Office of Public Health (OPH)

STD/HIV/Hepatitis Program (SHHP)

QUALITY ASSURANCE (QA) PROTOCOLS FOR RAPID HIV, HEPATITIS C, & SYPHILIS TESTING IN HEALTHCARE SETTINGS

I. DESCRIPTION OF INTERVENTION - RAPID TESTING IN HEALTHCARE SETTINGS

Rapid HIV, HCV, and Syphilis screening in healthcare settings is a public health intervention intended to increase awareness of one's health status, in general, and to identify undiagnosed individuals (including pregnant people) living with these STIs. The primary goal is to increase the percentage of people who are aware of their HIV, HCV, and syphilis statuses. Further, screening programs should make *every* effort to link persons diagnosed with an STI to treatment and prevention services. This protocol is based, in part, on the Centers for Disease Control and Prevention's *Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings* (MMWR2006; 55 (No. RR-14): [1-17]) and is intended to serve as guidance for healthcare settings partnering with, or supported by, the Louisiana Office of Public Health STD/HIV/Hepatitis Program (SHHP) to implement rapid testing as part of their routine medical service delivery. In the ideal situation, rapid testing should be conducted utilizing a rapid HIV, HCV, and syphilis test so that patients will receive their test results during their initial visit to the healthcare site; allowing those patients who have a preliminary positive test result to be immediately linked into clinical and prevention services.

1. **General Principles of HIV Screening:**
   - All patients between the ages of 13 and 65 should be screened for HIV at least one time after the patient is notified that testing will be performed and unless the patient declines (opt-out screening).
   - Persons who are increased risk of acquiring HIV should be screened for HIV at least annually.
   - Current Louisiana law does not require written consent for HIV testing but patients should be notified that HIV testing will be part of their medical care and given information about HIV testing and transmission. General consent for medical services is considered sufficient to encompass consent for HIV testing.
   - HIV prevention counseling is not required with HIV diagnostic testing or as part of HIV screening programs in healthcare settings but patients who are interested should be offered or referred to prevention counseling services and all patients should have an opportunity to ask questions about HIV testing and how the virus can be transmitted.

2. General Principles of HCV Screening:

- Any person who requests hepatitis C testing should receive it, regardless of disclosure of risk
- Hepatitis C screening at least once in a lifetime for all adults aged 18 years and older, except in settings where the prevalence of HCV infection (HCV RNA- positive/detected) is less than 0.1%
- Hepatitis C testing for all pregnant people during each pregnancy, except in settings where the prevalence of HCV infection (HCV RNA- positive/detected) is less than 0.1%
- One- time hepatitis C testing regardless of age or setting prevalence among people with recognized conditions or exposures:
    i. People with HIV
    ii. People who ever injected drugs and shared needles, syringes, or other drug preparation equipment, including those who injected once or a few times many years ago
    iii. People with selected medical conditions, including:
    iv. people who ever received maintenance hemodialysis
    v. people with persistently abnormal ALT levels
    vi. Prior recipients of transfusions or organ transplants, including:
        a. people who received clotting factor concentrates produced before 1987
        b. people who received a transfusion of blood or blood components before July 1992
        c. people who received an organ transplant before July 1992
        d. people who were notified that they received blood from a donor who later tested positive for HCV infection
    vii. Health care, emergency medical, and public safety personnel after needle sticks, sharps, or mucosa l exposures to HCV- positive blood
    viii. Children born to mothers with HCV infection
- All patients who are interested should be offered or referred to prevention counseling services and all patients should have an opportunity to ask questions about HCV testing and how the virus can be transmitted or acquired.

3. General Principles of Syphilis Screening:

- Screen asymptomatic adults at increased risk (history of incarceration or transactional sex work, geography, race/ethnicity, and males younger than 29 years) for syphilis infection
- Gay and bisexual men, if sexually active, should be screened at least annually or every 3 to 6 months if at increased risk
- People of trans experience should be screened at least annually based on reported sexual behaviors and exposure
- People living with HIV who are sexually active should be screened for syphilis at first HIV evaluation and *at least* annually after
- All patients who are interested should be offered or referred to prevention counseling services and all patients should have an opportunity to ask questions about HCV testing and how the virus can be transmitted or acquired.

4. **Principles of HIV, HCV, and Syphilis Screening for Pregnant Patients:**

    1. HIV screening should be included in the routine panel of prenatal screening tests for all pregnant patients.
    2. All pregnant patients should be screened for HIV after the patient is notified that testing will be performed unless the patient declines (opt-out screening).

