NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES

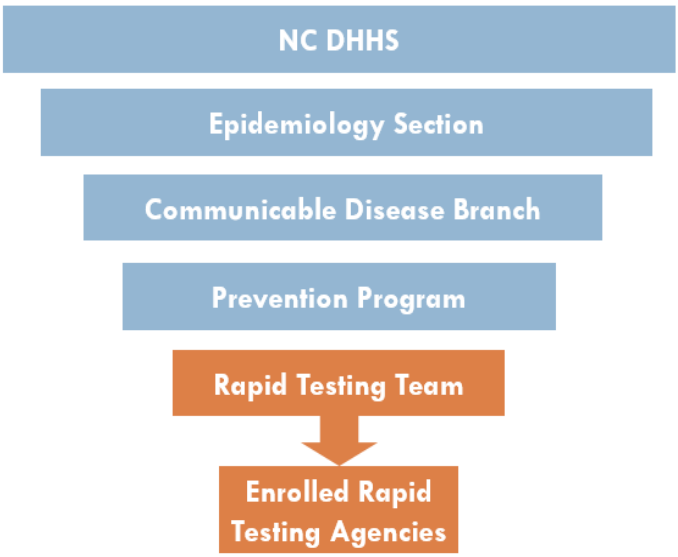
COMMUNICABLE DISEASE BRANCH

PREVENTION PROGRAM

RAPID TESTING PROGRAM QUALITY ASSURANCE MANUAL FOR STATE PURCHASED RAPID HIV/HCV/SYPHILIS TEST KITS AND CONTROLS

THE NC DHHS RAPID TESTING PROGRAM

As this guide is meant to be comprehensive, it is still understood that a testing agency might have more questions associated with the program and its requirements. This manual is meant to serve as a guide in which each agency can use to create an adapted program that both fulfills the protocols of the NC DHHS and fits the needs of the communities served. For more valuable insight into the program and viable contact information, please visit the NC DHHS Communicable Disease website.



To prevent and control HIV and other sexually transmitted diseases, the North Carolina Department of Health and Human Services (NC DHHS) supports confidential free testing and treatment in many diverse settings around the state. These include NC federally qualified health centers (FQHC), community-based organizations (CBOs), 340B eligible agencies (agencies do not have to receive direct funding to be a part of the NC DHHS Rapid Testing Program), nonprofits, local health departments, Syringe Exchange Sites, Disease Intervention Specialists (DIS), colleagues, and correctional facilities.

As a part of the Communicable Disease Branch, the HIV Prevention Program assists these agencies by providing free rapid testing technologies and other prevention materials for use in both their clinical and outreach environments.

The Rapid Testing Program began in 2004 with 10 enrolled agencies and steadily grew over the years to accommodate 65, reaching almost every area of the state. At the start, the Rapid Testing Program offered one brand of HIV rapid test. Today, the program has grown to accommodate funded and non-funded agencies and provides HIV, hepatitis C, and syphilis rapid testing technologies. This document is meant to act as a "one-stop-shop" program manual for all aspects involved with the NC DHHS Communicable Disease Prevention Rapid Testing Program. **You will find instructions for applying to the program and requesting testing items, quality assurance requirements, reporting instructions, and information on annual trainings.**

340B PRICING ELIGIBILITY INFORMATION

The 340B Drug Pricing Program enables covered entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services. *

In order to access 340B pricing, the Communicable Disease can confer 340B eligibility by giving an entity funds or in-kind support from one of the Section 318 eligible grants. One mechanism to provide in kind services is sending an agency supplies such as syphilis rapid test kits and confirming with HRSA that your agency receives the necessary in-kind support for eligibility. This provision of supplies or funds only confers eligibility. It is then up to the agency to apply through HRSA and meet the requirements of becoming a 340B covered entity and also to comply with all HRSA post approval requirements. The Communicable Disease Branch cannot assist with the application or meeting of requirements.

Being a 340B covered entity requires detailed inventory tracking to ensure appropriate use. 340B programs can be audited at any time. The CD Branch would like to take this opportunity to highlight just a few 340B requirements for covered entities. The full scope of requirements is available from HRSA throughout the 340B program website at https://www.hrsa.gov/opa/index.html. A covered entity must, among other requirements:

- Keep 340B OPAIS information accurate and up to date. Register new outpatient facilities and contract pharmacies as they are added.
- Recertify eligibility every year. If there is a change in a covered entity's eligibility status, the covered entity has a responsibility to immediately notify OPA and should stop purchasing drugs through the 340B Program.
- Prevent diversion to ineligible patients. Covered entities must not use, resell, or otherwise transfer 340B drugs to ineligible patients.
- Duplicate Discount Prohibition. Manufacturers are prohibited from providing a discounted 340B price and a Medicaid drug rebate for the same drug. Covered entities must accurately report how they bill Medicaid fee-for-service drugs on the Medicaid Exclusion File, as mandated by 42 USC 256b(a)(5)(A)(i).
- Prepare for program audits. Maintain auditable records documenting compliance with 340B Program requirements. Covered entities are subject to audit by manufacturers or the federal government. Any covered entity that fails to comply with 340B Program requirements may be liable to manufacturers for refunds of the discounts obtained.

See the FAQ and Prevention of Diversion Self Audit Tool from Apexus to aid you in assessing your entity's ability to maintain a 340B compliant program on pages 60-68. Also included is a sample letter of agreement from the CD Branch that you will be asked to sign before being authorized by the CD Branch for 340B eligibility on page 59. The HRSA training linked here: https://www.brainshark.com/apexus/340BTheBasics?&pause=1&nrs=1 may also be of use to those interested in 340B eligibility.

*Taken from the Health Resources & Services Administration website

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APPLYING TO THE PROGRAM

The North Carolina Department of Health and Human Services (NC DHHS) supports many different types of HIV and STD rapid testing agencies with rapid testing supplies, prevention supplies, and programmatic assistance. These agencies include, but are not limited to local health departments, community-based organizations (CBOs), Federally Qualified Health Centers (FQHCs), syringe exchange programs, and university-based testing centers.

To apply for the program, an agency (big or small) should complete an application (copy on pages 33-35) and send the completed form via email to a Rapid Testing Team member: Marti Eisenberg (marti.eisenberg@dhhs.nc.gov/984-236-1487) or Carlotta McNeill (carlotta.mcneill@dhhs.nc.gov/984-236-1484). If you have any questions on the application or any area of the program, reach out to a Rapid Testing Team member and they will assist you.

The Application

A testing program must complete an application in order to receive free rapid test items and other prevention supplies. Below is a list of requirements that must be fulfilled in order to be accepted into the NC DHHS Rapid Testing Program.

NC DHHS Rapid Testing Requirements

1. CLIA (Clinical Laboratory Improvement Amendments) Certificate of Waiver

   The purpose of a CLIA is to set minimum standards for laboratories and testing sites to follow and to ensure that these laboratories are achieving these standards. CLIA provides a "limited public health use" exception, under which a licensed laboratory can operate multiple satellite sites under the umbrella of a single CLIA certificate. Applications for this certificate and license can be found through the Division of Health Service Regulation (Form CMS-116, CLIA APPLICATION FOR CERTIFICATION). Additional information can be found online at: NC DHSR AHCLCS: Clinical Laboratory Improvement Amendments (CLIA) (ncdhhs.gov) or via phone at 919-855-4620.

2. HIV Testing License

   Applications for this certificate and license can be found through the Division of Health Service Regulation (Acute Care/CLIA Certification Section). Information can be found online at NC DHSR AHCLCS: Certify a Laboratory, Pap Smear, HIV Testing & Screening Mammography Service (ncdhhs.gov) or via phone at 919-855-4620. A copy of the most recent HIV Testing License application is also found on pages 36-37.

3. Medical Provider and Standing Order

Each testing agency must work under a medical provider's standing orders or policies and procedures which ensure that the testing site is providing appropriate testing services to their client population. An example of a standing order is on page 58.

4. Confirmation of Positive Test Results

Each testing agency must have a process in place to confirm preliminary HIV positive rapid test results (first rapid test taken for an individual revealing an initial positive result). Confirmation can be done by either exercising "Dual Protocol" (utilizing a different HIV rapid test brand directly after the initial rapid test is administered) or by taking a whole blood sample through means of phlebotomy (and sending it to the confirmed laboratory of choice).

You can choose either the Dual Protocol method or whole blood method. If the agency does not have any staff that are trained in phlebotomy, then the agency can opt to house at least two different brands of HIV rapid test and train their testing staff on each brand. This will enable the agency to properly perform dual protocol. More information on the Dual Protocol can be found on pages 16-18.

The whole blood confirmation method involves providing phlebotomy services. The State offers free phlebotomy courses to individuals working for funded and supported testing agencies. These courses take place throughout the year with limited slots available. If interested in enrolling a staff member in a phlebotomy class, contact the Rapid Testing Monitor at NC.Rapid.Testing@dhhs.nc.gov.

5. Referral Network

Each testing agency must describe their process for linking preliminary positive clients to care, treatment and support services, and include a list of referral networks. Linkage to care should consist of the following:

- Partnerships with local health departments and regional Network of Care Providers to secure appropriate HIV/AIDS support resources including laboratory services.
- HIV/AIDS primary and behavioral health care services.
- Other necessary support services (insurance, housing, food, transportation).

6. Training

Each testing agency must list staff members who have been trained in Rapid Testing and/or Counseling, Testing and Referral. If staff have not been trained, agencies must submit their training needs as indicated on pages 21-22.

Note: Once enrolled, agencies must enroll in a proficiency testing program or create their own agency specific proficiency and quality assurance plan as noted on pages 13-15. All rapid testing plans will be reviewed by the Rapid Testing Team at the specified site visit. Specific information regarding these plans is detailed throughout this manual.

RAPID TESTING AND PREVENTION SUPPLIES OFFERED

The NC DHHS HIV Prevention Program currently offers four different brands of HIV rapid tests, one brand of hepatitis C rapid tests, and one brand of syphilis rapid tests. Each company and type of test is listed below. The Prevention Program also routinely carries prevention items such as condoms, lubricant, and dental dams.

Rapid Tests

OraSure Technologies OraQuick Advance Rapid HIV-1/2 Antibody Test (OraQuick HIV)

- OraQuick test specimens can be oral fluid, finger-stick whole blood, venipuncture whole blood, or plasma with results interpreted between 20-40 minutes.
- Kit consists of a single-use test device and developer solution, a reusable test stand, and a disposable single-use specimen collection loop.
- A control will also be supplied (refrigeration upon arrival).

bioLytical INSTI HIV-1/ HIV-2 Rapid Antibody Test ("INSTI")

- INSTI tests specimens can be finger-stick whole blood, venipuncture whole blood, or plasma with results being interpreted in 60 seconds.
- Kit consists of a membrane unit, a sample diluent, a color developer, a clarifying solution, a single use pipette, a lancet, and a package insert.
- A control will also be supplied (refrigeration upon arrival).

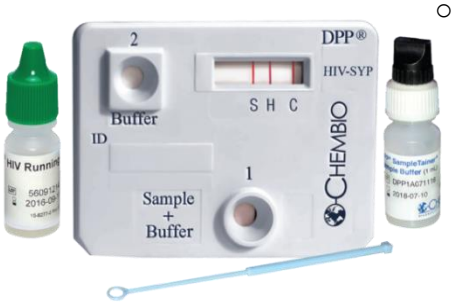
Diagnostic Direct Syphilis Health Check ("Syphilis Health Check")

- Syphilis Health Check test specimens can be finger-stick whole blood, serum, or plasma with results interpreted between 10-15 minutes.
- Kit consists of 20 test devices, 20 plastic pipettes, diluent dropper bottle, and quick reference instructions.
- A control will also be supplied (refrigeration upon arrival).

OraQuick HCV Rapid Antibody Test ("OraQuick HCV")

- OraQuick test specimens can be oral, finger-stick whole blood, serum, or plasma with results interpreted between 20-40 minutes.
- Kit consists of a single-use test device and developer solution, a reusable test stand, and a disposable single-use specimen collection loop.
- A control will also be supplied (refrigeration upon arrival).

Chembio Diagnostics DPP HIV-Syphilis Rapid Test



- Chembio test specimens can be finger-prick whole blood, venipuncture whole blood or plasma with results interpreted between 15-25 minutes.
- Kit consists of a single-use test device, desiccant pouch, disposable 10 uL Sample loop, 1mL phosphate buffer (Black cap), 6mL phosphate buffer (Green cap).
- A control will also be supplied (refrigeration upon arrival).

Prevention Supplies

- Latex Condoms
- Unflavored Lubricant
- Flavored Dental Dams

*The NC DHHS offers prevention supplies throughout the year. Contact the Rapid Testing Monitor to find out what is currently in stock. Contact information is listed on the last page of this manual.

Additional Rapid Testing Items

Agencies must purchase the following items to properly conduct HIV/STD rapid testing:

- Disposable absorbent workspace covers
- Biohazard waste disposal bags
- Latex/polyurethane/nitrile gloves
- Sharps container (for blood specimen testing only)
- Disposable lancets (for blood specimen testing only)
- Thermometers (one for the storage area, one for the refrigerator, one for mobile sites)
- Timers
- 10% bleach solution or FDA approved disinfectant
- Other materials deemed necessary

INSTRUCTIONS FOR ORDERING

Once an agency has been accepted into the program, rapid test kits, controls for the rapid tests, and prevention supplies can be requested. All requests should be made through the HIV Prevention Program. Rapid tests and prevention supplies are housed at the Raleigh, NC based NC DHHS Communicable Disease office building and are distributed by the Rapid Testing Team. Controls are distributed by the State Lab of Public Health also located in Raleigh, NC. Below you will find specific instructions and detailed information for ordering.

Ordering Process

1. An agency must contact a member of the Rapid Testing Team by phone or by email (information below).
   General contact (NC.Rapid.Testing@dhhs.nc.gov)
   Carlotta McNeill (carlotta.mcneill@dhhs.nc.gov / 984-236-1487)
   Rapid Testing Monitor (984-236-1440)

2. Message Contents
   - Rapid Tests/Controls
     - Within the request, the agency representative must specify how many boxes of which brand and how many controls are needed. It is not guaranteed that an agency will receive the full request amount, but the team will do the best they can to send the full request.
   - Prevention Items
     - Within the request, the agency representative must specify if they would like prevention supplies, and which type, condoms, lubricant, or dental dams. At times, the supply varies depending on State supported contracts. Check with the Rapid Testing Team about what items are in stock.

3. Confirmation
   - A Rapid Testing Coordinator will respond and confirm your request. They will reply with how many items will be sent and the expected date of delivery.

4. Shipment Dates
   - Rapid Tests/Prevention Supplies
     - All test kits and prevention supplies are housed at the NC DHHS Communicable Disease Six Forks office (333 E Six Forks Rd) and distributed, depending on supply, by the Rapid Testing Team on either Tuesday or Wednesday of each week.
   - Controls
     - Brand specific controls that match the test kits are sent along with every test kit order unless the agency already has enough controls.

- Controls are shipped by the State Lab of Public Health (SLPH) in Raleigh, NC. An agency does NOT need to contact the SLPH to receive controls; the Rapid Testing Team is the only agency that contacts the SLPH to request controls.
- Controls will be shipped within the week, usually on Wednesdays or Thursdays in insulated packaging.

