohol before/during sexual activity, underestimating personal risk, perceiving that precautionary changes are not an accepted peer norm, perceiving limited self-efficacy for successful change efforts, and perceiving vulnerability is associated with "luck" or "fate".

3. Conduct Step 3 (Identify safer goal behaviors) of the counseling process. When considering safer goal behaviors (Step 3), counselors should focus on reducing the client's current risks. Discussions regarding transmission modes and the meaning of test results should happen at other points in the process. However, when clients believe they have minimal risk but describe more substantial risk, the counselor should discuss the transmission risk associated with specific behaviors or activities the clients describe and then discuss lower-risk alternatives. For example, if clients indicate that they believe oral sex with a sex partner poses little or no HIV risk, the counselor can clarify that, although oral sex with a partner who is living with HIV might result in lower HIV transmission risk than anal sex, oral sex is not an entirely risk-free behavior. If clients indicate that they do not need to be concerned about HIV or HCV transmission among needle-sharing partners if they use clean needles, the counselor can clarify that HIV and HCV can be transmitted through sharing works or supplies such as cookers, cottons, or water used by several persons. With newly identified or uninformed HIV-infected clients, the counselor should discuss HIV transmission risks associated with specific sexual or drug-use activities, including those in which the client might not be currently engaged. Although the optimal goal might be to eliminate HIV risk behaviors, small behavior changes can reduce the probability of acquiring or transmitting HIV. Behavioral risk-reduction steps should be acceptable to the client and appropriate to the client's situation. For clients with several high-risk behaviors, the

counselor should help clients focus on reducing the most critical risk behaviors they are wanting to commit to changing.

4. Continue to assess client readiness to receive results. Counselors should strive to fully assess a client's readiness to receive same day test results in advance of the rapid test processing time/before timer goes off. Once the counselor interprets/reads the test results, they must provide the test results to the client unless the client objects to receiving their results at that time. Counselors should not attempt to assess client's readiness once the test results have been interpreted/read (for example, asking the client again if he/she is ready for their results after going to read the results- this should be done before interpreting/reading the results).

D. Required Activities After the Rapid Test Has Finished Processing (After Testing)

1. Provide the test result to the client (see section F. Specific Guidance on Delivering Test Results for more information).
2. Conduct Steps 4 (Create a client action plan), 5 (Offer referrals and provide support), and 6 (Summarize and Close). The action plan must be documented on the Risk Reduction Worksheet (Attachment RT-3.12).
3. Set up a follow-up appointment, if necessary, for those with non-reactive/negative test results to get re-tested.
4. Provide condoms and appropriate literature as appropriate and if client desires. Discuss PrEP, PEP, other harm/risk reduction tools.
5. Complete the remainder of the Test Form-Part 1.
6. Complete other documentation as needed.
7. Correctly dispose of used testing supplies following universal precautions and safe work practices at all times.

F. Specific Guidance on Delivering Rapid Test Results:

1. Preliminary Reactive Rapid HIV Test Result:
 - i. Accurately communicate results to client, such as" The test result is Reactive, meaning the test detected HIV antigens/antibodies, when you are ready I will conduct a second test to confirm" "The result shows signs of HIV p24 antigen and/or antibodies and a second test must be done to be sure." The only exception is if a client receives an antigen only Reactive result.

Antigen Only Reactive Result Delivery:

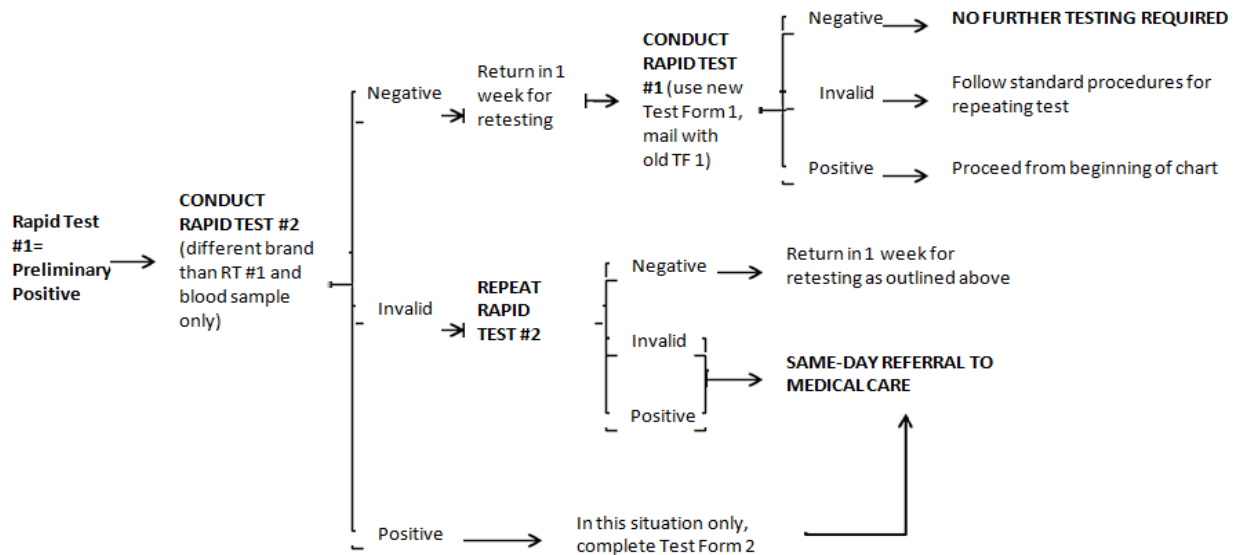
All clients testing Reactive for the p24 antigen only will NOT receive a second rapid test (because no other rapid test can detect the p24 antigen besides Determine) and will be referred directly to medical care for a viral load lab based blood draw. Explain to the client that their body has produced signs of early HIV infection and the only way to confirm that they the test is HIV Reactive is to see a doctor for a viral load. Emphasize that Determine is different from other rapid tests in that it catches infections sooner, so if the client goes to another agency to get re-tested and that agency only offers antibody testing, that test result may be non-reactive. Complete the HIV Test Form 1 and indicate the antigen Reactive result; however, you will not fill out a second column for rapid testing since you will not be conducting a second test.

Complete the Linkage into Care or Treatment (LinCT) Form and immediately contact the appropriate DIS in your region. If they are not reachable during testing hours, leave a message saying you have an antigen only Reactive. As always, do not include confidential client information in a voicemail or email.

Continue with the next steps listed below.

- ii. Allow time for emotional response. Do not rush the client into conversation.
 - iii. Ensure the client understands what the result means.
 - iv. Assess client concerns.
 - v. It is mandatory to offer a second rapid test if the first rapid is antibody Reactive. If the client tests antigen as well as antibody Reactive, the client must still be given a second rapid test. The second test must be a different rapid testing device than the first one used. 100 % of clients who have a reactive/preliminary Reactive rapid HIV test result must be offered a second rapid test and offered referrals to early intervention/medical care after receiving a second reactive test result. Conducting the second rapid test and delivering its result must be done in the same client visit.
 - If the second rapid test is invalid, repeat the test again. If two invalids are received, the client should be referred to medical care.
 - If the second rapid test is non-reactive, then clients should return one week later for retesting.
1. For follow up testing, if the first rapid test is non-reactive, no more testing is required.
 2. If the first rapid test is Reactive, follow normal procedures and conduct a second rapid test. (see testing algorithm flow chart below)
 3. A new Test Form-Part 1 should be filled out when the client returns for testing. Retain the Part 1 form from the first test in the client file until the client returns for the follow-up testing one week later, and mail both test forms to SHHP together.
 4. If the client does not return for the follow up test, mail the first Part 1 form to SHHP, and mark on the Part 1 'Client did not return for follow up testing'.
 - vi. Review the client's risk assessment and risk reduction plan.
 - vii. Emphasize the importance in taking health precautions while they wait to attend their first medical appointment.
 - viii. Provide additional referrals with client, including medical referrals and referrals to local HIV agency for other supportive services and case management.
 - ix. Remind clients that a DIS will contact them to offer assistance with notifying partners of their possible exposure to HIV.
 - x. Provide condoms and literature and discuss PrEP and PEP as deemed appropriate.
 - xi. LinCT Form should be completed when the client receives a second reactive rapid test.

Revised Algorithm for Rapid-Rapid Testing Model



2. Preliminary Positive Rapid Syphilis Test Result

- i. Accurately communicate results to client - the result shows signs of syphilis antibodies.
- ii. Allow time for emotional response. Do not rush the client into conversation.
- iii. Ensure the client understands what the result means.
- iv. Assess client concerns.
- v. It is mandatory to offer a follow up testing or make a referral to follow up testing. Follow up testing will include both non-treponemal tests (i.e. RPR or VDRL) as well as a treponemal test (i.e. TP-PA, FTA-ABS, or EIA). The appropriate lab code when ordering follow up syphilis testing for LabCorp is TPPA + Quant RPR. For CRL, the correct lab code for follow up testing is 3455: T. Pallidum antibody with reflex RPR. It is imperative that SHHP receives lab results from both test types in order to confirm diagnosis and treatment (including whether the syphilis infection is an active infection or one that occurred in the past and was successfully treated) or to determine whether a false positive has occurred.
- vi. Review the client's risk assessment and risk reduction plan.
- vii. Emphasize the importance in taking health precautions while they wait to attend their first medical appointment.
- viii. Negotiate additional referrals with client, including medical referrals and referrals to a local STD/HIV agency for other supportive services if needed. Discuss PrEP and PEP, as appropriate.