    - Current Louisiana law does not require written consent for HIV testing but patients should be notified that HIV testing will be part of their medical care and given information about HIV testing and transmission. General consent for medical services is considered sufficient to encompass consent for HIV testing.
    - Repeat screening in the third trimester is recommended in areas of the state with elevated rates of HIV among pregnant patients (see SHHP annual and quarterly surveillance reports). https://www.louisianahealthhub.org/data-reporting/

Consider age before testing patients

1. **HIV** testing supported through partnering with SHHP can be offered to individuals age 13 and older without parental consent - parents must be present and give consent before any child age 12 or younger is tested for HIV - except in cases of suspected perinatal HIV exposure when the mother will not consent for an HIV test in accordance with Louisianan HIV testing laws.
2. Rapid **Hepatitis C** testing can be offered to individuals age 15 and older without parental consent.
3. Rapid **syphilis** testing can be offered to individuals age 13 and older.

Additionally, healthcare test sites should always verify the appropriate age range approved by the United States Food and Drug Administration (FDA) when conducting any rapid test. Age limitations will be covered during the testing staffs training provided by SHHP and are also listed in the manufacturers' instructions, which are included in each box of rapid test kits

II. GENERAL REQUIREMENTS FOR TESTING ACROSS HEALTHCARE SITES

1. **Establish Appropriate Testing Area(s):** Rapid testing must also be conducted in locations that will assure optimal accurate processing and reading of each test. All rapid test sites must provide adequate lighting, temperature control, testing surface, confidentiality, and counseling area(s).
2. **Register All Rapid Testing Locations:** Healthcare testing sites must register both fixed and mobile sites through the SHHP Testing Supervisor using the Site Registration Form (see Attachment 2). SHHP's Regional Prevention Coordinator will visit each potential site to determine if it is appropriate for screening activities. SHHP will assign a unique site number for rapid testing back to the requesting site once the registration process is complete. OPH Parish Health Units have already been registered with SHHP.
3. **Register Rapid Testing with CUA:** Each testing site is required to obtain a Clinical Laboratory Improvement Amendments (CUA) certificate of waiver to conduct waived rapid HIV antibody testing or add the specific rapid test(s) that will be used to the site's current CUA registry. The OPH Parish Health Units have already been registered to operate under SHHP's CUA Waiver Certificate and do not need to take any additional steps to be in compliance with CUA requirements.
4. **Use CUA Waived Rapid Tests:** SHHP recommends the use of (and in some cases may provide) rapid HIV/HCV/syphilis antibody tests that have been classified as "CUA waived" tests. CUA deems waived tests as being easy to use and the possibility of obtaining inaccurate results is

very small. Additionally, CUA-waived tests can be administered and results given at the point of care for patients (during intake, in the examination room, etc.), which will increase the likelihood that patients will accept HIV screening as a part of their routine health care.

5. **Maintain Appropriate Supplies:** Healthcare test sites may be supplied with the Determine, Sure Check, INSTI, OraQuick HCV and/or Syphilis Health Check rapid testing devices - all technologies are single-use, qualitative immunoassays to detect antibodies to HIV, Hepatitis C, and Syphilis. Not all sites are approved for all of tests. Each site must obtain approval and receive training from OPH SHHP for each rapid test utilized. Rapid syphilis and hepatitis C testing is strongly encouraged to be conducted in conjunction with rapid HIV screening for approved sites. All test sites must develop a system to oversee the appropriate storage of test kits, reagents, and controls as required by the manufacturer and to ensure that, when outdated, they are properly disposed of. Proper maintenance of test kits, reagents, and controls include following appropriate temperature ranges for each corresponding test. Please reference Attachment 11 for allowable temperature ranges.

- Each **Sure Check HIV½ kit** pouch (single test) consists of:
  - One single-use Test Device with a Test Strip inside
  - One Buffer Cap attached to sampler (~3S0µL)
  - One sterile safety lancet
  - One Bandage
  - One Desiccant Packet

  Also provided in each box of Sure Check tests:
  - One Product Insert for the Chembio SURE CHECK HIVl/2 assay
  - 25 copies of Subject Information Notice
  - 25 disposable test stands

  Sure Check Pamphlet PDF:
  https://cliawaived.com/amfile/file/download/file/SS0/product/5377/

- Each **INSTI HIV-1/HIV-2 Antibody Test kit** foil pouch (single test) consists of:
  - A single-use testing device
  - Three vials of solution
  - A single-use safety lancet
  - Specimen Collection Capillary pipette with S0ul fill line
  - A single use 70% Isoproply Alcohol Swab