5. Upon Receiving
   - Rapid Test/Prevention Supplies
     - Rapid tests and prevention supplies must be stored at room temperature (specific temperatures for each brand of test kit are specified in the Rapid HIV, HCV, Syphilis Testing Comparison Chart on page 48-49).
   - Controls
     - Once received, the shipment of controls must be **refrigerated immediately.** If a control arrives room temperature or is damaged, contact a Rapid Testing Coordinator and a new control will be sent.
     - Email a confirmation of receipt to the Rapid Testing Program Monitor (contact information on page 69) once the controls arrive.
   - Vendor Direct Shipments
     - Once a vender direct shipment that was funded by the Rapid Testing Program is received, the packing slip/invoice must be immediately scanned and then sent to a Rapid Testing Program Monitor, Carlotta McNeill and Beth Dickens (beth.dickens@dhhs.nc.gov). If there is no invoice included with the shipment, email a list of the contents to the Rapid Testing Monitor, Carlotta McNeill, and Beth Dickens.

QUALITY ASSURANCE REQUIREMENTS

Once an agency has begun testing, it is required that essential quality assurance measures are carried out and recorded. Each required process is detailed below. If any questions arise, it is the agency's responsibility to contact a Rapid Testing Coordinator.

Test Kits and Controls:

1. Temperature Monitoring

   Test kits and controls must be monitored at least once a week to ensure testing supplies are maintained at an adequate temperature. Temperatures are to be documented in their respective temperature logs (examples included in the reference section in the back of the packet on pages 50-51). The specific temperatures that each brand of test kit and control are specified below.

The room temperature must also be recorded at the testing location on the day of testing. If testing is performed in a temperature-controlled environment, the temperature may be recorded once at the beginning of testing. If testing is performed outdoors or in a noncontrolled environment, the temperature should be recorded at frequent intervals to ensure the testing environment does not exceed the specific kit temperature requirements.

		OraSure Technologies OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test	Diagnostics Direct Syphilis Health Check™	OraSure Technologies OraQuick® HCV Rapid Antibody Test	INSTI HIV-1/HIV-2 Antibody Test	Chembio DPP HIV-Syphilis
Temperature Requirements	Control Storage	2° to 8°C (35° to 46°F)	2° to 8°C (35° to 46°F)	2° to 8°C (35° to 46°F)	2° to 30°C (35.6°-86°F)	2° to 8°C (36° to 46°F)
	Test Kit Storage	2 to 27°C (35° to 80°F)	4° to 30°C (39.2°-86°F)	2° to 30°C (35.6°-86°F)	2 to 30°C (35° to 86°F)	2° to 25°C (36° to 77°F)
	Testing Environment	15° to 37°C (59° to 99°F)	20° to 26°C (68° to 78.8°F)	15° to 37°C (59° to 99°F)	15° to 30°C (59°-86°F)	18° to 25°C (64° to 77°F)

2. Running Controls

A control must be run under each of the following circumstances:

- Each newly trained counselor prior to performing rapid testing on client specimens
- When opening a new test kit lot (lot numbers are printed on each box and device)
- Whenever a new shipment of test kits is received
- If the temperature of the test kit storage area falls outside of the specific temperature requirements of the kits, usually 8 to 27°C (37 to 70°F)
- If the temperature of the testing area falls outside of the specific temperature requirements of the kits, is usually 15 to 30°C (60 to 80°F). This may include testing at outreach locations.
- At periodic intervals as dictated by the user facility

The kit controls verify that the rapid HIV test is working properly and that users can properly administer and interpret the test. If the results of any one of the control tests do not match the expected result, rerun all controls using a new testing device. The control failure should be documented on the Corrective Actions Log, as well as the actions taken to resolve the issue. If the repeated control test run produces unexpected results, do not use any tests from that entire lot number and notify the Rapid Test Coordinator immediately. All results from control tests are to be documented in appropriate logs.

Also, each rapid test device contains a built-in control feature that demonstrates assay validity. A reddish-purple control line should appear in the area labeled "C". The control line must appear for the respective test to be valid, whether the sample is reactive or non-reactive.

Test results are considered "invalid" when:

- No reddish-purple line appears next to the area labeled "C" or "Control"
- A red background in the result window makes it difficult to read the result
- If any of the lines are not inside the appropriate control or test line areas

Required Submission/Documentation of HIV/STD Testing Activities

Documents/logs pertaining to registration, staff training, temperature storage, temperature during kit usage, results logs, and file storing safety should always be created and easily accessible to staff. Below is a list of documents that should be kept up to date and submitted when required.

Completed "2022 NC HIV Testing Data Form (4-25-22)" (HIV Testing Data Form), temperature logs, and results logs must be maintained in accordance with your agency's internal records retention policy.

The following is a description of all documentation that must be completed and maintained and/or submitted along with the submission timeline where applicable.

Submissions:

- Data-entry into Luther Consulting's EvaluationWeb (EvalWeb) database
  - All agencies are required to enter testing data at least WEEKLY into Eval Web, an online platform managed by Luther Consulting (CDC contractor). Prior to accessing/entering data in Eval Web, each staff person who will use Eval Web must be "e-authenticated" through CDC's SAMS. More information on the "e-authentication" process can be found on page 20 of this manual.
  - An HIV Testing Data Form should be completed for each test event. A test event is defined as the test/s performed on one person typically at one point in time. The HIV Testing Data form captures HIV rapid and blood testing, hepatitis C rapid and blood testing, syphilis rapid and blood testing, along with gonorrhea and chlamydia testing. The HIV Testing Data Form mimics the data entry screens in Eval Web.
  - Agencies are responsible to enter test events that have HIV results of negative or invalid, and test events that do not involve HIV testing. Test events with HIV results of positive, preliminary positive, discordant, or inconclusive must be mailed to the Prevention Data Manager (double envelope a copy of the completed HIV Testing Data Form and mail it to the Prevention Program). Additional details are available in the "Eval Web HIV Testing Data Form Procedure" document.
  - As of 1/1/19 all rapid testing is reported only through Eval Web. Rapid HIV testing should no longer be reported on the SLPH form, that form is reserved solely for submitting blood samples to the SLPH for HIV and/or Hepatitis C testing. The most recent version of the HIV Testing Data Form can be found in the back of this manual on pages 38-40.
  - The Prevention Program Data Team advises every agency to enter data into Eval Web at least weekly. Eval Web data entry must be completed for the prior month by the end of the following month. For example, all of July's Eval Web testing information must be entered in Eval Web by the end of August of that same year.

- Data-entry for Chembio HIV/Syphilis exemption
  - Agencies receiving Chembio Diagnostics DPP HIV/Syphilis Dual Rapid Test Kits **ONLY** will be allowed to submit data reporting on an excel spreadsheet drafted by the Rapid Testing Team versus entering data into Eval Web.
  - The agencies RECEIVING ONLY CHEMBIO must submit the data reporting onto an excel spreadsheet once a month with their testing results to the Rapid Testing general contact email (NC.Rapid.Testing@dhhs.nc.gov). An example of the excel spreadsheet is on page 44.
  - The spreadsheet is due on the 15th of every month (example: all testing results from the month of January 2024 would be due on February 15th 2024).

- Quarterly Reports

- All agencies who participate in the Rapid Testing program are also required to complete and submit Quarterly Reports on their rapid testing program. Please reach out to the Prevention Program Data Team or the Rapid Testing Program Team to request the template and instructions for the Quarterly Report. Additionally, agencies are required to complete the monthly inventory log located on page 55.

- Rapid Testing Kit Storage Temperature Log
  - All agencies are required to document temperatures in the storage room where test kits are located. Temperatures must be recorded weekly. These logs should be maintained in agency files and may be requested by the Rapid Testing Coordinator at any time. An example of this log can be found on page 50.

- Control Storage Temperature Log
  - All agencies are required to document temperatures in the storage area (refrigerator) where controls are located. Temperatures must be recorded daily. These logs should be maintained in the storage area and in agency files. These logs may be requested by the Rapid Testing Coordinator at any time (log located on page 51).

- Rapid Testing Kit Results Log
  - All agencies are required to document test results including invalid and reactive results. These logs should be maintained in agency files. An example of this log can be found on page 52.

- Control Results Log
  - All agencies are required to document control tests run at the testing site. These results must be logged on the control results log and maintained in agency files. An example of this log can be found on page 53.

- Inventory Log
  - All agencies are required to document the number of rapid test kits and each brand that is in stock, how many controls are in stock, and the expiration dates of each. These logs should be maintained in the storage area and in agency files. These logs will be requested by the Monitor only when they arrive for a site visit. DO NOT email the Rapid Testing Team your updated logs. An example of this log can be found on page 55.

- Registration Forms
  - All agencies must have a patient registration process in place that ensures confidentiality (i.e., ID numbers).

- Confidentiality Agreements
  - All agency staff and volunteers must require a signed annual confidentiality agreement on file at the testing agency.

- Trainings Records Form
  - All counselors must attend approved counseling, testing and referral training, rapid test kit training, and blood borne pathogens/universal precautions training. Staff and volunteers conducting rapid testing and prevention counseling activities are required to be skilled in client-centered counseling, safe work habits, collecting and processing rapid HIV test specimens accurately, and completing forms correctly. Skills and knowledge must be reinforced with

participation in ongoing training and evaluation activities. Certificates must be stored in agency files and may be requested by the Rapid Testing Coordinator. Example is found on page 54.

- Other Testing Policies
  - Agencies may have additional quality assurance measures in place with required staff compliance. Policies may be more specific than the state quality assurance plan but must meet the minimum requirements as described.

Proficiency Testing for Staff

Proficiency testing is a mandatory part of the state rapid HIV testing program under state law *10A NCAC 42D .0101, Certification for Laboratories Conducting HIV Testing*. It ensures that testing agencies are performing the test accurately and can interpret results correctly. The Rapid Testing Coordinator may request the results of proficiency testing as a part of the program evaluation. This is an annual occurrence that each NC DHHS rapid testing agency is required to obtain at their expense.

There are different options to choose from when it comes to proficiency testing. You may choose to enroll in a specific proficiency testing program. If you do not enroll in a Proficiency Testing Program, you can create your agency's own proficiency testing plan and maintain specific protocols to be reviewed by the Rapid Testing Team.

New agencies that have been accepted into the Rapid Testing Program will be expected to enact a proficiency testing program within two years of testing. See the following options:

1. Enroll in an official laboratory proficiency testing program such as the Wisconsin State Laboratory of Hygiene.

   The WSLH offers three samples sent twice a year for Anti-HIV Waived Methods (HVC) and offers 5 samples sent twice a year for hepatitis (YB) and syphilis serology (SS). More information is listed below. Participants should register by December 1 of the prior year for the next year's shipping cycle. Forms, catalogs, and further information are available at this link: Proficiency Testing Programs for Clinical Laboratory Quality (wslhpt.org). If you would like to get in contact with the lab directly you can email PTService@slh.wisc.edu or call 1-800-462-5261.

   The WSLH has also agreed to offer a 10% discount for any new lab that enrolls as part of the North Carolina Department of Health and Human Services Group. In order to receive the discount for the calendar year, labs must enter: NC DHHS DISCOUNT in the "Order comments" box just before the Order Total section on the enrollment form. Locations that are already the State's current customer this year should be receiving Re-enrollment paperwork that needs to be reviewed, list any changes needed, and turned back in to enroll again for future years. Any of these sites that already have that discount applied will continue receiving the discount.

   Please contact the Rapid Testing Coordinator to ensure receipt of this discount.

Any site enrolling with WSLH will also be assessed a $75 annual processing fee. The WSLH does provide the option of ordering a binder for $15 to store PT records/reports. Payment Methods can be with Purchase Order Number (entered on the enrollment form), or you will be invoiced (can pay by VISA/MC or check). We suggest enrollments are turned in by December 1st.

If an agency has used the WSLH as the chosen proficiency program in the past, please use this link to order or update your account; Customer Change Form - WSLH Proficiency Testing (wslhpt.org).

Those who are current customers should receive re-enrollment paperwork to be reviewed, list changes needed, and turned back in to enroll again. Any of these sites that already have that discount applied will continue receiving the discount. Approximate shipment dates are early February and early June.

Those using OraQuick HIV (waived), INSTI (waived) or Chembio (waived) can select the HIV Waived Methods (HVW) item. Anyone using the Syphilis Health Check (waived) or Chembio (waived) would select the Syphilis Serology (SS) item and those using the OraQuick HCV would select the Hepatitis program. Again, the Hepatitis PT04190 would be for those reporting HIV Waived (HVW) or no HIV at all. The PT04195 would be for those that order the HIV Ag/Ab Combo (HVC) 5 sample program as well.

Wisconsin State Laboratory of Hygiene Program Information and Pricing

Anti-HIV Waived Methods (HVW)
3 samples each shipment, 2 shipments per year
Item# PT04040
$214 for the year
Compatible with rapid waived kits such as OraQuick HIV, bioLytical INSTI and Chembio (HIV/Syphilis)

Hepatitis C- Waived Methods (YBC)
3 samples each shipment, 2 shipments per year
Item# PT04192 – if ordering alone or with HVW and/or SS
$290
Item# PT04193 – can only order this item as add-on if you also order HV or HVC
$290 - Compatible with OraQuick HCV

Syphilis Serology- Waived Methods (SSW)
3 samples each shipment, 2 shipments per year
Item# PT04272
$150
Compatible with Syphilis Health Check

2. Run controls every 3 months to ensure that testing staff are correctly reading test kits. Ensure staff run controls every three months on each brand of rapid test that is utilized by the testing agency.

3. Adapt your agency's own proficiency testing plan to your agency. If your agency participates in an alternative program, check with a Rapid Testing Coordinator for compliance. Ensure that specific material for rapid HIV testing proficiency is ordered.

Policies and Procedures

To ensure adequate and consistent performance and service from your staff, guidance documents that envelope these key procedural aspects listed below should be created and easily accessible to staff for reference during training and in everyday practice. These key aspects include, dissemination of Prevention Program updates, risk behavior assessment, confirmatory testing, process for referrals, process for contacting DIS, incentive procedures, field safety for outreach and testing activities, and CTR training.

Dissemination of NC DHHS HIV Prevention Program Updates

All agency staff should be kept abreast of pertinent information involving changes to the Rapid Testing Program, including key training dates, new materials, and new state testing requirements. A staff member (i.e., program manager or program coordinator) needs to be designated as a disseminator of information for testing staff.

Risk Behavior Assessment Guidance and Forms

As a part of your risk behavior assessment/pretest counseling intake form, we suggest you include a portion that is a self (client) administered questionnaire to determine risk behaviors. More information can be found on page 27.

> Example questions include: "How often do you wear a condom?" or "Who do you have sex with…men, women or both?"

Confirmatory Testing for Preliminary Positives

Mentioned in the application check list, a confirmatory plan is important for an agency pinpoint before testing in the community and in community/clinical settings. A follow up to an HIV preliminary positive test should include either "dual protocol" or a venipuncture whole blood sample. In order to confirm a preliminary positive result for syphilis or HCV the agency should collect a venipuncture whole blood sample for confirmatory testing. As it relates to syphilis, the blood test should be conducted to determine if the infection has been treated previously or is a new infection. An agency should also have a plan for reporting a positive HIV/HCV/syphilis test to either a local DIS (Disease Intervention Specialist) network, to the local health department, or to the State Laboratory of Public Health.