- ix. Remind clients that a DIS will contact them to assist with notifying partners of their possible exposure to syphilis.
- x. Provide condoms and literature as client is accepting.

3. Preliminary Positive Rapid HCV Test Result

- i. Accurately communicate results to client - the result shows signs of hepatitis C antibodies.
- ii. Allow time for emotional response. Do not rush the client into conversation.
- iii. Ensure the client understands what the result means.
- iv. Assess client concerns.
- v. It is mandatory to offer a follow up testing or make a referral to follow up testing to assess
- vi. Review the client's risk assessment and risk reduction plan.
- vii. Emphasize the importance in taking health precautions while they wait to attend their first medical appointment.
- viii. Discuss additional referrals/services with client, including medical referrals and referrals to a local STD/HIV agency for other supportive services if needed.
- ix. Provide condoms and literature and discuss PrEP and PEP, as necessary/preferred.

Follow up and Paperwork Procedures for SHC and HCV Testing at Agencies conducting follow up lab-based testing

If both the rapid and follow up tests are being conducted in the same agency all tests should be recorded on the same Part 1 form. The steps below outline the process when the SHC and rapid HCV is conducted outside of the Wellness Center, during venue based testing, or at the CBO when follow up testing is not immediately available:

- i. The agency will be responsible for delivering a copy of the Part 1 form to the site where the follow up testing (blood draw) will take place. The top, white Part 1 form will be mailed to SHHP per protocol on a weekly basis. Do not hold the Part 1 form with the SHC, HCV, and HIV results while waiting for results of the follow up tests.
- ii. Each agency will create a plan with the DIS in their region as to how and when the DIS will be notified of a SHC positive and when follow up testing will occur. Agencies will work with the DIS supervisor or assignee in their region to determine the best time of day and frequency to make these notifications. This will ensure services are not duplicated and clients are not contacted by DIS before follow up testing and/or treatment occurs. To obtain a contact sheet of DIS in your agency's LDH Region, please contact your Regional Prevention Coordinator.
- iii. A new Part 1 form will be completed for all clients who arrive for the syphilis and/or HCV follow up tests. Write the Pnumber from the original Part 1 form (the form with the documented SHC/HCV positive on it) at the top of the new Part 1 form. This will help connect the first Part 1 to the second Part 1, thereby making it easier to track a client through the entire testing process.
- iv. The person completing the new Part 1 form will indicate a syphilis and/or hepatitis C conventional blood test has been done and indicate any other STD testing that may

have taken place during the visit. This Part 1 form will be mailed to SHHP. DO NOT HOLD ONTO THE PART 1 FORM WHILE WAITING FOR LAB TEST RESULTS. Clients arriving to give a blood sample for follow up testing may receive syphilis treatment at the same time so as to avoid an additional trip to the CBO. If a client does not need to return to the CBO for treatment, a phone call will be sufficient to inform the client of their follow up syphilis and/or HCV test results. On date of testing inform clients that they may receive STI testing results over the phone (none will be given over email, text message or on voicemail), clients can opt for this while signing the consent form. Inform clients that they can either call us or we will call them within two weeks of the initial testing date and they will be asked two identifying questions while on the phone based on basic contact information (i.e. date of birth, street name, zip code, etc.). If clients do not want to be contacted by telephone, inform them they must return in person for their results. When calling a client to give a STD test result, follow the following script:

- Hello, this is X calling from the (CBO Name), I'm looking to speak to...X*
- Hi X, can I please get your date of birth and the street name you provided when you last visited this agency?
- Thank you.... do you have a moment to talk in private?

v. Attach a copy of the lab result(s) to the LinCT Form and mail those two items to SHHP in the confidential double envelope system. Write the Pnumber at the top of the LinCT form so that the original positive rapid test(s) can be connected to the follow up test results. For HCV, write the date of the confirmatory test on the LinCT form.