  INSTI Pamphlet PDF: https://www.fda.gov/media/79719/download

- Each **Syphilis Health Check (SHC)** box consists of:
  - SYPHILIS HEALTH CHECK test devices: 20
  - Disposable plastic fixed volume (50µ1) pipettes: 20
  - Diluent in a dropper bottle containing saline buffer, detergent and sodium azide (NaN3, 0.1%): 5 ml
  - Package insert

  Syphilis Health Check Pamphlet PDF:
  https://www.diagnosticsdirect2u.com/downloadmanager/download.aspx?id=1

- Each **OraQuick HCV Rapid Antibody Test Kit** divided pouch (single test) consists of:
  - One single use test device
  - An absorbent packet
  - One single use developer solution vial

Also provided in each box of OraQuick HCV tests:

- Disposable single use specimen collection loops
- Reusable test stands
- One package insert OraQuick

Pamphlet PDF:
https://orasure.com/documents/products/hcv/ package_inserts/3001-1530-OraQuick_HCV_PI_US-ENG.pdf

- Each box of **Determine HIV-1/2 Antigen/ Antibody Combo tests** consist of:
  - Aluminum ziplock pouch containing Alere Determine™ HIV-1/2 Ag/Ab Combo Cards Each Card consists of 5 or 10. Test Units which can be separated from each other by tearing along the perforated lines.
  - A Desiccant Package
  - Chase Buffer: 1 in the 25 Test Units kit, 2 in the 100 Test Units kit. Containing sodium chloride, disodium hydrogen phosphate, and Nipasept as a preservative.
  - Quick Reference Card
  - Package Insert
  - Subject Information Notices: 25
  - Customer Letter
  - Disposable Capillary Tubes: For collection and transfer of fingerstick samples: 25
  - Disposable workstations: 25

  Determine pamphlet PDF:
  https://www.fishersci.com/content/dam/fishersci/ en_US/documents/ programs/healthcare/technical-documents/instruction-sheets/alere-determine-package-i nsert-instructions.pdf

- **Additional supplies needed:**
  - Determine, Sure Check, INSTI, OraQuick HCV, or Syphilis Health Check control sets
  - Disposable absorbent workspace covers
  - Biohazard waste disposal bags
  - Disposal latex/polyurethane/nitrile gloves
  - Alcohol prep pads (for some tests)
  - Sterile gauze (for blood specimen testing)
  - Sharps Container (for blood specimen testing)
  - Disposable Lancets (for blood specimen testing)
  - Thermometers (one for the area where test is processing, one for the storing area, one for the refrigerator, one for mobile sites)
  - Timers
  - 10% bleach solution, bleach wipe, or FDA approved disinfectant
  - Standard phlebotomy equipment for confirmatory testing or a Memorandum of Understanding (MOU) or similar agreement documenting a relationship with an agency to link patients for confirmatory testing and treatment
  - Appropriate transportation supplies for confirmatory specimens (e.g., mailing bags and specimen canisters)
  - HIV Test forms-(Part 1 and LINCT form) (unless reporting data electronically)

Testing supplies will be provided by the STD/HIV/Hepatitis Program as specified in the Memorandum of Understanding (MOU) negotiated between SHHP and the partnering test site. Test sites may be required to obtain certain items at their own expense. Testing 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 the STD/HIV/Hepatitis Program before additional supplies will be sent to the test site (see required documentation). Maintaining appropriate testing supplies in inventory is the responsibility of each healthcare test site.

6. **Assign a Quality Assurance Coordinator:** Healthcare test sites must identify, in writing, the name of their designated Quality Assurance Coordinator using the Quality Assurance Coordinator Registration Form (see attachment 3). This is sometimes/typically also the same person identified to CLIA as the laboratory director, such as an ED Director, Lab Director, Head Nurse, Prevention Manager, etc. The site's rapid testing Quality Assurance Coordinator will be responsible for informing other testing staff on updates and/or revisions to manufacturer's instructions and the State of Louisiana's Quality Assurance Protocols for HIV and STI Testing as well as any recalls that may occur on testing supplies. The Quality Assurance Coordinator is also responsible for ensuring his/her agency is in compliance with the quality assurance protocol including the proper use, storage and documentation of rapid testing devices/activities. Quality Assurance Coordinators must be fully trained on the rapid testing device(s) being used at their agency.