Dual Rapid Algorithm (Preliminary Positive OraQuick Advance HIV Rapid Test)

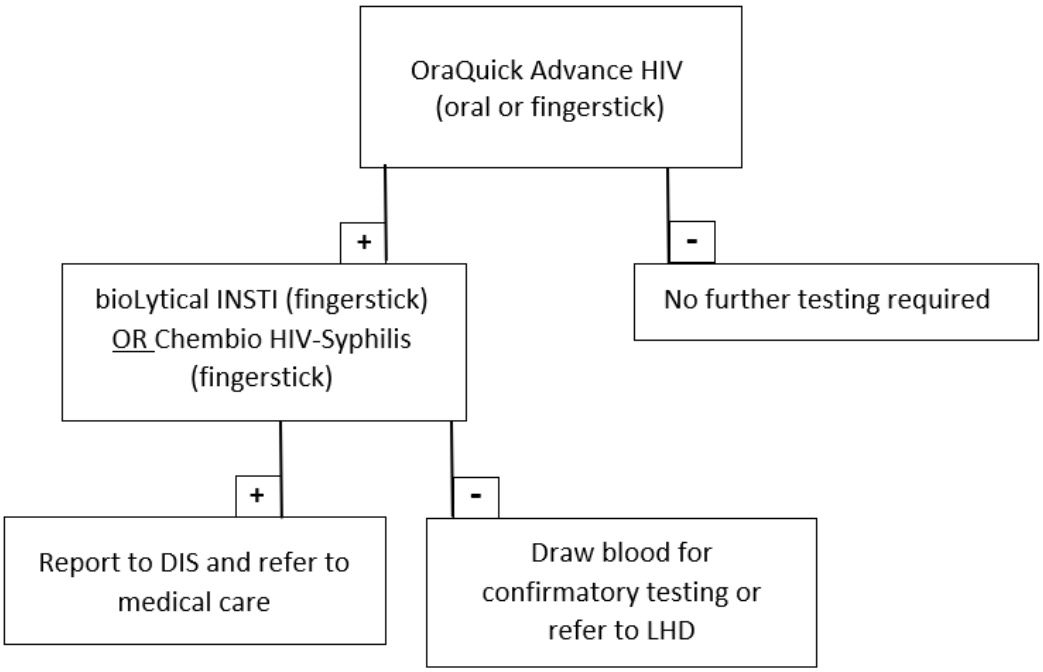
The dual rapid algorithm allows for early referral to care for rapid positives. A repeatedly positive HIV antibody test meets the case definition for HIV infection. Clients testing positive on two different rapid testing kits may be considered for linkage to care and is reportable to DIS as case positive. Agencies should communicate with their linkage partners to ensure that the algorithm is acceptable for entrance into care.

Agencies may start with any of the state supplied rapid testing kits. The second rapid test must be a finger-stick specimen of a different brand of test kit. The example below starts with OraQuick Advance.

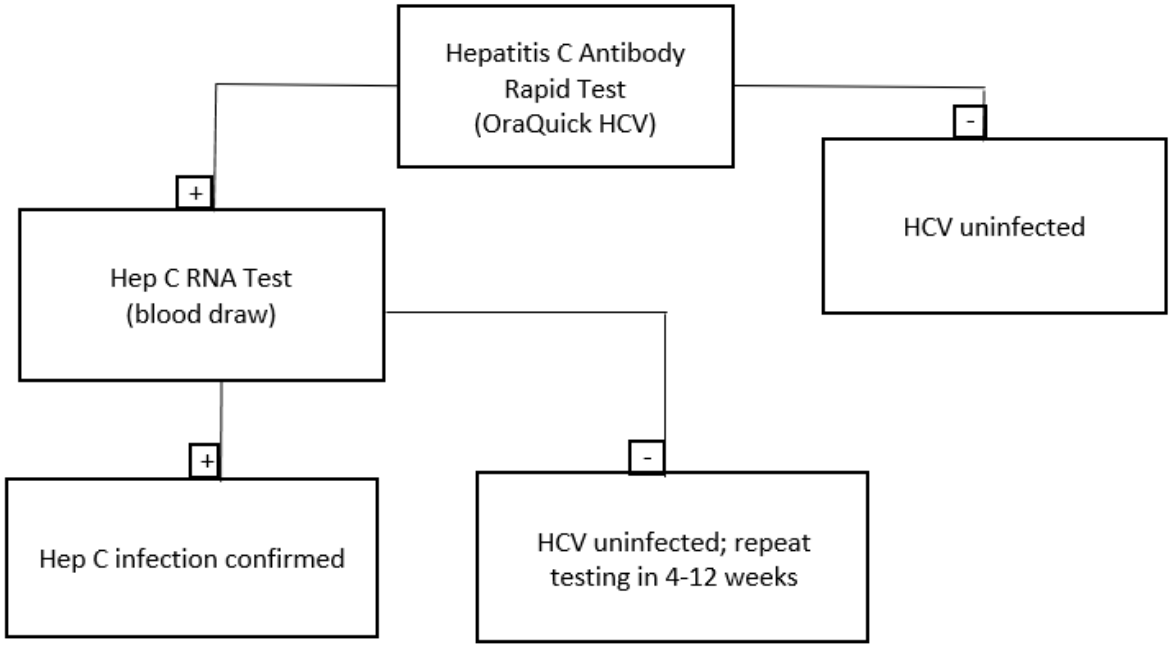
An example of a proper Dual Rapid Algorithm is outlined on the next page.

Example Dual Protocol Process

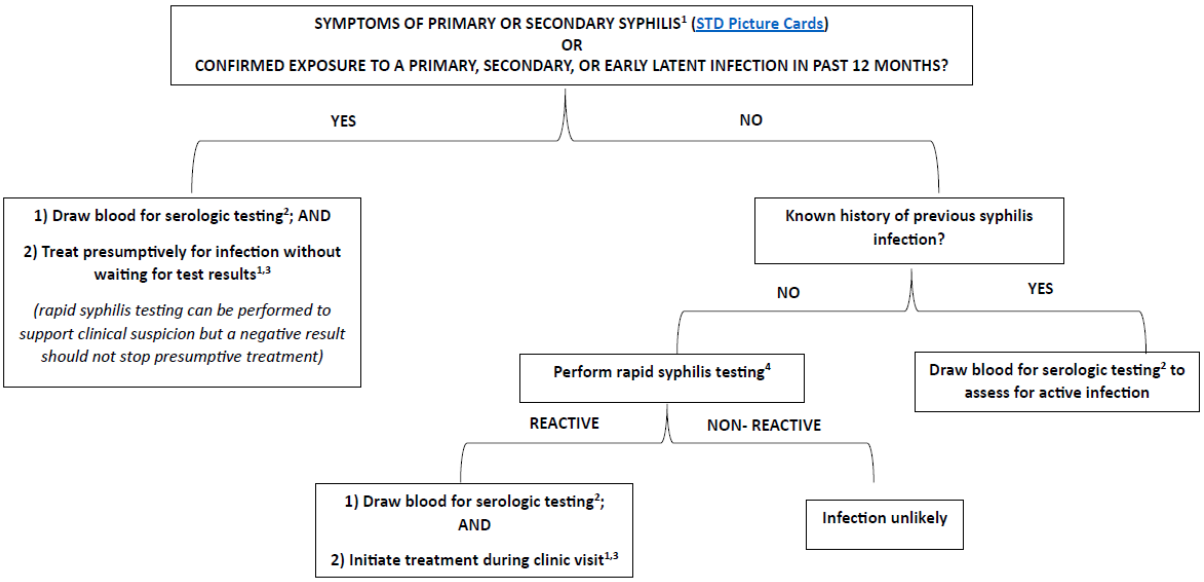
The following example starts with OraQuick HIV:



Confirmatory Testing Algorithm for Hepatitis C infections



Confirmatory Testing Algorithm for Syphilis infections



1. All patients diagnosed with syphilis should be assessed for signs of neurosyphilis (i.e., new HAs, confusion, personality changes, muscle weakness, or numbness), ocular syphilis (i.e., new visual changes, spots, blurred vision, floaters), or otosyphilis (i.e., new hearing deficits or tinnitus) and if present, additional evaluation and treatment is indicated: Neurosyphilis, Ocular Syphilis, and Otosyphilis - STI Treatment Guidelines (cdc.gov)

2. Serologic testing is necessary to distinguish between past and active infection and to monitor for an appropriate response to treatment (denoted by a 4-fold decrease in RPR or VDRL titers); diagnosing syphilis requires 2 serologic tests: a nontreponemal test (i.e., RPR or VDRL) AND a treponemal test (i.e., TPPA, EIA, FTA-ABS); assistance with interpreting serologic results can be found here: Clinical Interpretation of Syphilis Screening Algorithms (californiaptc.com)

3. CDC STI Treatment Guidelines can be accessed here: Syphilis - STI Treatment Guidelines (cdc.gov); treatment recommendations during periods of penicillin shortages can be found here: Clinical Reminders during Bicillin L-A® Shortage (cdc.gov)

4. Currently available rapid syphilis tests detect treponemal antibodies, which remain positive for like in >85% of individuals with a history of syphilis infection, therefore these tests cannot be used to determine current infection status in persons who have had a past syphilis infection; Information on the FDA approved rapid tests can be found here: Syphilis Health Check™ and DPP® HIV-Syphilis

Process for Referrals

Each client has individual needs, and sometimes a client's needs that are separate from disease intervention should be addressed first. Examples include food security, housing security, prenatal medical attention, and chronic medical concerns. Individual risk assessment should aid in carving a path towards correctly referring a client not only towards HIV/HCV clinical needs, but also towards other assistance programs accessible to the client.

Process for Contacting/Utilizing Disease Intervention Specialists (DIS)

Disease Intervention Specialists need to be contacted once an HIV result has been confirmed positive or when a new/ untreated syphilis infection has been confirmed. They will aid in ensuring that confidential partner notification and follow-up counseling are completed.

Incentive Procedures

Some agencies provide incentives for those that come in to get tested (i.e., bus passes, gift cards).

Field Safety for Outreach and Testing Activities

Testing and counseling in the field is necessary for disease intervention, but also includes a certain amount of risk. Field tester safety guidelines should be highlighted, documented, and enforced.

Counseling, Testing, and Referral Training (CTR)

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

CTR training is not required for testing in clinical settings (i.e., substance abuse clinics, community health centers, etc.). State funded agencies that receive rapid testing kits must send all non-clinical staff to Whetstone Consultations for CTR training. State supported rapid testing agencies may attend Whetstone Consultations or conduct approved internal CTR training. Licensed practical nurses may not attend Whetstone Consultations nor give post-test counseling.

If possible, clients should only see one counselor. Consistency of the client and counselor relationship helps the client feel secure, reduces misunderstanding, and promotes the likelihood of effective risk/harm reduction. If a different counselor must provide follow-up prevention counseling sessions, careful record keeping is recommended to ensure high-quality counseling.

REPORTING INSTRUCTIONS

The Division of Public Health Communicable Disease Branch received new CDC Funding Cycle (PS18-1802) beginning in 2018. This is the first time HIV Prevention and HIV Surveillance funding has been combined in a CDC grant. New HIV testing data requirements include new questions on PrEP and other essential support services, documentation of STD testing, and more data requirements associated with HIV care.

- As of 1/1/19 MOST agencies are required to enter data directly into Evaluation Web, an online platform managed by Luther Consulting (contractor with CDC).
  - With approval from the Rapid Testing Team, some agencies may be allowed an exemption from entering data into EvalWeb. Examples of these exemptions could be staffing issues, utilization of EvalWeb would interfere with implementing other programs within the agency, improper equipment or lack of equipment. If exemptions are approved, the agency would submit an excel spreadsheet once a month with their testing results. An example of the excel spreadsheet is on page 44.
  - Agencies only receiving Chembio Diagnostics DPP HIV/Syphilis Dual Rapid Test Kits ARE EXEMPT FROM ENTERING DATA INTO EVAL WEB.
- A data collection form has been created for use in North Carolina, which mirrors data entry in Eval Web. Eval Web captures HIV rapid and blood testing, hepatitis C rapid and blood testing, syphilis rapid and blood testing, along with gonorrhea and chlamydia testing. No other rapid testing reporting forms are needed as of 1/1/19.
- Eval Web provides easy access to agency data and reporting capability.

Quarterly Reports will also be required to be submitted. Failure to submit a quarterly report it failing to communicate with a Rapid Testing Team Member regarding report update status may forfeit agency from receiving test kits and prevention items in the future.

Eval Web Requirements

Each agency should identify at least 2 staff to become Eval Web users. A new user's contact information (name as it appears on photo ID, phone number, email, agency name and address) must be sent to both the Rapid Testing Program team and the Prevention Data Manager via email with the request to gain access to Eval Web. All Eval Web users must complete the e-authentication process through CDC's Secure Access Management Services (SAMS).

The e-authentication process does take time and is comprised of several parts:

1. Send the request to become an Eval Web user to the Rapid Testing Program team and the Prevention Data Manager.
2. The Prevention Data Manager will share the contact information with CDC's SAMS.
3. The future Eval Web user will then receive an email from SAMS_No_Reply@CDC.gov with the subject "CDC: SAMS Partner Portal – Identity Verification Request Form". This email describes your two options to choose from to complete e-authentication; either through Experian (online) or through submitted a completed application.

4. If you are not approved via Experian or you choose the second method then the email/application must be printed, completed, and notarized along with copies of 2 photo ID's (further details are in the email).
5. Once the completed application has been notarized the ideal way to submit the paperwork to SAMS is to scan it along with the copies of 2 photo ID's and upload that to SAMS.
6. When your documentation has been approved by SAMS you will receive an email indicating your e-authentication is complete. Then you must choose a secondary identification method of either a mailed Grid Card or a Soft Token app. This email will also provide directions on how to get set up with Eval Web access (by calling the Luther Consulting Help Desk).
7. Once you have successfully accessed Eval Web email the Prevention Data Team to advise, and we will verify your permissions in Eval Web are accurate.

There are several training resources available to Eval Web users on the Luther Consulting Eval Web Help page. There is also a webinar recorded by the NC Data Team that is available for viewing at any time. Please email the Prevention Data Manager, to request a link to the most recent version.

Data Collection and Entry

The "2022 HIV Testing Data Form (4-25-22)" is a helpful tool and mimics the data entry screens in Eval Web. The full HIV Testing Data Form can be found on pages 38-40.

Please complete one HIV Testing Data Form for each client tested using a rapid HIV, and/or rapid Syphilis, and/or Rapid Hepatitis C test kit provided by the Prevention Rapid Testing Program. Be sure to include coinfection test results with the HIV test result when applicable. These include Hepatitis C, Syphilis, Gonorrhea, and Chlamydia testing.

The HIV Testing Data Form does include client name and date of birth, as this information is necessary for the verification of positive, preliminary positive, discordant, and inconclusive HIV results (see the "2022 Eval Procedures" guide for details on pages 41-46).

All test events with HIV results of positive, preliminary positive, discordant, and inconclusive are required to be sent to the Prevention Program Data Team, according to the instructions in the "Eval Web HIV Testing Data Form Procedures" document on pages 41-46. Double envelope a photocopy of the completed HIV Testing Data Form/s and mail it/them to the Prevention Data Manager. Please mail the copies as soon as they are complete, and please do not enter these test events into Eval Web as the Prevention Program Data Team will do that for you. Please note that all agencies are responsible for data entry into Eval Web for test events with HIV results of negative and invalid and test events that do not involve HIV testing and should do so by the deadline of the month prior's test events by the last business day of the following month. For example, January's test events must be entered into Eval Web by the last business day of February.

Eval Web does not allow any identifiable information to be entered into a test event, such as names (whole name, partial name, initials) or dates of birth (except for the Client Year as it is a required data entry field). As previously mentioned, the HIV Testing Data Form includes name and DOB.

Data entry into Eval Web should be done at least weekly.

Contact the Rapid Testing Program team and the Prevention Program Data Team by phone or by email (see contact information at the end of this document).