Follow up and Paperwork Procedures for SHC and HCV Testing at Agencies NOT conducting follow up testing

1. The Part 1 form will indicate that a rapid HCV and/or SHC test was administered as well as delivery of the rapid test result. This test should be noted on the same Part 1 form as all other tests the client received that day and mailed to SHHP per protocol on a weekly basis.
2. The person delivering a positive rapid HCV and/or SHC test result will immediately assist the client in making an appointment for confirmatory testing with the agency noted in their MOU. If the client is being referred outside of the CBO (i.e. OPH Health Unit, private physician, etc.) for follow up testing, write that location on the Part 1 form.
3. CBOs will obtain a copy of the patient's HCV and/or syphilis confirmatory test result, attach this to a completed LinCT form, and mail to SHHP in the confidential double envelope system. Write the Pnumber from the original rapid test at the top of the LinCT so that rapid tests can be connected to confirmatory results. For HCV, write the date of the confirmatory test and treatment date on the LinCT form.
4. Non-reactive/negative Rapid Test Result (HIV, HCV, and syphilis):
 - i. Review with the client their risk assessment and risk reduction plan.
 - ii. Discuss plans for staying non-reactive/negative.
 - iii. Assess need to retest.
 - iv. Provide condoms and other harm/risk reduction tools and appropriate literature.

- v. Discuss PrEP and/or PEP.
 - vi. Assess the client's need for other referrals.
 - vii. Make sure client understands the window period and whether they need to be retested at a later date.
5. Invalid Rapid Test (HIV, HCV, and syphilis):
- i. Explain that there was a problem running the test, either related to the test device or the specimen collected.
 - ii. Assess client concerns and emotional response.
 - iii. Assure client that quality assurance procedures are in place.
 - iv. Collect new specimen and run it with new rapid test device or refer to a public health unit if the client refuses an additional rapid test.
 - v. Provide condoms, other harm/risk reduction tools and appropriate literature.
 - vi. Review the client's risk assessment and risk reduction plan. Emphasize the need to take same risk reduction precautions as established.
 - vii. Personally checked all QA logs before testing another client.

IV. REQUIRED DOCUMENTATION OF CTR ACTIVITIES

A. Send all required documentation/forms to:

**Testing Department
Office of Public Health
1450 Poydras St., Suite 2136
New Orleans, LA 70112**

B. To insure proper confidentiality measures, forms must be enclosed in two envelopes and marked "confidential" on the inside envelope. Testing information should be addressed to the Office of Public Health without any reference to "HIV", "AIDS" or "syphilis" in either the sender's address or the recipient's address. Forms that are hand delivered will not be accepted unless they are enclosed in two envelopes and properly addressed.

C. The destruction of the Test Forms-Part 1, LinCT, and Informed Consent forms are to occur by shredding ONLY (cross-cut shredding is recommended). All testing forms related to a confidential test including (Test forms and Informed Consent forms) should be maintained for at least 7 years. All testing forms related to an Anonymous test (Test forms & Informed Consent forms) should be maintained for at least 3 years and then destroyed.

D. HIV Test Forms must never be e-mailed. Part 1 Forms noting a Reactive HIV result may be faxed to the confidential fax line ONLY, which is 504-568-8384.

E. Timeline for Submission of all documentation that must be completed and/or submitted to SHHP

1. Weekly Submission: The following documentation/forms must be sent to SHHP at least weekly.

i. Test form-Part 1: The top white copy of the STD/HIV Test form-Part 1 must be completed and submitted to SHHP for each rapid HIV and syphilis test conducted. This must be done at least weekly. The two carbon copies may be kept in the client file, or one can be kept and the other

shredded or offered to the client. Instructions for completing the STD/HIV Test form are available from the SHHP Regional Coordinator.

ii. Linkage into Care or Treatment (LinCT) Form: This form is completed for every second HIV test conducted after an initial reactive rapid HIV test. This form should be completed for an antigen only Reactive result from the Determine HIV test. It should be mailed to SHHP along with the corresponding Part 1 form immediately after it is completed. For clients who do not stay to receive their first or second rapid test result, hold on to the LinCT form NO LONGER than 10 working days before submitting it to SHHP, and write in large letters across the top: CLIENT LEFT BEFORE RESULT AND DID NOT RETURN.

2. As needed: The following documentation should be submitted to SHHP as needed.

i. Ordering Supplies: Please visit www.louisianahealthhub.org to submit an online request to SHHP when supplies are needed. On the homepage, click on Order Center, then select CBO Testing Supplies. Please allow at least 4 weeks for processing and delivery.

ii. CTR Rapid Site Assessment and Registration Form: (Attachment RT-3.5) Prior to commencing rapid HIV testing activities at any site, this form must be approved by the Regional Coordinator. All sites must be registered and approved by SHHP prior to the start of any rapid testing activities. Please allow up to four (4) weeks for approval of each site. A copy of this form should be kept on site.