7. **Conduct Worker Competency Assessments:** Although not required by CLIA for sites operating waived testing devices, it is good laboratory practice and highly recommended that partnering test sites develop a system to continually assess the ability of rapid testing staff to operate testing devices correctly, interpret results accurately, and work safely following universal precautions. SHHP has provided a Testing Competency Assessment for Health Care Testing Staff (see Attachment 8) which sites are encouraged to use for evaluating the competency of their staff prior to conducting testing with patients and annually thereafter.

8. **Run Controls Appropriately on Test Devices:** The respective kit controls (Determine, Sure Check, INSTI, SHC, and OraQuick HCV) verify that the rapid antibody test is working properly and that users are able to properly administer and interpret the test results. Kit controls must be documented using Attachment 7 and maintained on site. Kit Controls must be run under the following circumstances:
    - Each newly trained staff prior to performing rapid testing on patient/patient specimens
    - When opening a new test kit lot (lot numbers are printed on each box and device package)
    - Whenever a new shipment of test kits is received
    - If the temperature of the test kit storage area falls outside of the acceptable temperature range for that type of test kit
    - If the temperature of the testing area falls outside of the acceptable range for that type of test kit
    - Prior to using test kits at remote locations (when the test kits are used away from the area where they are stored, e.g., mobile vans, outreach testing, prisons/jails, drug treatment centers)
    - At monthly intervals (sites may run controls more frequently than specified above but must at least meet the above minimum requirements for running controls).

    If the results of any one of the control tests do not match the expected result, rerun 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 Statewide Testing Supervisor immediately. Also, each rapid test device contains a built in control feature that demonstrates assay validity. A reddish-purple control line (or dot in the case of lNSTI) should appear in the area labeled "C" or "Control" depending on the specific device being used. The control line must appear in order for the respective test to be valid, whether or not the test line suggests reactivity. Test results are considered "invalid" when:
    - No reddish-purple line or dot appears next to the area labeled "C" or "Control"

- A red background in the result window makes it difficult to read the result after the appropriate processing time has elapsed.
- If any of the lines are not inside the appropriate control or test line areas.

9. **Appropriately Dispose of Testing Equipment:** All used HIV, HCV, and SHC testing supplies should be disposed of in biohazard waste material bags and/or sharps containers and be disposed of in accordance with state and site-specific regulations for disposal of infectious waste. Control specimens and all blood products should be handled in accordance with universal precautions and the manufacturer's instructions. Proper disposal of biohazardous waste materials will be the responsibility of the site conducting testing. Shipping or transporting of used testing equipment outside of the test area is prohibited, unless stored in a closed biohazard waste container. Paper, wrappers, product inserts, and other non-biohazardous materials should be disposed with regular trash unless contaminated with biohazardous materials.

10. **Submit Completed HIV Test Forms Weekly:** Test Forms MUST be completed in their entirety and submitted to SHHP on a **WEEKLY BASIS AT MINIMUM.** Healthcare test sites will not be provided additional supplies if the Test Forms are not completed accurately and submitted to SHHP on at least a weekly basis. This does not apply to OPH Health Units.

11. **Cooperate with OPH Disease Intervention Specialists (DIS), Field Epidemiologists (Epis), Linkage to Care and Linkage to Cure Coordinators (LTCs and LCCs):** All partnering sites are required to cooperate with efforts by Office of Public Health DIS and Field Epis to collect information on patients who have been diagnosed with HIV, HCV, and/or syphilis. This includes confirming and/or updating current address and phone numbers for the purpose of disease investigation and partner services. Any special circumstances or additional information surrounding these activities should be noted to the DIS, LTCs, and LCCs.

12. **Request Assistance as Needed:** Healthcare test sites are encouraged to request assistance from SHHP as the need may arise. SHHP can assist with developing testing protocols, establishing appropriate referral networks, and providing a number of other technical assistance trainings related to implementing HIV/HCV/syphilis screening. SHHP staff can be in attendance during the site's first day of screening to help resolve logistic or technical problems, if the site requests this assistance.

III. GENERAL REQUIREMENTS OF TESTING STAFF

1. **Complete Training Requirements:** All healthcare professionals conducting screening in partnership with SHHP must complete a brief training on testing and be assigned a unique Testing Staff ID Number. The Testing for Healthcare Professionals training includes specific instruction on the type of test(s) that staff will be using and training on strategies for delivering test results and making referrals to other services. The SHHP Capacity Building Specialist will schedule these trainings as needed to satisfy this requirement and provide healthcare testing staff with certificates of completion containing their Testing Worker ID Number.
2. **Complete Universal Precautions Training:** All healthcare professionals conducting screening using blood specimens (or blood products) must be trained on universal precautions for the prevention of transmission of HIV/HCV/syphilis and other blood borne infections, safe work practices, and disposal of biohazardous materials. It is expected that healthcare test sites will provide this training to their own employees/staff.
3. **Follow Manufacturer's Instructions:** Testing staff must read and follow the manufacturer's

instructions provided by the manufacturer of the rapid test device they will be using. Not following the manufacturer's instructions may result in inaccurate test results.