ANNUAL TRAININGS AND TRAINING RESOURCES

Rapid Test Trainings

All Brand Rapid Test Trainings:
The NC DHHS HIV Prevention Program provides an "All Brands Rapid Test Training" on an annual basis. This is a great opportunity for State funded and State supported rapid testing agencies who are looking to have their staff trained in all rapid testing technologies that the State offers. These training courses usually take place one to two days and are the most efficient way to certify and recertify testing employees.

Regional Based Trainings:
Can't make it to one of the All Brand Rapid Testing Training? Have one particular brand that you need your staff trained in? Each agency is able to request on-site brand specific training through one of the below brand representatives. A Rapid Testing Monitor can assist you with site scheduling. The Rapid Testing Team asks that you bring at least 10 attendees to an onsite training course in which a brand representative is traveling for. You may partner with other nearby rapid testing agencies that also need staff trained in the specific rapid testing technology. You may request this through one of the Rapid Testing Coordinators or requests this training directly through one of the representatives mentioned below. **If you request directly, you must inform a Rapid Testing Coordinator.**

Web-Based Trainings:
You can contact any of the representatives mentioned below to offer web-based training to you and your staff in the wake of COVID-19 restrictions.

OraSure Technologies
Heather Bronson, Public Health Account Manager
hbronson@orasure.com
484-241-8377
(OraQuick ADVANCE HIV Rapid HIV -1/2 Antibody Test, OraQuick HCV Rapid Antibody)

Diagnostics Direct
Jeff Tobias, Vice President-Sales and Marketing
jtobias@dd-2u.com
866-358-9282 ext. 102
(Syphilis Health Check)

bioLytical Laboratories Inc.
Leahjane Lavin
llavin@biolytical.com
360-922-4135
(INSTI HIV-1/ HIV-2 Rapid Antibody Test)

Chembio Diagnostics
Katie Pryor
kpryor@chembio.com
(954) 546-3768
(Chembio DPP HIV-Syphilis Rapid Test)

Before contacting any of the representatives listed below, please contact the Rapid Testing Team to ensure the most updated contact information.

CTR Whetstone Consultations Trainings:

As mentioned above in earlier sections, "Counseling, Testing, and Referral" (CTR) Trainings are available to State supported agencies through Whetstone Consultations. Through a grant from HIV/STD Prevention and Care, Whetstone Consultations provides training to local health departments and community-based organizations that provide HIV counseling and testing services to their clients. For information about training objectives, registration, available dates, and locations, see https://www.whetstoneconsultations.com/.

Whetstone training is free for State supported agencies. Testing agencies are responsible for providing funds concerning mileage, hotel stay, and food for their respective staff attending the training.

If Whetstone is not used for training agency staff in CTR, then another form of training must be approved by a Rapid Testing Counselor.

Phlebotomy Training:

The Communicable Disease Branch has quarterly trainings throughout the State. Agencies should contact the Rapid Testing Monitor for upcoming training dates.

CONSEQUENCES OF PROTOCOL VIOLATIONS

Failure to follow North Carolina's rapid testing and prevention counseling protocol may result in a cease of rapid testing activities indefinitely or until protocol issues are resolved. Protocol violations witnessed by or reported to the Rapid Testing Coordinator 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 the HIV Prevention Program

An immediate halt of testing activities can occur when:

- Confidentiality is compromised in the test processing area or through handling of documentation.

- Quality assurance records/documents are not maintained as specified in this protocol.
- The agency fails proficiency testing.
- Informed consent is not obtained from clients prior to specimen collection.
- Completed HIV Test forms are not stored in a confidential manner and the specified copies are not submitted at frequent intervals
- Rapid test kits or other testing supplies are distributed to and/or used by unauthorized entities or are unaccounted for.
- The agency's CLIA waiver or HIV license expires without intent to renew.
- Confirmatory testing is not offered/referred to a client who has a preliminary positive rapid test result.
- There is a failure to submit monthly Eval Web documentation by the end of the following month.
- Documentation for clients who test positive or inconclusive or discordant for HIV is not filled out completely and accurately and is not mailed to the Data Team **(Positive/Inconclusive/Discordant HIV tests must be reported to the Prevention Data Team by mailing a copy of the completed HIV Testing Data Form).**
- Clients who test positive for HIV are not linked to appropriate HIV medical treatment services and/or follow-up on HIV medical care linkages are not made and/or documented.
- Data is not entered into Eval Web within 3 months of collection, or no notification is sent to the Rapid Testing Coordinator.

REFERENCE MATERIAL

HIV/ STD Facts for Educational Materials

HIV Facts (HIV Basics | HIV/AIDS | CDC)

- HIV is spread through Blood, Semen, Vaginal Fluids & Breast Milk. If one of these fluids is not involved in sufficient quantity to infect, then transmission will not occur. In addition, there must be a way for the fluid to get out of the body of the infected person, and into the body of an uninfected person.
- HIV is most widely spread through sexual contact and sharing needles. Transmission is affected by the fluids involved, the type of sex and the role (receptive or incentive; receiver or giver.)
- HIV disease is potentially deadly and there is no cure, but there are good treatments that can extend the length of life and improve the quality of life.

- Some physicians will not prescribe the medications for some clients (e.g., people who are homeless, persons with mental illness, etc.)
- Numerous and difficult side effects of the medications are experienced by many patients. Overall, the benefits of HIV medicines far outweigh the risk of side effects. In addition, newer HIV regimens cause fewer side effects than regimens used in the past.
- Early diagnosis and assessment by an HIV experienced physician can greatly improve the health and happiness of clients.
- The window period is the time during which a person can be infected, but antibody tests will not detect infection. This varies from 3 weeks to 3 months depending on the lab test that is being performed.
- Acute HIV occurs shortly after infection (2-6 weeks) and includes symptoms like those of severe flu or mononucleosis: fever, generated aches and pains, fatigue. It may also include rashes, nausea, swollen lymph nodes, and diarrhea. During this time, the viral load of the patient is high and therefore the client is highly infectious.

Hepatitis Facts (What is Viral Hepatitis? | CDC)

- Hepatitis A:
    - Found in feces.
    - Can be contracted by contaminated food, sharing of drug use supplies, and oral-anal sexual contact
    - Symptoms: Fatigue, fever, chills, loss of appetite, joint pain, sick stomach and yellowish eyes and skin (jaundice)
    - Vaccination: YES

- Hepatitis B:
    - Contracted by exposure through unprotected sex with an infected person, blood to blood exposure (ex. sharing needles or other drug equipment with an infected person, workplace needlestick injury), or anal intercourse
    - Symptoms: Fatigue, fever, chills, loss of appetite, joint pain, sick stomach and yellowish eyes and skin (jaundice). People can also have no symptoms or minor symptoms when they are infected with Hepatitis B
    - Vaccination: YES

- Hepatitis C/HCV:
    - Contracted by exposure through unprotected sex with an infected person, blood to blood exposure (ex. sharing needles or other drug equipment with an infected person, workplace needlestick injury), or anal intercourse
    - Rarely people get HCV from unprotected sex with an infected person
    - Symptoms: Fatigue, fever, chills, loss of appetite, joint pain, sick stomach and yellowish eyes and skin (jaundice). People can also have no symptoms or minor symptoms when they are infected with Hepatitis C
    - Vaccination: NO, but curative treatment is available and accessible regardless of insurance status

Syphilis Facts (About Syphilis | Syphilis | CDC)

- Syphilis is a sexually transmitted infection that can cause serious health problems without treatment. Infection develops in stages; primary, secondary, latent, and tertiary. Each stage can have different signs and symptoms.
- Syphilis can be spread by direct contact with a syphilis sore during vaginal, anal, or oral sex. It can also be spread by a mother with syphilis to her unborn baby while pregnant (congenital syphilis).
    - All pregnant people should be tested for syphilis during their first prenatal visit.
- Without treatment, syphilis can spread to the brain and nervous system, the eye, or the ear.
- Syphilis can be cured with the right antibiotics, but it might not undo any damage the infection causes.
- Even if you are successfully treated and cured of a syphilis infection, you can get it again. Previous infections do not stop a person from contracting syphilis in the future.

- Primary Stage signs and symptoms:
    - A single or multiple sores that usually occur in, on, or around the penis, vagina, anus, rectum, lips or in the mouth. The sores are where syphilis entered the body. The sores are usually firm, round, and painless. They last 3-6 weeks and heal regardless of treatment.

- Secondary Stage signs and symptoms:
    - A person may develop skin rashes and/ or sores in the mouth, vagina, or anus. The rash can look rough, red/ reddish-brown, and usually not itchy. Other symptoms are fever, swollen lymph nodes, sore throat, patchy hair loss, headaches, weight loss, muscle aches and fatigue. Symptoms will go away even if you do not seek treatment.

- Latent Stage:
    - There are no visible signs or symptoms of this stage. Without treatment you can have syphilis in your body for years.

- Tertiary Stage:
    - This stage is very serious and occurs 10-30 years after a person has been exposed to syphilis. The disease damages the internal organs and can result in death.

- Congenital Syphilis:
    - Can cause miscarriage, stillbirth, premature birth, low birth weight or death shortly after birth.
    - If a baby is born with congenital syphilis they may have deformed bones, severe anemia, enlarged liver and spleen, jaundice, brain and nerve problems, meningitis and skin rashes.
        - Some babies can be born with no symptoms but develop serious problems later on.
    - Babies with congenital syphilis must be treated right away or they are at risk for serious health problems.
    - Cases have tripled in recent years, more that 2,000 cases were reported in 2021, the highest since 1994.

Risk Behavior Assessment Guidance

Assessment:
Any activity that can result in the transmission of HIV is considered a risk behavior. Example may include having sex without a condom, getting semen or vaginal fluids in your mouth, or sharing needles.

Risk Screening:
In order to determine a client's risk of contracting HCV or HIV, an agency can choose to instruct their staff to partake in a variety of assessments.
These include:

- Self-Administered Questionnaire
- History Taking
- Conversation with the Client
- Or a combination of three

Personalized Risk Assessment:
In order to start the counseling session, the counselor can ask, "Tell me what you know about how someone gets HIV." Make sure to determine that HIV is transmitted primarily though sex and sharing needles.

You can also include in your opening statement, "Since sex and sharing needles are the two primary ways HIV is transmitted, those are the things we have to talk about with our clients. I am going to ask some important, but personal, questions so I can understand your risks and help you keep from becoming infected."

Make sure to ask these specific questions:

- "What kind of sex do you have: oral (your mouth on someone's genitals or someone's mouth on your genitals) or vaginal (penis inserted into a vagina) or anal (penis in an anus)?"
- "What is the gender of the people you have sex with?"
- "How many people have you had sex with in the past 6 months?"
- "When was the last time you put something in your body with a needle?" or "What experience have you had with drugs and needles?" and then "How do you get high? Stoned? Altered?"

Conducting Rapid Testing and Prevention Counseling with a Client (Pre and Post Test Counseling)

Risk Reduction Planning
Along with a risk reduction assessment, the counselor can use the "pre" test time period to educate the client on HIV/HCV and how to reduce exposure risk.

If a client is **having sex**, then suggest that they can use condoms (if not all the time, then at least sometimes) and to try and limit the number of people you have sex with. If they are **sharing needles**, ask them if they can clean them before they use them.

To do this you can ….

- Provide a brochure or show a video in a waiting room
- Verbally inform clients
- Link risk assessment to specific risk reduction strategies
- Counsel client on individualized strategies
- Offer options (some might be less likely to cause infection but do not eliminate risk)

Goal Setting & Action Plans

- Find out what goals the client wants to adopt to directly prevent HIV/HCV transmission (ex: knowing HIV status of partners, not sharing needles)
- The counselor can help the client pinpoint specific actions that they can take to achieve this goal (ex: carrying condoms, talking openly with each partner)

Testing

There are steps in place that you can follow leading up to the testing.

- Explain the test and how the specimen will be collected, how and when the test will be given, and what the test means.
- Determine if the client is ready to know their status.
- Refer a client to the appropriate services. This is explained in the presentation portion of the packet
- Develop a follow up plan with the client so that they can receive the news of their status.

All agencies conducting the HIV Prevention Counseling and Rapid Testing intervention in North Carolina should model sessions with clients according to the format and guidelines listed below.

Before performing a rapid HIV test:

- Introduce yourself to the client. Give the client your name and welcome them to the testing site.
- Assess client's readiness to receive the results on the same day. Ask the client questions to determine their motivation for getting tested and what, if any, support system is in place.
- Offer options for testing (oral swap, finger-stick, venipuncture, etc.) that are available at the testing site. Offer clients the choice of receiving results the same day or at a later date.
- Describe the testing process, what type of specimen will be collected, how long the entire 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 are preliminary positive, negative, and invalid. Clients should also be informed what actions will take place after each of the results.

- Explain to the client that if a preliminary positive result is received, a confirmatory test will be conducted. According to the CDC, an 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 to confirm the result. Counselors must assess if testing is beneficial at this time based on the client's response to how they would react to getting a preliminary positive result.

Persons who have identified themselves as HIV positive should not be retested with a rapid test. Individuals infected with HIV-1 and/or HIV-2 who are prescribed antiretroviral medication can produce false negative rapid test results under some circumstances. Self-identified HIV infected persons can be offered a conventional HIV test and should be referred to case management and/or medical care.

- Address Partner Services, including that if the client tests positive, a DIS (Disease Intervention Specialist) will contact them to offer services. Emphasize that this is a free and confidential service that provides clients with help in contacting partners and other referral services.

- Offer the client a confidential test and explain what confidential testing means. Confidential testing indicates that a client is willing to provide personal identifiers that can be used to link the individual to his/her rapid HIV test result.

- Obtain Informed Consent. Informed Consent (verbal or written) for HIV testing must be obtained prior to clients receiving any HIV testing. Clients testing confidentially must provide written consent or verbal consent must documented in the client's records.

- Provide an appropriate subject information pamphlet for the rapid test being conducted. The FDA requires that 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 test kits.

- Collect and run the specimen. Testers must follow the manufacturer's instructions provided by the manufacturer of the rapid test device he/she will be using. In addition to manufacturer instructions, identifying stickers from the HIV Test form should be placed on the testing device (or on the developer solution vial for OraQuick tests) to ensure quality control. Not following the manufacturer's instructions may result in inaccurate test results.

While a rapid HIV test is processing:

- Identify personal risk behaviors and safer goal behaviors of the counseling process. A personalized risk assessment should explore previous risk-reduction efforts and identify successes and challenges in those efforts. Factors associated with continued risk behavior that might be important to explore include using drugs or alcohol before sexual activity, underestimating personal risk, perceiving that precautionary changes are not an accepted peer norm, perceiving limited self-efficacy for successful change efforts, receiving reinforcement for frequent unsafe practices (e.g., a negative HIV test result after risk behaviors), and perceiving that vulnerability is associated with "luck" or "fate".

  When considering safer goal behaviors, counselors should focus on reducing the client's current risk and educating about HIV transmission modes. Counselors should discuss the HIV 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 risky sex partner poses little or no HIV risk, the counselor can clarify that, although oral sex with an infected partner might result in lower HIV transmission risk than anal sex, oral sex is not a risk-free behavior, particularly when commonly practiced. If clients indicate that they do not need to be concerned about HIV transmission among needle-sharing partners if they use clean needles, the counselor can clarify that HIV can be transmitted through the cooker, cotton, or water used by several persons sharing drugs. 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 they are willing to commit to changing.

- Continue to assess client readiness to receive result. Counselors have until the timer goes off, thus indicating the rapid test is finished processing, to assess whether the client is ready to receive same day test results. Counselors may not give test results before the kit is fully resolved per the manufacturer guidelines. If the counselor leaves to interpret the test result, they must provide the result upon returning to the client.