3. Maintain on site: The following documentation must be maintained at each agency conducting HIV and/or syphilis testing activities:

i. CLIA Waiver Certificate: Each testing agency must obtain a CLIA waiver certificate prior to requesting approval for any rapid testing activities from the SHHP. Information on obtaining a CLIA waiver certificate can be obtained from SHHP Regional Coordinator or SHHP Statewide Testing Supervisor. The agency's CLIA waiver certificate number must be included on every Site Registration Form submitted to SHHP. Waivers must be current and a copy must be provided to the SHHP prior to starting any rapid testing activities.

ii. Test Device Temperature Log: (Attachment RT-3.1) Documentation of storage room **temperature must be recorded daily** for test kits. Again, the high and low temperature for the test devices should be recorded every day that the office is open. Thermometers should be reset daily to accurately record daily temperatures. Record any action steps taken to address instances when test devices fall out of acceptable storage range.

iii. Control Kit Temperature Log: (Attachment RT-3.2) Documentation of control kit storage **temperature must be recorded daily for control kits**. Again, the high and low temperature for the control kits should be recorded every day that the office is open. Thermometers should be reset daily to accurately record daily temperatures. Record any action steps taken to address instances when control kits fall out of acceptable storage range.

iv. Daily Rapid Test Log: (Attachment RT-3.3) All rapid tests conducted must be recorded on a daily test log. These logs are kept in agency files and may be requested by SHHP at any time.

v. Control Kit Log: (Attachment RT-3.4) All control tests run at the testing site must be logged on the Control Log and signed by the Quality Assurance Coordinator. Any corrective action taken as a result of control testing must be documented on this log

vi. Confidentiality Agreements: All agency staff and volunteers must have a confidentiality agreement signed and on file at the testing agency.

vii. Counselor Training and Counselor Number Certificates: ONLY counselors certified by SHHP in Rapid HIV Testing and Prevention Counseling are allowed to conduct the intervention in Louisiana. Staff and volunteers conducting rapid testing and prevention counseling activities are required to be skilled in client-centered counseling, collecting and processing rapid test specimens accurately, and completing forms correctly. Skills and knowledge must be reinforced with participation in ongoing training and evaluation activities. The SHHP requires that all counselors (volunteers and staff) become certified prior to conducting rapid HIV testing activities. Certificates must be stored in agency files.

viii. Create An Agency Specific Quality Assurance Procedure Manual: Agencies conducting CTR activities must have an agency specific quality assurance procedure manual available to certified counselors conducting CTR at all times. The CTR Protocol provided in the CBO manual (this document) should be used as the basis for an agency's specific quality assurance procedural manual but should be supplemented with specific procedures to follow related to client referrals, follow-up testing, discordant results, etc that are particular to each agency and location where CTR activities are conducted. Further, agencies are required to have written crisis intervention policies related to situations both involving personnel and clients.

ix. Risk Reduction Worksheet: (Attachment RT-3.12) Each client's risk reduction plan should be documented and kept in the confidential client file. It is acceptable for clients to receive a copy of their risk reduction plan.

V. CONSEQUENCES OF PROTOCOL VIOLATIONS

A. Failure to follow Louisiana rapid testing and prevention counseling protocol may result in a cessation of rapid testing activities until protocol issues are resolved or indefinitely. Protocol violations witnessed by or reported to SHHP staff will be discussed with the testing site as soon as possible. Corrective action, if any, will be documented and submitted to the testing site and SHHP Testing Supervisor. An immediate halt of testing activities can occur when:

1. Confidentiality is compromised in the test processing area or through handling of documentation.
2. Quality assurance records/documents are not maintained as specified in this protocol
3. Informed consent is not obtained from clients prior to specimen collection
4. Completed HIV Test forms are not stored in a confidential manner and the specified copies are not sent to SHHP on at least a weekly basis.

5. Rapid test kits or other testing supplies are distributed to and/or used by unauthorized entities or are unaccounted for.
6. Proper quality assurance of rapid test kits is not maintained (failure to keep adequate control, temperature and/or daily testing logs, etc.)
7. Testing is performed in locations not approved by SHHP.
8. An agency's CLIA waiver expires without renewal.
9. Confirmatory testing is not offered to a client who has a preliminary reactive/positive rapid test result.
10. Documentation for clients with reactive HIV test results is not filled out completely/correctly and/or submitted to SHHP at least weekly.
11. Clients with reactive HIV test results are not referred to appropriate HIV medical treatment services and/or follow-up on HIV medical care referrals is not made and/or documented.

B. According to Louisiana Law RS 40: 1300.13, community-based organizations conducting HIV testing services are required to follow all applicable HIV testing protocols established by the Office of Public Health STD/HIV/Hepatitis Program.