4. **Do Not Conduct Rapid Testing Any Patients Who Know They Are Living With HIV, Syphilis, and or Hepatitis C (or have been given a positive test result in the past):** Patients who identify themselves as living with HIV/HCV/syphilis should not be retested with a rapid test. Individuals living with HIV-1 and/or HIV-2 who take antiretroviral medication or who have severely damaged immune systems may produce false negative rapid test results. Persons who have self-identified as living with HIV who need documentation of their HIV status should be offered a conventional immunofluorescence assay (IFA) or Western Blot (WB) HIV test and should be referred to case management and medical care. Clients who have ever been previously diagnosed with syphilis and/or hepatitis c should not receive the rapid antibody test since those results will always be reactive. Those individuals should, instead, receive laboratory testing to verify their status.

IV SPECIFIC REQUIREMENTS OF TESTING STAFF - BEFORETESTING A PATIENT

1. **Obtain Informed Consent:** Separate written consent is not necessary for HIV/HCV/syphilis testing but all patients should be notified at some point during their visit (and prior to being tested) that HIV/HCV/syphilis testing will be conducted as part of routine procedure. Patients should be given information about HIV/HCV/syphilis transmission and the meaning of test results prior to being tested. Patients must have the right and ability to decline HIV/HCV/syphilis testing (to opt-out).
2. **Inform Patients of Partner Notification Policies:** All patients must be informed of the importance of notifying sex and/or needle-sharing partners should their test results be reactive/positive for HIV/HCV/syphilis. A discussion of Partner Services should be provided before testing begins for all patients and a more detailed discussion should be conducted after providing a patient with a reactive (preliminary positive) rapid test result. Testing staff should record patients' contact information on the Test Forms Part 1 to facilitate referral follow-up and partner services. Testing staff must discuss the Louisiana Office of Public Health policy to contact all persons testing confidentially and reactive to HIV regarding Partner Services.
3. **Offer Patients the Available Options for Testing (Confidential or Anonymous):** Patients must be offered the option of anonymous or confidential HIV testing in accordance with Louisiana Testing Law (RS:1300.12). 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 his/her test result. Anonymous testing is only an option for HIV and HCV, not for syphilis rapid testing. If anonymous testing is not available at the testing site, the patient should be referred to a site that is able to provide anonymous testing upon request. Confidential testing is strongly encouraged to facilitate the entry into follow-up medical services for individuals who have been living with HIV, HCV, or syphilis and should be encouraged for all confirmatory testing. Confidential testing indicates that a client is willing to provide personal identifiers that can be used to link individuals to their rapid test result. Patients should also have the choice of which type of specimen (fingerstick whole blood, venipuncture whole blood, etc.) will be collected for HIV testing (according to which testing technologies are in use at the testing site) and when test results will be given (same day or at a later return visit).
4. **Discuss possible test results for the type of test being conducted:** Testing staff should discuss all of the possible test results and the applicable follow-up procedures for the type of test being used with each patient prior to collecting a specimen for testing.
5. **Provide appropriate subject information pamphlet:** The FDA requires that all patients having a rapid HIV test, receive the "Subject Information" pamphlet produced by the manufacturer of the rapid test device being used prior to having a specimen collected for testing. These pamphlets are included in each box of rapid testing kits. Contact the SHHP Capacity Building Specialist for additional copies of these pamphlets.