After the rapid HIV test has developed:

- Provide the test result to the client.
- Create a client action plan, offer referrals and provide support, summarize and close
- Set up follow-up appointment for preliminary positive clients to receive confirmatory result or, if necessary, those testing negative to get retested.
- Provide condoms, other risk/harm reduction tools and appropriate literature.
- Complete the remainder of the HIV Testing Data Form, Kit Results Log and other documentation as needed.
- Correctly dispose of used testing supplies following universal precautions and safe work practices at all times.

Continue counseling session based on the results of the test:

Preliminary Positive:

- Accurately communicate results with client—if the result shows signs of HIV antibodies or antigen, then a confirmatory test must be done to be sure.
- Allow time for emotional response. Do not rush the client into conversation.
- Ensure the client understands what the result means and assess client concerns.
- Offer to take a confirmatory whole blood sample (using phlebotomy) or offer to test them using a second brand of HIV rapid test (in accordance with the dual protocol algorithm). Clients who have a reactive/preliminary positive rapid HIV test result must be offered a confirmatory test or second rapid test and linked to early intervention after receiving their preliminary positive result. North Carolina allows for dual rapid confirmatory algorithm to increase the efficiency of linkage to care. See page 17 for the algorithm.

- Review the client's risk assessment and risk reduction plan.
- Emphasize the importance of taking the same health precautions as a person who may have a confirmed HIV positive test result. HIV positive clients must be informed about control measures under state law 10A NCAC 41A .0202, *Control Measures—HIV*.
- Negotiate additional referrals with the client, including potential medical and partner services.
- Set appointment to return for confirmatory blood draw test results.
- Provide condoms and literature as deemed appropriate.
- Document the result on the HIV Testing Data Form and Kit Results Log

Negative:

- Review with the client his/her risk assessment and risk reduction plan. Discuss plans for staying negative.
- Assess the need to retest.
- Provide condoms and other risk/harm reduction tools and appropriate literature.
- Assess the client's need for other referrals.
- Make sure client understands the window period and whether he/she needs to be retested at a later date.
- Document the result on the HIV Testing Data Form and Kit Results Log

Invalid:

- Explain that there was a problem running the test, either related to the test device or the specimen collected.
- Assess client concerns and emotional response.
- Assure client that quality assurance procedures are in place. NOTE: If you have not personally checked all storage logs that day, do so before retesting.
- Collect new specimen and run it with new rapid test device or conduct a conventional test if the client refuses an additional rapid test.
- Provide condoms, other risk/harm reduction tools and appropriate literature.
- Review the client's risk assessment and risk reduction plan. Emphasize the need to take the same risk reduction precautions as established.
- Document the invalid result on the Kit Results Logs. Document the repeated rapid test result on the HIV Testing Data Form and Kit Results Log.

Confirmatory HIV Testing

Following a preliminary positive rapid test, the client must be administered a confirmatory HIV test. This can be done with a second rapid test or a blood draw.

Negative or Indeterminate (therefore Discordant Result):

- The client should be told that their HIV status is not certain at this point and further testing is needed.
- Explain that this is a discordant result. Do not use the terms "false positive" or "false negative" as these are not appropriate descriptions of this situation.
- Assess client's concerns.

- The client should be given an appointment to return for retesting in 2 weeks. It is highly recommended and compliant with CDC rapid testing protocol that follow-up confirmatory testing be conducted with a new specimen whenever possible.
- Review the client's risk assessment and risk reduction plan.
- Provide condoms, other risk/harm reduction tools and appropriate literature.
- Document the result on the HIV Testing Data Form and Kit Results Log and Corrective Actions Log. The Rapid Testing Coordinator should be notified as soon as possible of discordant results.
    - A copy of the completed HIV Testing Data Form with discordant results must be mailed (double envelope) to the Prevention Program Data Team. Do not enter a test event with a result of HIV discordant into Eval Web, as the Prevention Program Data Team will do that for you.

Positive:

- Allow time for an emotional response. Do not rush the client into a conversation.
- Ensure client understands what test result means.
- Make client aware of need for medical evaluation and the availability of treatment.
- Provide linkage to care. Linkage to care links newly identified HIV-infected persons, not currently in care, to a primary care provider. The counselor also educates basic facts about HIV and may link clients to other services when barriers are identified.
- Reassess the client's risk for transmitting HIV infection to others. Discuss partner counseling options and discuss the client's plan to inform his/her partners.
- Assist client in identifying necessary linkages. Make appropriate connections and set appointments.
- If working with a positive woman who is pregnant and not in prenatal care, link the client to prenatal care.
- Provide condoms and appropriate literature.
- Inform DIS. Clients are to be informed of the importance of contacting sex and/or needle sharing partners. Counselors should record clients' full contact information on the appropriate areas of HIV Testing Data Form facilitate referral follow up, partner services, and surveillance. Counselors must discuss the North Carolina public health policy that provides for DIS to contact all persons testing reactive to HIV to discuss and offer partner services.
- After 30 days if linkages cannot be confirmed, make appropriate documentation in client's patient information and document the result on the Kit Results Logs.

Once the HIV Testing Data Form is complete, mail a copy of the form (double envelope) to the Prevention Program Data Team. Do not enter a test event with a result of HIV Positive into Eval Web, as the Prevention Program Data Team will do that for you.

NC Rapid HIV/HCV/Syphilis Testing Program Enrollment Requirements

This document outlines the enrollment requirements for the Rapid Testing Program. Please complete all sections and return them to the Rapid Test Coordinator. For questions, contact Carlotta McNeill at the Communicable Disease Branch at 984-236-1484 or NC.Rapid.Testing@dhhs.nc.gov.

1. Contact Information	
Agency Name:	
Contact Person:	Title:
Mailing Address (No P.O. Box):	
City, State, Zip Code:	
Shipping Address (if different than mailing):	
Phone Number:	Fax:
Email Address:	

2. CLIA Certificate of Waiver Number and HIV Testing License Number
Indicate your CLIA Certificate of Waiver and HIV Testing License numbers below. ***To apply, contact the Division of Health Service Regulation, https://info.ncdhhs.gov/dhsr/ahc/clia/ or azzie.conley@dhhs.nc.gov, 919-855-4620.***
CLIA Certificate of Waiver Number:
HIV Testing License Number:

3. Medical Provider
List the name of the medical provider who will be responsible for your agency's standing orders.
Name:
Office Phone Number:
Address:

4. Confirmation of Positive Results
How will your agency confirm a preliminary positive result, i.e., draw blood, dual rapid test, referral to LHD or DIS? **Please indicate if you need assistance with this process.**

5. Referral Network
Describe your referral agencies for linking preliminary positive clients to care, treatment and support services.

6. Rapid Testing (RT) and Counseling, Testing and Referral (CTR) Trainings			
List each staff member who has been trained in RT and/or CTR. Indicate below if your staff will need either of these trainings.			
Name	Brand of Rapid Test	Rapid Test Training (Needed or Already Completed)	Counseling, Testing and Referral Training (Needed or Already Completed)

By signing, I verify the accuracy of the information and documentation listed above in meeting the Communicable Disease Branch enrollment requirements for implementing rapid testing.

Service Provider

_____ _____ _____/_____/_____

Print Name Signature Date

Communicable Disease Branch (Designate)

_____ _____ _____/_____/_____

Print Name Signature Date

Post Approval Expectations:

Within 3 months of application approval, the newly accepted rapid testing program is expected to:

1. Create a Quality Assurance (QA) Plan
    - Agency must have rapid HIV testing policies, procedures, and QA plan that are consistent with State policies. QA plan must include records management protocols such as test run logs, control log, temperature logs, and storage logs. It must also include the testing protocol and use of test and control kits. State QA plan and associated documents is provided in the supplementary documents of this enrollment packet, and is also found on the website: http://epi.publichealth.nc.gov/cd/stds/programs/testing.html.
2. Plan for staff training and update training logs
    - Required trainings include Whetstone Trainings (pre- and post-test counseling), brand specific rapid testing trainings, and phlebotomy training.
3. Create a confidentiality policy
    - Agency must have a confidentiality policy that includes the agency's rapid HIV testing confidentiality policies and procedures that address informed consent, legal and ethical policies, client confidentiality, and data security. These policies must be signed on an annual basis.

STATE OF NORTH CAROLINA

2019 HIV Testing Certification

Initial/Renewal Application

NC GS130A-148; 15A NCAC 20D and GS143B-165; 10NCAC 3W

Complete form to APPLY for or to RENEW Certification for HIV testing. Complete one application form for each HIV testing site location.

CERTIFICATION FOR HIV TESTING

[ ] RENEW [ ] NEW DATE MAILED [**STATE GOVERNMENT USE ONLY**]: _____

Name_____ CERTIFICATE # _____

DBA (if different from above)_____

Site LOCATION_____

CITY_____State_____ZIP_____

MAILING ADDRESS (if different from site) _____

_____

PHONE (___)_____EIN#_____ Medicare # _____

OWNED by_____

FDA MQSA#_____ #Units: FIXED_____ MOBILE_____

Name/Title of Director_____

COMPLETE AS APPLICABLE

HIV Confirmatory Test(s) performed [ ] Name:_____

HIV Proficiency Testing Program_____

CLIA ID#_____Expires_____
AABB ID#_____Expires_____
JCAHO ID#_____Expires_____
CAP ID#_____Expires_____

_____

CONTACT PERSON TITLE PHONE

_____

AUTHORIZED SIGNATURE TITLE DATE

Registration and Renewal Process for Providers of HIV Testing, PAP Smear Screening & Mammography Screening

This is a registration process for identification of facilities in NC providing these services.

- A certificate is issued every two years.
- Certificates expire on December 31st.
- Certificates are printed and mailed to facilities.
- There is no fee at this time for this certificate.
- All are renewed at the same time regardless of application date.
- Initial applications received during the year will have the same expiration date for that certification period.
- Completed applications can be emailed to DHSR.CLIA@dhhs.nc.gov for your convenience. It is not necessary to send them in the mail.

Division of Health Service Regulations
Acute Care/CLIA
Certification Section
2713 Mail Service Center
Raleigh NC 27699-2713

HIV Testing License Application/ Renewal (ncdhhs.gov)

Form CMS-116, CLIA APPLICATION FOR CERTIFICATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

Form Approved
OMB No. 0938-0581

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA) APPLICATION FOR CERTIFICATION

ALL APPLICABLE SECTIONS OF THIS FORM MUST BE COMPLETED.

I. GENERAL INFORMATION

☐ Initial Application Anticipated Start Date _____

☐ Survey

☐ Change in Certificate Type

☐ Change in Laboratory Director

☐ Other Changes (Specify) _____

Effective Date _____

CLIA IDENTIFICATION NUMBER

_____ D _____

(If an initial application leave blank, a number will be assigned)

FACILITY NAME

FEDERAL TAX IDENTIFICATION NUMBER

EMAIL ADDRESS _____

☐ RECEIVE NOTIFICATIONS INCLUDING ELECTRONIC CERTIFICATES VIA EMAIL

TELEPHONE NO. *(Include area code)*

FAX NO. *(Include area code)*

FACILITY ADDRESS — ***Physical Location of Laboratory (Building, Floor, Suite if applicable.)*** *Fee Coupon/Certificate will be mailed to this Address unless mailing or corporate address is specified*

NUMBER, STREET *(No P.O. Boxes)*

CITY | STATE | ZIP CODE

MAILING/BILLING ADDRESS *(If different from facility address) send Fee Coupon or certificate*

NUMBER, STREET

CITY | STATE | ZIP CODE

SEND FEE COUPON TO THIS ADDRESS

PICK ONE:

☐ Physical
☐ Mailing
☐ Corporate

SEND CERTIFICATE TO THIS ADDRESS

PICK ONE:

☐ Physical
☐ Mailing
☐ Corporate

CORPORATE ADDRESS *(If different from facility) send Fee Coupon or certificate*

NUMBER, STREET

CITY | STATE | ZIP CODE

NAME OF DIRECTOR *(Last, First, Middle Initial)*

Laboratory Director's Phone Number

CREDENTIALS

FOR OFFICE USE ONLY

Date Received _____

II. TYPE OF CERTIFICATE REQUESTED *(Check only one) Please refer to the accompanying instructions for inspection and certificate testing requirements)*

☐ Certificate of Waiver *(Complete Sections I – VI and IX – X)*

NOTE: Laboratory directors performing non-waived testing (including PPM) must meet specific education, training and experience under subpart M of the CLIA regulations. Proof of these qualifications for the laboratory director must be submitted with this application.

☐ Certificate for Provider Performed Microscopy Procedures (PPM) *(Complete Sections I-VII and IX-X)*

☐ Certificate of Compliance (Complete Sections I – X)

☐ Certificate of Accreditation (Complete Sections I – X) and indicate which of the following organization(s) your laboratory is accredited by for CLIA purposes, or for which you have applied for accreditation for CLIA purposes.

☐ The Joint Commission ☐ ACHC ☐ AABB ☐ A2LA

☐ CAP ☐ COLA ☐ ASHI

If you are applying for a Certificate of Accreditation, you must provide evidence of accreditation for your laboratory by an approved accreditation organization as listed above for CLIA purposes or evidence of application for such accreditation within 11 months after receipt of your Certificate of Registration.

PRA Disclosure Statement

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0581. Expiration Date: 03/31/2027. The time required to complete this information collection is estimated to average one hour per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850. *****CMS Disclaimer*****Please do not send applications, claims, payments, medical records or any documents containing sensitive information to the PRA Reports Clearance Office. Please note that any correspondence not pertaining to the information collection burden approved under the associated OMB control number listed on this form will not be reviewed, forwarded, or retained. If you have questions or concerns regarding where to submit your documents, please contact https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/cliasa.pdf and https://www.cms.gov/files/document/clia-operations-branch-contacts.pdf.

III. TYPE OF LABORATORY *(Check the one most descriptive of facility type)*

- ☐ 01 Ambulance
- ☐ 02 Ambulatory Surgery Center
- ☐ 03 Ancillary Testing Site in Health Care Facility
- ☐ 04 Assisted Living Facility
- ☐ 05 Blood Bank
- ☐ 06 Community Clinic
- ☐ 07 Comp. Outpatient Rehab Facility
- ☐ 08 End Stage Renal Disease Dialysis Facility
- ☐ 09 Federally Qualified Health Center
- ☐ 10 Health Fair
- ☐ 11 Health Main. Organization
- ☐ 12 Home Health Agency
- ☐ 13 Hospice
- ☐ 14 Hospital
- ☐ 15 Independent
- ☐ 16 Industrial
- ☐ 17 Insurance
- ☐ 18 Intermediate Care Facilities for Individuals with Intellectual Disabilities
- ☐ 19 Mobile Laboratory
- ☐ 20 Pharmacy
- ☐ 21 Physician Office
- ☐ 22 Practitioner Other *(Specify)* _____
- ☐ 23 Prison
- ☐ 24 Public Health Laboratories
- ☐ 25 Rural Health Clinic
- ☐ 26 School/Student Health Service
- ☐ 27 Skilled Nursing Facility/ Nursing Facility
- ☐ 28 Tissue Bank/Repositories
- ☐ 29 Other *(Specify)* _____

IV. HOURS OF LABORATORY TESTING *(List times during which **laboratory testing** is performed in HH:MM format)* *If testing 24/7 Check Here* ☐

	SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY
FROM:							
TO:							

(For multiple sites, attach the additional information using the same format.)

V. MULTIPLE SITES *(must meet one of the regulatory exceptions to apply for this provision in 1-3 below)*

Are you applying for a single site CLIA certificate to cover multiple testing locations?