V. SPECIFIC REQUIREMENTS OF TESTING STAFF - WHILE TESTING A PATIENT

1. **Complete Test Form - Part 1:** All applicable sections ofTest Forms - Part 1 should be completed for all clients who receive a rapid test. It is recommended that Part 1 be filled out while the test is processing in order to keep the patient occupied and possibly lower their anxiety about the pending test results. OPH Health Units and sites reporting electronically do not fill out the Part 1 form and instead enter all relevant testing information in the electronic health record (EHR).
2. **Complete LinCT form (Attachment 1) for testing provided after *any* first rapid test with reactive/positive results.**
3. **Conduct Other Medical Exams/Services:** After completing the appropriate sections of the Test Forms - Part 1, or entering all relevant testing information in the EHR, testers should initiate other health care services as needed/available. It is preferable to conduct these activities while the HIV/HCV/syphilis test is being processed if possible.
4. **Provide Support:** Testing staff are encouraged to provide patients with condoms, other harm/risk reduction tools, education, and/or prevention literature as appropriate and available. These items may be ordered from SHHP by visiting the Order Center - Louisiana Health Hub - STD/HIV/Hepatitis Program.
5. **Assess patient readiness to receive results:** Testing staff should check with patients prior to interpreting/reading the test results to ensure that the patient still wishes to receive their test results at that time. If the patient does not wish to receive the test result at that time, the tester should schedule a follow-up appointment for the patient to receive the test results (the tester should document the test results in the patient's chart for later use).

Proceed with the Patient in the following ways based on the test results:

If Result is Negative/Nonreactive:

- Accurately communicate results with patient
- Allow time for emotional response. Do not rush the patient into conversation.
- Ensure the patient understands what the result means.
- Assess patient concerns.
- Recommend a follow-up time for the patient to be retested for HIV/HCV/Syphilis based on section I guidelines.
- Assess the patient's need for other referrals

- Document negative result on HIV Test Form - Part 1. OPH Health Units and sites reporting electronically will not complete a Part 1 form and instead will enter HIV test information in their EHR.
- Set an appointment for the patient to return for follow-up testing if needed.
- Provide prevention materials and literature as deemed appropriate.

If the Result is Positive/Reactive (for sites conducting a rapid test followed by a blood draw for lab-based confirmatory testing):

- Accurately communicate results with the patient (if a rapid test, inform the patient that the result shows signs of HIV antibodies and a confirmatory test must be done to be sure.)
- Allow time for emotional response. Do not rush the patient into conversation.
- Ensure the patient understands what the result means.
- Assess patient concerns.
- Collect confirmatory specimen if rapid test was conducted: Patients who have a reactive/preliminary positive rapid HIV test result must be given a follow-up confirmatory test unless they decline and be provided with referrals to early intervention medical services during the delivery of their preliminary positive result. If possible, blood specimens should be collected for confirmatory HIV testing. All HIV testing sites are expected to inform 100% of patients of their reactive test results.
- Complete Appropriate Lab Requisition: The appropriate form/documentation should be completed to ensure that the results of the confirmatory test will be traceable to the patient being tested and that results will be available as soon as possible. For sites sending specimens to the Louisiana Public Health Laboratory, the Louisiana Laboratory Requisition Form must be completed and mailed along with the confirmatory specimen.

The appropriate forms can be found here:

- **STD/HIV Combined Lab Test Request Form** (https://ldh-oph.qualtraxcloud.com/ShowDocument.aspx?ID=11159) - This form is used to request testing for HIV, Syphilis, Neiseria gonorrhoae and Chlamydia trachomatis.
- **LAB FORM 96 -Virology/Immunology** (https://ldh-oph.qualtraxcloud.com/ShowDocument.aspx?ID=6893) - This form is used for Lab Test requests in Virology for the following assays: Influenza, Norovirus, Hepatitis A, Band C, Arbovirus, Rubella IgG and many others.

- However, if the submitting facility is already onboard and currently ordering lab tests on the portal, then there is no need to use the manual requisition forms. They should submit samples in batch with the shipping manifest printed from the portal. For additional questions, please contact SHHP's Statewide Testing Supervisor.

- Emphasize the importance of taking the same precautions as a person who may have a confirmed HIV positive test result in terms of vulnerability to other STIs and transmission prevention to others.
- Negotiate additional referrals with patient, including potential medical and partner services referrals.
- Complete and submit a LINCTform. OPH Health Units and sites reporting electronically will not complete a LINCT form and will enter appropriate information in their EHR.

- Best practice to obtain IGRA (Interferon-Gamma Release Assay) to test for TB infection. Testing is done by QuantiFERON®-TB Gold In-Tube test (QFT-GIT) or T-SPOT®.TB test. For OPH Health Units- T-SPOT®.TB test is REQUIRED.

- Set an appointment for the patient to return for confirmatory test results.
- Provide prevention materials and literature as deemed appropriate.