☐ No. If no, go to section VI. ☐ Yes. If yes, complete the remainder of this section.

Indicate which of the following regulatory exceptions applies to your facility's operation.

1. Is this a laboratory that is not at a fixed location, that is, a laboratory that moves from testing site to testing site, such as mobile unit providing laboratory testing, health screening fairs, or other temporary testing locations, and may be covered under the certificate of the designated primary site or home base, using its address?

   ☐ Yes ☐ No

   If yes, a list of temporary testing sites must be included on or attached to the Form CMS-116. If a mobile unit is providing the laboratory testing, record the vehicle identification number(s) (VINs) and attach to the application.

2. Is this a not-for-profit or Federal, State, or local government laboratory engaged in limited (not more than a combination of 15 moderate complexity or waived tests per certificate) public health testing and filing for a single certificate for multiple sites?

   ☐ Yes ☐ No

   If yes, provide the number of sites under the certificate _____ and list name, address and test performed for each site below.

3. Is this a hospital with several laboratories located at contiguous buildings on the same campus within the same physical location or street address and under common direction that is filing for a single certificate for these locations?

   ☐ Yes ☐ No

   If yes, provide the number of sites under this certificate _____ and list name or department, location within hospital and specialty/subspecialty areas performed at each site below.

If additional space is needed, check here ☐ and attach the additional information using the same format.

NAME AND ADDRESS/LOCATION		TESTS PERFORMED/SPECIALTY/SUBSPECIALTY
NAME OF LABORATORY OR HOSPITAL DEPARTMENT		
ADDRESS/LOCATION *(Number, Street, Location if applicable)*		
CITY, STATE, ZIP CODE	TELEPHONE NO. *(Include area code)*	
NAME OF LABORATORY OR HOSPITAL DEPARTMENT		
ADDRESS/LOCATION *(Number, Street, Location if applicable)*		
CITY, STATE, ZIP CODE	TELEPHONE NO. *(Include area code)*	

In the next three sections, indicate testing performed and estimated annual test volume.

VI. WAIVED TESTING *If only applying for a Certificate of Waiver, complete this section and skip sections VII (PPM Testing) and VIII (Non-Waived Testing).*

Identify the waived testing (to be) performed by completing the table below. Include each analyte, test system, or device used in the laboratory.

ANALYTE / TEST	TEST NAME	MANUFACTURER
Example: Streptococcus group A	Ace Rapid Strep Test	Acme Corporation

Indicate the **ESTIMATED TOTAL ANNUAL TEST** volume for all waived tests performed _____

☐ Check if no waived tests are performed

If additional space is needed, check here ☐ and attach additional information using the same format.

VII. PPM TESTING *If only applying for a Certificate for PPM, complete this section and skip section VIII (Non-Waived Testing).*

Listed below are the **only** PPM tests that can be performed by a facility having a Certificate for PPM. Mark the checkbox by each PPM procedure(s) to be performed.

- ☐ Direct wet mount preparations for the presence or absence of bacteria, fungi, parasites, and human cellular elements
- ☐ Potassium hydroxide (KOH) preparations
- ☐ Pinworm examinations
- ☐ Fern tests
- ☐ Post-coital direct, qualitative examinations of vaginal or cervical mucous
- ☐ Urine sediment examinations
- ☐ Nasal smears for granulocytes
- ☐ Fecal leukocyte examinations
- ☐ Qualitative semen analysis (limited to the presence or absence of sperm and detection of motility)

Indicate the **ESTIMATED TOTAL ANNUAL TEST** volume for all PPM tests performed _____

If also performing waived complexity tests, complete Section VI. For laboratories applying for a Certificate of Compliance or Certificate of Accreditation, also include PPM test volume in the specialty/subspecialty category and the "total estimated annual test volume" in section VIII.

☐ Check if no PPM tests are performed

If additional space is needed, check here ☐ and attach additional information using the same format.

VIII. NON-WAIVED TESTING *(Including PPM testing if applying for a Certificate of Compliance or Certificate of Accreditation) Complete this section only if you are applying for a Certificate of Compliance or a Certificate of Accreditation.*

Identify the non-waived testing (to be) performed by completing the table below. Be as specific as possible. This includes each analyte, test system, or device used in the laboratory. Use (M) for moderate complexity and (H) for high complexity.

ANALYTE / TEST	TEST NAME	MANUFACTURER	M or H
Example: Potassium	Quick Potassium Test	Acme Lab Corporation	M

If additional space is needed, check here ☐ and attach additional information using the same format.

If you perform testing other than or in addition to waived tests, complete the information below. If applying for one certificate for multiple sites, the total volume should include testing for ALL sites.

Place a check (✓) in the box preceding each specialty/subspecialty in which the laboratory performs testing. Enter the estimated annual test volume for each specialty. Do not include testing not subject to CLIA, waived tests, or tests run for quality control, calculations, quality assurance or proficiency testing when calculating test volume. (For additional guidance on counting test volume, see the instructions included with the application package.)

If applying for a Certificate of Accreditation, indicate the name of the Accreditation Organization beside the applicable specialty/subspecialty for which you are accredited for CLIA compliance. (The Joint Commission, ACHC, AABB, A2LA, CAP, COLA, or ASHI)

SPECIALTY / SUBSPECIALTY	ACCREDITING ORGANIZATION	ANNUAL TEST VOLUME	SPECIALTY / SUBSPECIALTY	ACCREDITING ORGANIZATION	ANNUAL TEST VOLUME
HISTOCOMPATIBILITY 010			**HEMATOLOGY 400**		
☐ Transplant			☐ Hematology		
☐ Nontransplant			**IMMUNOHEMATOLOGY**		
MICROBIOLOGY			☐ ABO Group & Rh Group 510		
☐ Bacteriology 110			☐ Antibody Detection (transfusion) 520		
☐ Mycobacteriology 115			☐ Antibody Detection (nontransfusion) 530		
☐ Mycology 120			☐ Antibody Identification 540		
☐ Parasitology 130			☐ Compatibility Testing 550		
☐ Virology 140			**PATHOLOGY**		
DIAGNOSTIC IMMUNOLOGY			☐ Histopathology 610		
☐ Syphilis Serology 210			☐ Oral Pathology 620		
☐ General Immunology 220			☐ Cytology 630		
CHEMISTRY			**RADIOBIOASSAY 800**		
☐ Routine 310			☐ Radiobioassay		
☐ Urinalysis 320			**CLINICAL CYTOGENETICS 900**		
☐ Endocrinology 330			☐ Clinical Cytogenetics		
☐ Toxicology 340			**TOTAL ESTIMATED ANNUAL TEST VOLUME:**		

IX. TYPE OF CONTROL (CHECK THE ONE MOST DESCRIPTIVE OF OWNERSHIP TYPE)

VOLUNTARY NONPROFIT	FOR PROFIT	GOVERNMENT
☐ 01 Religious Affiliation	☐ 04 Proprietary	☐ 05 City
☐ 02 Private Nonprofit		☐ 06 County
☐ 03 Other Nonprofit		☐ 07 State
_____ (Specify)		☐ 08 Federal
		☐ 09 Other Government
		_____ (If 09 is selected, please specify the country or the province.)

Does this facility have partial or full ownership or control by a non-United States-based government or entity?

☐ Yes ☐ No

If Yes, what is the country of origin for the foreign entity? _____

X. DIRECTOR AFFILIATION WITH OTHER LABORATORIES

If the director of this laboratory serves as director for additional laboratories that are separately certified, please complete the following:

CLIA NUMBER	NAME OF LABORATORY

ATTENTION: READ THE FOLLOWING CAREFULLY BEFORE SIGNING APPLICATION

Any person who intentionally violates any requirement of section 353 of the Public Health Service Act as amended or any regulation promulgated thereunder shall be imprisoned for not more than 1 year or fined under title 18, United States Code or both, except that if the conviction is for a second or subsequent violation of such a requirement such person shall be imprisoned for not more than 3 years or fined in accordance with title 18, United States Code or both.

Consent: The applicant hereby agrees that such laboratory identified herein will be operated in accordance with applicable standards found necessary by the Secretary of Health and Human Services to carry out the purposes of section 353 of the Public Health Service Act as amended. The applicant further agrees to permit the Secretary, or any Federal officer or employee duly designated by the Secretary, to inspect the laboratory and its operations and its pertinent records at any reasonable time and to furnish any requested information or materials necessary to determine the laboratory's eligibility or continued eligibility for its certificate or continued compliance with CLIA requirements.

PRINT NAME OF DIRECTOR OF LABORATORY

PRINT NAME OF OWNER OF LABORATORY

SIGNATURE OF OWNER/DIRECTOR OF LABORATORY *(SIGN IN INK OR USE A SECURE ELECTRONIC SIGNATURE)* | DATE

NOTE: Completed 116 applications must be sent to your local State Agency. Do not send any payment with your completed 116 application.

STATE AGENCY CONTACT INFORMATION CAN BE FOUND AT:
https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf

Data Submission Excel for Chembio HIV/ Syphilis Rapid Testing Kits

[AGENCY NAME] Monthly Testing Counts 2024

HIV

	Males Tested	Male Positives	Females Tested	Females Positives	Females Age 14-45 Tested	Females Age 14-45 Positives	All Persons Tested	All Confirmed Positives
JAN	0	0	0	0	0	0	0	0
FEB	0	0	0	0	0	0	0	0
MARCH	0	0	0	0	0	0	0	0
APRIL	0	0	0	0	0	0	0	0
MAY	0	0	0	0	0	0	0	0
JUNE	0	0	0	0	0	0	0	0
JULY	0	0	0	0	0	0	0	0
AUGUST	0	0	0	0	0	0	0	0
SEPTEMBER	0	0	0	0	0	0	0	0
OCTOBER	0	0	0	0	0	0	0	0
NOVEMBER	0	0	0	0	0	0	0	0
DECEMBER	0	0	0	0	0	0	0	0
TOTALS:	0	0	0	0	0	0	0	0

SYPHILIS

	Males Tested	Male Positives	Females Tested	Female Positives	Females Age 14-45 Tested	Females Age 14-45 Positives	All Persons Tested	All Positives
JAN	0	0	0	0	0	0	0	0
FEB	0	0	0	0	0	0	0	0
MARCH	0	0	0	0	0	0	0	0
APRIL	0	0	0	0	0	0	0	0
MAY	0	0	0	0	0	0	0	0
JUNE	0	0	0	0	0	0	0	0
JULY	0	0	0	0	0	0	0	0
AUGUST	0	0	0	0	0	0	0	0
SEPTEMBER	0	0	0	0	0	0	0	0
OCTOBER	0	0	0	0	0	0	0	0
NOVEMBER	0	0	0	0	0	0	0	0
DECEMBER	0	0	0	0	0	0	0	0
TOTALS:	0	0	0	0	0	0	0	0

2022 Evaluation Web® HIV Testing Data Form - NORTH CAROLINA

Name

First _____ MI _____ Last _____

Agency Name _____

Region _____

Program/Funding

- ○ Expanded Testing (ET)
- ○ Rapid Kits Only (RT)
- ○ Integrated Targeted Testing (ITTS)
- ○ Other _____

Form ID (from Eval Web data entry) _____

Form Completed By _____

Form Entered into Eval Web By _____

1 Agency and Client Information (complete for all persons tested)

Session/Test Date

Month _____ Day _____ Year _____

Program Announcement

- ○ PS18-1802
- ○ Other _____

Test Site/Setting *(select one only)*

- ○ College/School
- ○ Community Health Ctr
- ○ Emergency Department
- ○ HD DIS Field Visit
- ○ HD Family Planning
- ○ HD Prenatal/OB
- ○ HD STD Clinic
- ○ HD TB Clinic
- ○ HD Other
- ○ Self Testing
- ○ HIV Testing Site
- ○ Hospital/Private MD
- ○ Jail/Correctional
- ○ Mobile Unit
- ○ Outreach/Community
- ○ Pharmacy
- ○ Substance Abuse Treatment
- ○ Syringe Services Program
- ○ Other non-Clinical

Local Client ID - OPTIONAL

Date of Birth

Month _____ Day _____ Year (1800 if Unknown) _____

Client State *(USPS abbreviation)*

Client County Name

Client ZIP Code

Client Ethnicity *(select one only)*

- ○ Hispanic or Latino
- ○ Not Hispanic or Latino
- ○ Don't know
- ○ Declined to Answer

Client Race *(select all that apply)*

- ☐ American Indian/Alaska Native
- ☐ Asian
- ☐ Black/African American
- ☐ Native Hawaiian/Pacific Islander
- ☐ White
- ☐ Not Specified
- ☐ Declined to Answer
- ☐ Don't Know

Client Assigned Sex at Birth *(select one only)*

- ○ Male
- ○ Female
- ○ Declined to Answer

Client Current Gender Identity *(select one only)*

- ○ Male
- ○ Female
- ○ Transgender Male to Female
- ○ Transgender Female to Male
- ○ Transgender Unspecified
- ○ Declined to Answer
- ○ Another Gender

Has the client had an HIV test previously? *(select one only)*

- ○ No
- ○ Yes

2 Testing Information *(complete for all persons)*

HIV Test Election ○ Confidential ○ Test Not Done

Test Type *(fill out both if needed but only 1 can be entered in Eval Web-see note below)*

- ○ CLIA-waived point-of-care (POC)/ Rapid Test(s)
- ○ Laboratory-based Test

POC/Rapid Test Result *(definitions on page 3)*	Laboratory-based Test Result
○ Preliminary Positive* (POC Pos x 1)	○ HIV-1 Positive*
○ Positive* (POC Pos x 2)	○ HIV-1 Positive, possibly acute*
○ Negative	○ HIV-2 Positive*
○ Discordant* (2 POC tests with 2 different results)	○ HIV Positive, undifferentiated*
○ Invalid	○ HIV-1 Negative, HIV-2 Inconclusive*
	○ HIV-1 Negative
	○ HIV Negative
	○ Inconclusive*

If POC/Rapid test(s) AND a Laboratory-based test were performed, write all results above. Eval Web only allows one result to be entered so if both were done, enter just the Laboratory-based test result in Eval Web. Then go to Local Use Field 1 on page 3 and enter RHIV.

*** ALL HIV Positive results (New and Previous), HIV Discordant and HIV Inconclusive results:**
DO NOT ENTER Test Event into EVAL WEB
Follow instructions on procedures document and mail a copy of the completed HIV testing data form to the Prevention data team.

Result provided to client?

- ○ No
- ○ Yes
- ○ Yes, client obtained the result from another agency

This form is based on one created by Luther Consulting LLC for CDC, approved OMB No. 0920-0696

2022 Eval Web HIV Testing Data Form - North Carolina Client Name: _____

3 Negative Test Result
(complete for ALL persons at time of testing)

Is the client at risk for HIV infection?
○No ○Yes ○Risk Not Known ○Not Assessed

Client screened for PrEP eligibility? ○No ○Yes

Is the client eligible for PrEP referral?
○No/Not Asked ○Yes, CDC criteria ○Yes, Local criteria

Was the client given a referral to a PrEP provider?
○No/Not Asked/Not Eligible ○Yes

Was the client provided with services to assist with linkage to a PrEP provider?
○No/Not Asked/Not Eligible ○Yes

4 Positive Test Result
(Agency Staff to Complete ALL questions for ALL persons testing POSITIVE for HIV)

Did the client attend an HIV medical care appointment after this positive test?
○Yes, confirmed ○No
○Yes, self-report ○Don't Know
If Yes, Date: / /

Has client ever had a positive HIV test BEFORE this test event's POSITIVE result?
○No ○Yes ○Don't Know
If Yes, Date: / /

Client provided with behavioral risk-reduction counseling?
○No ○Yes

Client contact info to Health Dept for DIS/Partner Services?
○No ○Yes

Client's most severe housing status in the last 12 months?
○Literally homeless ○Not asked
○Unstably housed or at risk of losing housing ○Declined to Answer
○Stably housed ○Don't know

If the client is female, is she pregnant?
○No ○Yes ○Don't know ○Declined to Answer

If YES →
- Is the client in prenatal care?
  ○No ○Don't know ○Declined to answer
  ○Yes ○Not asked
- Screened for need of perinatal HIV services?
  ○No ○Yes
- Need identified for perinatal HIV services?
  ○No/Not Asked ○Yes
- Was the client referred for perinatal HIV services?
  ○No/Not Asked/Not Needed ○Yes

5 Additional Tests
(complete for all persons)

Client tested for any co-infections? ○No ○Yes

SYPHILIS Tested? ○No ○Yes *If Rapid → Local Use Field 2*
Result: ○Reactive/New Infection ○Not Infected ○Don't Know

GONORRHEA Tested? ○No ○Yes
Result: ○Positive ○Negative ○Don't Know

CHLAMYDIAL INFECTION Tested? ○No ○Yes
Result: ○Positive ○Negative ○Don't Know

HEPATITIS C Tested? ○No ○Yes *If Rapid → Local Use Field 3*
Result: ○Positive ○Negative ○Don't Know

Show Supplemental HIV Test 1
OPTIONAL, answer NO every time

6a PrEP Awareness *(complete for all tested clients)*

Has client ever heard of PrEP?	○No	○Yes
Is client currently taking PrEP medication?	○No	○Yes
Has client used PrEP in the last 12 months?	○No	○Yes

6b Priority Populations *(complete for all tested clients)*

Sex with Male *(past 5 yrs)*?	○No	○Yes
Sex with Female *(past 5 yrs)*?	○No	○Yes
Sex with Transgender Person *(past 5 yrs)*?	○No	○Yes
Inject Drugs/Substances *(past 5 yrs)*?	○No	○Yes

7 Essential Support Services
(complete as indicated, please answer each question)

Complete for clients testing HIV-Positive only	Screened for need	Need found	Provided or referred
Navigation services for linkage to HIV medical care	○No ○Yes	○No ○Yes	○No ○Yes
Linkage services to HIV medical care	○No ○Yes	○No ○Yes	○No ○Yes
Medication adherence support	○No ○Yes	○No ○Yes	○No ○Yes
Complete for ALL tested Clients	**Screened for need**	**Need found**	**Provided or referred**
Health benefits navigation and enrollment	○No ○Yes	○No ○Yes	○No ○Yes
Evidence-based risk-reduction intervention	○No ○Yes	○No ○Yes	○No ○Yes
Behavioral Health Services	○No ○Yes	○No ○Yes	○No ○Yes
Social Services	○No ○Yes	○No ○Yes	○No ○Yes

8 Local Use Fields

Local Use Field 1 –
*If HIV POC/Rapid test(s) AND a Laboratory-based test were performed, enter **RHIV***

Local Use Field 2 –
*If Syphilis POC/Rapid test was performed, enter **RSYPH***

Local Use Field 3 –
*If Hepatitis C POC/Rapid test was performed, enter **RHCV***

ALL HIV Positive results (New and Previous), HIV Discordant and HIV Inconclusive results:
DO NOT ENTER Test Event into EVAL WEB
Follow instructions on procedures document and mail a copy of the completed HIV testing data form to the Prevention data team. Please include a copy of the Laboratory Test Results for each Test Event you mail that included Laboratory Testing.

Value Definitions for POC/Rapid Test HIV Results

Preliminary positive - One or more of the same POC/Rapid tests were reactive and none are non-reactive and no supplemental testing was done at your agency

Positive - Two or more different (orthogonal) POC/Rapid tests are reactive and none are non-reactive and no laboratory-based supplemental testing was done

Negative - One or more POC/Rapid tests are non- reactive and none are reactive and no supplemental testing was done

Discordant - One or more POC/Rapid tests are reactive and one or more are non-reactive and no laboratory- based supplemental testing was done

Invalid - A CLIA-waived POC/Rapid test result cannot be confirmed due to conditions related to errors in the testing technology, specimen collection, or transport

Value Definition for Inconclusive Lab HIV Result

Inconclusive, further testing needed - A blood sample was sent to a lab but a result could not be determined. Reasons include: hemolyzed sample; the lab report indicates "status undetermined"; or the lab report recommends repeat testing. Any questions contact Meghan Furnari at Meghan.Furnari@dhhs.nc.gov.

9 State Health Department Entry Only
Prevention Data Team to complete for persons testing POSITIVE for HIV

eHARS STATE Number

eHARS City/County Number

New or Previous diagnosis?
- ○ New diagnosis, verified
- ○ New diagnosis, not verified
- ○ Previous diagnosis
- ○ Unable to determine

Has the client seen a medical care provider in the past six months for HIV treatment?
- ○ No
- ○ Yes
- ○ Declined to Answer
- ○ Don't know

Partner Services Case Number

Was the client interviewed for Partner Services?
- ○ Yes, by a health department specialist
- ○ Yes, by a non-health department person trained by the health department to conduct partner services
- ○ No
- ○ Don't Know

If Yes, Date of Interview: / /

Notes

Evaluation Web HIV Testing Data Form – NORTH CAROLINA
Data Collection and Data Entry Procedures

1. **Use Form for All HIV Testing Events since 1/1/2019**
    a. Applies to agencies and health departments funded or supported through the following:
        i. Expanded Testing (Community Health Centers, Emergency Departments, Jails)
        ii. Integrated Targeted Testing (ITTS)
        iii. Rapid Kits Only – *when the test event involves the Rapid Kit/s provided by the State Prevention Program*
        iv. Ending the HIV Epidemic (ETE/EHE) under Program Announcement PS20-2010
    b. Does NOT apply to regular testing in health department clinics
    c. If a client declines HIV testing but is tested for other STIs, still use the form to enter the data
    d. Use this form to *collect* your data as of 1/1/2019
    e. If no testing was provided during a client interaction, then do NOT enter the test event into Eval Web

2. **Printing and Copying**
    a. Always use the most current version of the HIV Testing Data Form
        i. As of 4/25/22 you must use the version named "2022 NC HIV Testing Data Form (4-25-22).pdf"
    b. The form can be printed locally, and it is fine to photocopy it as well
    c. We suggest that you utilize 2-sided photocopies for the three-page HIV Testing Data Form

3. **Use with Agency Intake Forms**
    a. Data should ultimately be recorded on the most current version of the HIV Testing Data Form, but if your agency uses a separate client or counselor 'intake' form first, that is fine
    b. If so, make sure that all of the necessary data elements are covered on your local intake form and transferred to the most current version of the HIV Testing Data Form.
    c. The HIV Testing Data Form is designed to be filled out by a trained HIV test counselor
        i. Please do not give this form to the tested client for them to fill out
        ii. Any forms that are given to clients to fill out should be designed specifically for that purpose

4. **Format**
    a. The order of the data elements follows the order of data entry in Evaluation Web (Eval Web)
        i. The order may not make the most sense for client encounters so you will need to skip around a little
        ii. Oval bubbles mean "select only one" and square boxes mean "check all that apply"

iii. Note that Name and full Date of Birth are needed by the Prevention Data Team in order to look up the client in the Surveillance System in the event that the person tests positive or inconclusive for HIV (more on that under number 8. Below)
    1. Eval Web does *not* capture name and requires only year of birth

5. **Data to Collect at Time of Testing**
    a. Name and Program information at the top
        i. Write in client's full name
            1. Repeat Client name on top of page 2 and page 3
        ii. Fill in the bubble to choose the "Program/Funding" appropriate to this test event
        iii. Fill in your name beside "Form Completed By"
        iv. Fill in your agency's name beside "Agency Name"
        v. Fill in the region in which this test event took place beside "Region"
        vi. Skip "Form ID" for now – this unique identification number will be automatically generated by Eval Web at the time of data entry
        vii. Skip "Form Entered into Eval Web by" for now
    b. Section 1 – Agency and Client Information
        i. Fill in the bubble to choose the "Program Announcement"
            1. Most Prevention Testing efforts fall under PS18-1802
                a. If you are entering testing data as part of the Ending the HIV Epidemic efforts with Mecklenburg County Health Department then Program Announcement will be PS20-2010
        ii. Fill in one bubble to choose the appropriate "Test Site/Setting" for the location of this testing event
        iii. "Local Client ID" is completely optional, if you choose to complete it please do NOT include any identifiable information
        iv. Client Demographics
            1. "Date of Birth" – write in the full DOB – MM/DD/YYYY
            2. "Client State" – write the state of the client's current residence
            3. "Client County Name" – write in the name of the county of the client's current residence
            4. "Client Zip Code" – write in the zip code of the client's current residence
            5. "Client Ethnicity" – fill in one bubble
            6. "Client Race" – fill in all check boxes that apply
            7. "Client Assigned Sex at Birth" – fill in one bubble
            8. "Client Current Gender Identity" – fill in one bubble
                a. Please keep in mind that that the "Assigned Sex at Birth" and "Current Gender Identity" responses should align (for example, if a client's assigned sex at birth was "Male" then you should not choose "Female" or "Transgender Female to Male" as their Current Gender Identity.
        v. Previous HIV Test
            1. "Has the client had an HIV test previously?" – select one Yes or No

c. Section 2 –Testing Information
    i. HIV Test Election = Confidential or Test Not Done
        1. Choose Test Not Done only when an HIV test was not performed as part of this test event/client interaction
    ii. HIV Test Type and Results Sections
        1. For Rapid testing only complete CLIA-waived point-of-care (POC)/Rapid test/s
            a. Then choose the one result from the POC/Rapid Test Result choices
        2. For lab testing complete Laboratory-based Test
            a. Lab Test Results section must be completed after the results have been received from the lab
        3. If both Rapid/POC testing and Laboratory-based testing was done
            a. Fill out both POC/Rapid Results section once the rapid tests are completed, and Laboratory Results sections after results have been received from the lab.
            b. ALSO, Complete Local Use Field 1 on page 3 with "RHIV"
        4. *Reminder - If the Rapid are Preliminary Positive, Positive, or Discordant, and/or the Lab HIV test results are Positive or Inconclusive you will not perform data entry for this test event*
    iii. Result provided to client – choose one; "No", "Yes", or "Yes client obtained from another agency"
        1. If the answer is "No" please describe the situation on Page 3's Notes section
d. Section 3 – Negative Test Result
    i. Collect information for ALL clients tested
        1. Risk for HIV infection, select one
        2. Use the Eval Web PrEP Questions Guidance to complete the screened, eligible, referral given questions
        3. If the client is eligible for PrEP based on the NC PrEP Criteria, please complete the PrEP Referral and Linkage Form, and follow the PrEP guidance to complete all steps
e. Section 5 – Additional Tests
    i. Fill out which tests were performed and wait for results
        1. If the client was tested for Syphilis, and/or Gonorrhea, and/or Chlamydia, and/or Hepatitis C complete all applicable questions in Section 5
    ii. If Syphilis Rapid Testing was done, record results and complete Local Use Field 2 on page 3 "RSYPH"
    iii. If HCV Rapid Testing was done, record results and complete Local Use Field 3 on page 3 "RHCV"
    iv. If lab testing was performed update this section with the results after received from the lab

f. Section 6a – PrEP Awareness
    i. Three No/Yes questions that must be completed and are related to each other
        1. For example, if the client has never heard of PrEP (Has client ever heard of PrEP? = No) then the other two PrEP questions (currently taking PrEP and used PrEP in the last 12 months) should also be "No"
        2. For example, if the client is currently on PrEP then all the PrEP questions should be answered with "Yes"
g. Section 6b - Priority Populations
    i. Risk history questions – answer each of the four questions with either "Yes" or "No"
h. Section 7 – Essential Support Services
    i. Complete the last 4 rows of questions; this includes health benefits navigation and enrollment, evidence-based risk-reduction intervention, behavioral health services, and social services
    ii. You must answer all 12 questions with either "Yes" or "No"
i. Section 8 – Local Use Fields. As of now, we are using fields 1, 2, 3 to indicate rapid testing for HIV, Syphilis, HCV. Please refrain from using Local use Fields 4-8.

6. **Fill Out Separate Form(s) to Order HIV and STI Testing from Laboratories**
    a. For HIV and HCV testing at the State Laboratory of Public Health (SLPH), use the current HIV testing form.
        i. You can skip Test1, Test2 and the behavioral risk factors
        ii. Send Lab form and blood sample to SLPH for testing in accordance with their guidelines
    b. For Syphilis, Chlamydia, Gonorrhea testing, fill out form(s) for appropriate State, County, or Private Lab
        i. Send Lab form and blood sample to appropriate lab for testing

7. **Agency Filing System Needed**
    a. **Create the following categories to separate all HIV Testing Data Forms at this point:**
        i. Forms awaiting Laboratory Results
        ii. Forms with all results complete awaiting data entry
        iii. Forms that have been entered
        iv. Forms for HIV-Positives that have been copied and sent to CDB
        v. <u>All forms need to be kept in a secure, locked location</u>
            1. <u>Preferably a locked cabinet within a locked room</u>

8. **Record All Results on HIV Testing Data Form**
    a. Record POC/Rapid test results should be added to the HIV Testing Data form as soon as they are complete
    b. Record Lab test results as they come in
        i. If HIV-positive, fill out as much of Section 4 – Positive Test Result as you are able; it is fine if you don't know all of it, the Prevention Data Team will check the surveillance system for some of these answers

ii. *Reminder - If the Lab HIV test results are Positive (or Inconclusive) you will not perform data entry for this test event*
iii. Keep forms filed as above until all results have been recorded

c. When ALL HIV/STI test results have been recorded, file separately:
   i. HIV Negative, Invalid tests (regardless of results from other STI testing) and NO HIV testing (Coinfection only with all results)
      1. These forms are now ready for data entry
      2. Further sort the forms by Program Funding and Region
         This will make data entry easier (see below)
   ii. HIV Positive, Preliminary Positive, Discordant, and Inconclusive HIV tests
      1. Make a photocopy of the HIV Testing Data Form AND the HIV Lab Result (when applicable) and send to the Prevention Data Team:
         a. Place form/s and lab result/s in an **inner** envelope that is **sealed** and marked "**Confidential**"
         b. Place that sealed inner envelope inside an **outer** envelope and send to:

            Meghan Furnari
            Prevention Program Data Team
            1200 Front St, Suite 104
            Raleigh, NC 27609
      2. Prevention Data Team will check the HIV Case Surveillance system and will fill out the remainder of Section 4 (Positive Test Result) and Section 9 (Health Department Use Only) when applicable
      3. Prevention Data Team will then enter these forms in Eval Web after performing all necessary research

9. **Data Entry into Eval Web – please use Google Chrome as your web browser, Firefox and Microsoft Edge are alternative options as well**
   a. Agencies will enter the data for the HIV-Negative forms, and all Testing Events that do not include HIV testing
      i. Enter regularly, preferably weekly or at least every other week
      ii. Choose the "Program" carefully, as many agencies have more than one to choose from and they are very similar
         1. The "Programs" are your agency ID number (assigned by Prevention Data Team) followed by the Program/Funding abbreviation and then the Region in which the testing takes place
            a. One agency could have the following programs:
               i. 123_ET_TGA; 123_ETE_TGA; 123_RT_TGA; 123_ITTS_TGA
      iii. Indicate that each form has been entered by filling in the "Form ID" on the top of Page 1 (located between "Region" and "Form Entered into Eval Web by") and by filling in your name beside "Form Entered into Eval Web by"
         1. Agency staff must write the "Form ID" on the HIV Testing Data Form during data entry as this is the only time you will see the "Form ID"

a. If the client has been referred to PrEP the "Form ID" must be noted on the PrEP Referral and Linkage Form as well