If Result is Positive/Reactive (for sites conducting rapid/rapid testing)

- Accurately communicate results with patient (the result shows signs of HIV, HCV, or syphilis antibodies and a second test must be done to be sure)
- Allow time for emotional response. Do not rush the patient into conversation.
- Ensure the patient understands what the result means.
- Assess patient concerns.
- Offer 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 positive 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 lab-based testing and provider care.
- If the second rapid test is negative, then clients should return one week later for retesting.
- For follow-up testing, if the first rapid test is negative, no more testing is required.
- If the first rapid test is positive, follow normal procedures and conduct a second rapid test.
- A new Part 1 STD/HIV Test Form 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.
- 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'.

- Review the client's risk assessment and risk reduction plan.
- Refer to HIV clinic for medical care so that viral load can be initiated.
- Best practice to obtain IGRA (Interferon-Gamma Release Assay) to test for TB infection. Testing is done by QuantiFERON®-TB Gold In-Tube test (QFT-GIT) or T-SPOT®.TB test. For OPH Health Units- T-SPOT®.TB test is REQUIRED.
- Emphasize the importance of taking health precautions while they wait to attend their first medical appointment.
- Negotiate additional referrals with client, including medical referrals and referrals to local HIV agency for other supportive services and case management.
- Remind clients that a DIS will contact them to assist with notifying partners of their possible exposure to HIV. SHHP has linkage to care and linkage to treatment coordinators available to assist as an additional resource. If there are any questions or difficulties connecting someone to care, please call 504-568-7474.

If Rapid Test is Invalid:

- Explain that no result is available due to a malfunction with the testing process.
- Assess patient concerns and emotional response.
- Quickly assess the testing environment for appropriateness for the specific rapid test being used (ensure operating temperature is acceptable, test kits are not expired, etc.)
- Repeat the test using a new rapid test device or conduct a conventional test (OraSure or blood draw) if the patient refuses an additional rapid test.
- Provide condoms, other harm/risk reduction tools and appropriate literature.
- BEFORE TESTING ANOTHER PATIENT: Run external controls to ensure testing devices are working correctly and assess quality assurance documentation paying attention to temperature and control logs. Discontinue testing if controls do not pass or testing environment is inappropriate and complete documentation of this problem on all logs.

If Discordant Result (Reactive rapid test and indeterminate or negative confirmatory test)

- Assess patient concerns.
- Establish plans for follow-up testing to occur 4 weeks after the initial preliminary positive result. It is highly recommended and in line with CDC rapid testing protocol that follow-up confirmatory testing be conducted with a blood specimen.
- Provide condoms, other harm/risk reduction tools and appropriate literature.
- Notify the SHHP Testing Supervisor immediately.

3. 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 deemed appropriate.
xi. SHHP has linkage to care and linkage to treatment coordinators available to assist as an additional resource. If there are any questions or difficulties connecting someone to care, please call 504-568-7474.

4. 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 oftaking 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.
ix. Provide condoms and literature and discuss PrEP, PEP, and DoxyPEP as deemed appropriate.
x. SHHP has linkage to care and linkage to treatment coordinators available to assist as an additional resource. If there are any questions or difficulties connecting someone to care, please call 504-568-7474.

6. Sites 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 active 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 or other document) 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 911call)

c. The process for reporting syphilis and HCV treatment confirmation back to SHHP, including how the agency will obtain confirmatory test results and/or confirmation of treatment from the referral agency. The LINCT form should be completed to document that confirmation tests were conducted and what the process for treatment was.
d. Identification and contact information for the agency staff responsible for ensuring client follow-up, etc.

IV. REQUIRED DOCUMENTATION

All documentation/forms related to HIV/HCV/syphilis testing that are designated "Submit to SHHP" in the header should be mailed to the following address. This does not apply to OPH Health Units and sites reporting electronically who enter all testing information in their EHR:

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

To insure proper confidentiality measures, forms containing identifying patient information 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" and/or "AIDS" 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.

Following is a description of documentation that must be maintained and/or submitted to SHHP along with the submission timeline where applicable.

1. **Maintain on site: The following documentation should be kept on file at testing sites for at least 3 years.**

   a) **Test Device Temperature Log** (Attachment 4): Documentation of storage room temperature must be recorded daily for test kits.
   b) **Control Kit Temperature Log** (Attachment 5): Documentation of control kit storage temperature must be recorded daily for control kits.
   c) **Daily Rapid Testing Log** (Attachment 6): All rapid tests conducted must be recorded on a daily test log. These logs are kept in agency files and may be reviewed by SHHP at any time.
   d) **Control Kit Log** (Attachment 7): 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. Submit this form to Statewide Testing Coordinator on a quarterly basis.
   e) **HIV Testing Competency Assessment for Health Care Testing Staff** (Attachment 8): Internal monitoring of the quality of test processing for individuals involved in rapid HIV testing activities may be conducted using this form. It is highly recommended that all HIV testing staff be observed at least once per year by a supervisor or the designated Quality Assurance Coordinator to ensure quality HIV testing services are maintained. Competency assessments should be kept on site in employee files.

2. **Weekly Submission: The following documentation must be sent to SHHP at least weekly. OPH Health Units and MOU sites reporting electronically do not fill out these forms and instead enter all testing data in the EHR. MOU sites must submit their data weekly to SHHP's data department. Contact Testing Supervisor for details and setup.**

   Rapid Testing Form - Part 1: Part 1 of the Test Form should be completed for every patient who receives a HIV/HCV/syphilis test that is in any way supported by SHHP. Instructions for completing the Test Forms are available in a separate document and may be requested from the SHHP Capacity Building Supervisor or Regional Prevention Coordinator.

   Linkage to Care/Treatment (LinCT) Testing Form - LinCT: This form should be completed and sent to SHHP if ANY lab based OR rapid test is positive. *Negative lab based results will be obtained from surveillance information. Any inconsistencies/missed results will be addressed by your regional coordinator.*

   • If you have a POSITIVE lab screening test, send this form
   • If you have a POSITIVE rapid test, and the confirmatory/lab test is NEGATIVE, send this form.
   • If you have a POSITIVE rapid test, and the confirmatory/lab test is POSITIVE, send this form.
   • If you have a NEGATIVE rapid test, and the confirmatory/lab test is NEGATIVE, do **not** send this form.

3. **As needed: Submit the following documentation as needed.**

   Supply Orders: Supplies can be ordered online, please allow for up to four weeks for delivery: https://www.louisianahealthhub.org/for-community-partners/order-center/ Contact the Testing Supervisor for further assistance or troubleshooting.
   Testing Site Registration Form (Attachment 2): Prior to conducting HIV testing activities at any site, a Site Registration Form must be completed and submitted to the SHHP Clinical Testing Promoter. All HIV testing sites must be approved by SHHP prior to the start of any HIV testing activities. Please allow up to four (4) weeks for approval of each site. A copy of this form should

be kept on site.
Discordant Test Report (Attachment 9): All confirmatory test results that are negative or inconclusive must be followed up with a Discordant Test Report.

V.DEFINITIONS OF KEY TERMS

Testing Sites - refers to clinics, agencies or community-based organizations that offer rapid testing in cooperation or partnership with SHHP in addition to other healthcare services but who do not receive monetary funding from SHHP to do so.

Rapid Testing- Performing/conducting a rapid test.

Testing Staff- (also referred to as tester, worker or staff) this is a person who conducts/administers a rapid test or the person who collects the specimen for testing when the actual test occurs at a lab or remote location. Rapid testing staff generally conduct testing for screening purposes and may not be trained to conduct HIV/ST! Prevention Counseling.

Rapid Testing Worker ID Number- a unique identifying number assigned to every rapid testing staff after he/she completes the required training on screening protocol and rapid testing.

HIV/HCV/Syphilis Screening- Performing a rapid test for all persons in a defined population.

Informed consent-A process of communication between patient and provider through which an informed patient can choose whether to undergo rapid testing or decline to do so. Elements of informed consent typically include providing oral or written information regarding HIV/HCV/syphilis, the risks and benefits of testing, the implications of HIV/HCV/syphilis test results, how test results will be communicated, and the opportunity to ask questions.

Opt-out Screening - Performing HIV/HCV/syphilis screening after notifying the patient that 1) the test will be performed and 2) the patient may elect to decline or defer testing. Consent is inferred unless the patient declines testing.

-END OF PROTOCOLS-

SHHP Testing Contacts as of April 2024:

- Statewide Testing Supervisor: Nouri.Ningbinnin@la.gov
- Statewide Testing Coordinator: Diamond.Vines@la.gov
- Regional Coordinator Supervisor: Sarah.Fleming@la.gov
- Regional Coordinator Regions 1 & 3: Zoey.Ponder@la.gov
- Regional Coordinator Regions 2 & 9: Rochelle.Cole@la.gov
- Regional Coordinator Regions 4, 5, & 6: Swanzette.Bonnet@la.gov
- Regional Coordinator Regions 7 & 8: Brett.Malone@la.gov
- Capacity Building Supervisor: Kelley.Anderson@la.gov
- Capacity Building Specialist Lead: Chivas.Michael@la.gov
- Capacity Building Specialist: Shawn.Windham@la.gov