2. If a test event that you entered that needs to be deleted, email the Prevention Data Team (Meghan.Furnari@dhhs.nc.gov)
    a. Provide the "Form ID" AND Date of Test/Session Date
    b. Provide the reason the test event needs to be deleted
        i. For example – duplicate entry error, problem with Eval Web during data entry, etc.

iv. File all entered forms; we suggest filing them by Session/Test Date
    1. *Remember all forms that have been entered should have a "Form ID" written on the top right of Page 1*
    2. For now, ***please keep all forms***
        a. All forms need to be kept in a secure, locked location
            i. Preferably a locked cabinet within a locked room

b. Prevention Data Team will enter the test events sent by mail, which includes the HIV-Positives, Preliminary Positives, Inconclusives, and Discordant HIV results

10. Rapid Testing Data Procedures - Recap

a. HIV POC Rapid Test(s) only - Negatives
    i. Use the "POC/Rapid Test Result" in Section 2

b. HIV POC Rapid Test(s) only - Positives
    i. Complete the HIV Testing Data Form (including Section 4) and then make a copy of the form and send the copy to Prevention Data Team. File your own copy. Prevention Data Team will enter data.
        1. If you mistakenly entered the test event, be sure the "Form ID" has been completed on Page 1 before copying/mailing the HIV Testing Data form to the Prevention Data Team

c. HIV POC Rapid Test(s) AND Laboratory-based test – Negatives
    i. Fill out information for both types of testing in Section 2
    ii. In Eval Web, choose Laboratory-based testing and enter the Lab result
    iii. Enter RHIV in Local Use Field 1 on page 3 of the HIV Testing Data Form AND in Eval Web during data entry

d. HIV POC Rapid Test(s) AND Laboratory-based test – Positives
    i. Fill out information for both types of testing in Section 2.
    ii. Enter RHIV in Local Use Field 1 on page 3
    iii. Complete the HIV Testing Data Form (including Section 4) and then make a copy of the form and send the copy to Prevention Data Team. File your own copy. Prevention Data Team will enter data.

e. Syphilis POC Rapid Test
    i. Complete the entire Section 5 including entering test result (all results)
    ii. Enter RSYPH in Local Use Field 2 on page 3 AND in Eval Web during data entry

f. Hepatitis C POC Rapid Test
    i. Complete the entire Section 5 including entering test result (all results)
    ii. Enter RHCV in Local Use Field 3 on page 3 AND in Eval Web during data entry

Division of Public Health
Confidentiality Agreement

Effective Date: May 1, 2011

Ensuring the confidentiality of all health reports, records, and files containing patient names and other individually identifying information is of critical importance in the Division of Public Health. Breaches of confidentiality could undermine public trust in the Public Health Division and thereby hinder efforts to prevent and control morbidity and mortality and to protect the public from disease and injury.

Federal and state laws, including the HIPAA Privacy Rule and NC General Statute § 130A-12, provides for the protection, privacy, and security individual health information.

These laws provide requirements to ensure that the protection of certain individually identifiable health information that is created, received, and maintained in any form or medium, by the North Carolina Department of Health and Human Services (DHHS) and the Division of Public health, is safeguarded and protected

Employees of the Division of Public Health may only use and disclose individually identifiable health information as provided by and subject to all of the limitations and requirements specified in the DHHS Policies and Procedures Manual and in the Division of Public Health privacy policies and procedures as defined in the Division of Public Health Privacy and Security Manual.

Employee Acknowledgement:

- I understand that I may have direct or indirect access to confidential individually identifiable health information in the course of performing my work activities and I agree to protect the confidentiality of any individually identifiable health information to which I may have access.
- I shall adhere to all the Division business procedures that provide for minimizing the intentional and unintentional conveyance of individually identifiable information to unauthorized parties through written or oral interactions.
- I must make all reasonable efforts to limit individually identifiable health information to that which is *minimally necessary* to accomplish the intended purpose for the use, disclosure, or request for information.
- I understand that there are state and federal laws and regulations that ensure the confidentiality of an individual's identifying health information.
- I understand that there are DHHS and Division policies and procedures with which I am required to comply related to the protection of individually identifiable health information. Should questions arise about how to protect information to which I have access, I will immediately notify my supervisor and/or the DPH Privacy Official.
- I understand that my failure to observe and abide by these policies and procedures may result in disciplinary action, which may include dismissal and/or contract termination, and/or punishment by fine and/or imprisonment. I understand that there may be sanctions resulting from failure to comply with DHHS and Division privacy policies and procedures and the Division shall use the procedures in the State Personnel Manual to apply appropriate sanctions against members of its staff who fail to comply with these privacy policies and procedures.
- I have been informed that this signed acknowledgement will be retained on file for future reference.

I have read the above confidentiality statement and understand its implications for my position in the Division of Public Health.

PRINT NAME: _____

Employee or Contractor Signature: _____ Date: _____

Rapid HIV HCV Syphilis Testing Comparison Chart

2023 Comparison of Rapid Testing Technology Offered by N.C. Rapid Testing Program

		OraSure Technologies OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test	**Diagnostics Direct Syphilis Health Check™**	**OraSure Technologies OraQuick® HCV Rapid Antibody Test**	**INSTI HIV-1/HIV-2 Antibody Test**	**Chembio DPP HIV-Syphilis**
Specimen Collection	Venipuncture Whole Blood	Yes	No	No	Yes	Yes
	Fingerstick Whole Blood	Yes	Yes	Yes	Yes	Yes
	Plasma	Yes	Yes	Yes	Yes	Yes
	Serum	No	Yes	Yes	No	No
	Oral Fluid	Yes	No	No	No	No
Complexity	Waived	Oral fluid, Fingerstick whole blood, Venipuncture Whole Blood	Fingerstick whole blood	Fingerstick whole blood, Venipuncture whole blood	Fingerstick whole blood	Fingerstick whole blood
	Moderate	Plasma	Venipuncture whole blood, Plasma, Serum	N/A	Venipuncture whole blood, Plasma	Venipuncture whole blood, Plasma
Shelf Life	Control Kits	12 months unopened 8 weeks opened	24 months	12 months unopened 8 weeks opened	12 months	24 months
	Test Kits	24 months	24 Months	18 months	15 months	24 months
Temperature Requirements	Control Storage	2° to 8°C (35° to 46°F)	2° to 8°C (35° to 46°F)	2° to 8°C (35° to 46°F)	2° to 30°C (35.6°-86°F)	2° to 8°C (36° to 46°F)
	Test Kit Storage	2 to 27°C (35° to 80°F)	4° to 30°C (39.2°-86°F)	2° to 30°C (35.6°-86°F)	2 to 30°C (35° to 86°F)	2° to 25°C (36° to 77°F)
	Testing Environment	15° to 37°C (59° to 99°F)	20° to 26°C (68° to 78.8°F)	15° to 37°C (59° to 99°F)	15° to 30°C (59°-86°F)	18° to 25°C (64° to 77°F)
Time	Minimum Time for Development	20 minutes	10 minutes	20 minutes	1 minute	15 minutes
	Read Window	20 to 40 minutes	10 to 15 minutes	20 to 40 minutes	5 minutes	15 to 25 minutes
Sensitivity (95% confidence limits for HIV 1)	Venipuncture Whole Blood	99.6%			99.9%	99.5% (HIV) 96.5% (Syphilis)
	Fingerstick Whole Blood	99.6%	98%	98%	99.8%	99.4% (HIV) 94.7% (Syphilis)
	Plasma	99.6%	99.9%	N/A	99.9%	99.3% (HIV) 96.8% (Syphilis)
	Serum	N/A		N/A	N/A	N/A
	Oral Fluid	99.3%	N/A	N/A	N/A	N/A

Comparison of Rapid Testing Technology Offered by N.C. Rapid Testing Program

		OraSure Technologies OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test	Diagnostics Direct Syphilis Health Check™	OraSure Technologies OraQuick® HCV Rapid Antibody Test	INSTI® HIV-1/HIV-2 Antibody Test	Chembio DPP HIV-Syphilis
Specificity (95% confidence limits)	Venipuncture Whole Blood	100%	100%	98%	100%	99.5% (HIV) 94.3% (Syphilis)
	Fingerstick Whole Blood	100%	99.5%	98%	99.5%	99.6% (HIV) 95.5% (Syphilis)
	Plasma	99.9%	100%	98%	100%	99.6% (HIV) 93.9% (Syphilis)
	Serum	N/A	N/A	98%	N/A	N/A
	Oral Fluid	99.8%	N/A	N/A	N/A	N/A
Detection Time Frame* Days **after** HIV-1 RNA is detectable (~10 days)		23.7 days	N/A	N/A	21 days	14-28 days
HIV-2 Detection		Yes	N/A	N/A	Yes	Yes
Materials Provided in Test Kit (not including manufacturer supplied paperwork)		Test device, developer solution, reusable test stands, specimen collection loops	Test device, disposable pipettes, diluent in dropper bottle containing saline buffer	Test device, buffer, pipette, moisture pad	Test device, membrane Unit, bottle 1, sample diluent (1.5ml), Bottle 2, color developer (1.5ml), bottle 3, clarifying solution (1.5ml), lancet, capillary test pipette, alcohol swab	Test device, desiccant pouch, disposable 10 uL Sample loop, 1mL phosphate buffer (Black cap), 6mL phosphate buffer (Green cap)
Available Kit Sizes		100 test kits 25 test kits	20 test kits	25 test kits	50 test kits	20 test kits
Generation of detection		3rd generation lateral flow	N/A	N/A	3rd generation immunofiltration "flowthrough"	3rd generation

*Median of 95% confidence intervals representing the estimated ranges of days that HIV-1 tests begin to detect HIV-1 infection AFTER HIV-1 RNA is detectable. The interval between HIV infection and the appearance of HIV-1 RNA is estimates to be around 10 days, but the absolute range is not yet known. See https://www.cdc.gov/hiv/pdf/testing/hiv-tests-advantages-disadvantages_1.pdf for further details.

October 2023

Please feel free to copy, duplicate, and print the following temperature logs, results logs, and recording logs.

Rapid Testing Kit Storage Temperature Log

Thermometer location:
Rapid test kit brands monitored:
Acceptable temperature range: 8°C to 27°C (46°F to 80°F). Recommended to keep kits at room temperature.
Month/Year

Day	Temperature	Min	Max	Initials	Day	Temperature	Min	Max	Initials
1					17				
2					18				
3					19				
4					20				
5					21				
6					22				
7					23				
8					24				
9					25				
10					26				
11					27				
12					28				
13					29				
14					30				
15					31				
16									

NOTE: Periodically (e.g., every six months) check thermometer performance and document. Min/Max thermometers maintain a record of the highest and lowest temperature recorded during an observation period and are highly recommended.

Kits should be checked at least once a week with a preference to daily monitoring. Weekly monitoring should be performed with a min/max thermometer in place.

Corrective Action

Date	Action Taken	Initials

Reviewed by:	Date:

Rapid Testing Control Storage Temperature Log

Thermometer location:
Rapid test kit brands monitored:
Acceptable temperature range: 2°C to 8°C (35°F to 46°F)
Month/Year

Day	Temperature	Min	Max	Initials	Day	Temperature	Min	Max	Initials
1					17				
2					18				
3					19				
4					20				
5					21				
6					22				
7					23				
8					24				
9					25				
10					26				
11					27				
12					28				
13					29				
14					30				
15					31				
16									

NOTE: Periodically (e.g., every six months) check thermometer performance and document. Min/Max thermometers maintain a record of the highest and lowest temperature recorded during an observation period and are highly recommended.

Controls should be checked at least once a week with a preference to daily monitoring. Weekly monitoring should be performed with a min/max thermometer in place.

Corrective Action

Date	Action Taken	Initials

Reviewed by:	Date:

Rapid Testing Kit Results Log

Client ID*	Date/Time	Test Room/Area Temp	Kit name and lot#	Kit exp. date	Specimen type	Time Test Started	Time Test Interpreted	Test Result	Confirm. Test Required?	Date Results Given	Initials of Tester
			Brand: Lot:		☐ Blood ☐ Oral			☐ Non-reactive ☐ Reactive ☐ Invalid	☐ Yes ☐ No		
			Brand: Lot:		☐ Blood ☐ Oral			☐ Non-reactive ☐ Reactive ☐ Invalid	☐ Yes ☐ No		
			Brand: Lot:		☐ Blood ☐ Oral			☐ Non-reactive ☐ Reactive ☐ Invalid	☐ Yes ☐ No		
			Brand: Lot:		☐ Blood ☐ Oral			☐ Non-reactive ☐ Reactive ☐ Invalid	☐ Yes ☐ No		
			Brand: Lot:		☐ Blood ☐ Oral			☐ Non-reactive ☐ Reactive ☐ Invalid	☐ Yes ☐ No		
			Brand: Lot:		☐ Blood ☐ Oral			☐ Non-reactive ☐ Reactive ☐ Invalid	☐ Yes ☐ No		
			Brand: Lot:		☐ Blood ☐ Oral			☐ Non-reactive ☐ Reactive ☐ Invalid	☐ Yes ☐ No		
			Brand: Lot:		☐ Blood ☐ Oral			☐ Non-reactive ☐ Reactive ☐ Invalid	☐ Yes ☐ No		

*Unique Client ID

Reviewed by:	**Date:**

Rapid Testing Control Results Log

Date	Time	Test Area Temp	Kit name and lot#	Kit exp. date	Control lot#	Control exp. date	Date controls opened	Reason running controls*	Negative Control Results	Positive Control Results	Initials of Tester
			Brand: Lot:							HIV-1: HIV-2:	
			Brand: Lot:							HIV-1: HIV-2:	
			Brand: Lot:							HIV-1: HIV-2:	
			Brand: Lot:							HIV-1: HIV-2:	
			Brand: Lot:							HIV-1 HIV-2:	

*Options for reason running controls: new user, new shipment, new lot#, out of range kits, out of range testing area, training

Corrective Action

Date	Action Taken	Initials

Reviewed by:	Date:

Rapid HIV Testing Training Records Log

Please list the name of each staff member who conducts rapid testing. Indicate the date of their most recent training and who provided the training. Keep a record of this document for internal use and update as needed. **As different brands of rapid test kits come in, make sure to edit this internal template to reflect the current rapid test brand availability.**

Staff Member Name	**OraQuick HIV/HCV**	**Chembio DPP HIV-Syphilis**	**INSTI**	**Syphilis Health Check**	**Whetstone**	**Safe Work Habits**	**Bloodborne Pathogens**
	Date: Provided by: ☐ State ☐ Manufacturer ☐ Internal Agency ☐ Other	Date: Provided by: ☐ State ☐ Manufacturer ☐ Internal Agency ☐ Other	Date: Provided by: ☐ State ☐ Manufacturer ☐ Internal Agency ☐ Other	Date: Provided by: ☐ State ☐ Manufacturer ☐ Internal Agency ☐ Other	Date: Provided by: ☐ State ☐ Manufacturer ☐ Internal Agency ☐ Other	Date: Provided by: ☐ State ☐ Manufacturer ☐ Internal Agency ☐ Other	Date: Provided by: ☐ State ☐ Manufacturer ☐ Internal Agency ☐ Other
	Date: Provided by: ☐ State ☐ Manufacturer ☐ Internal Agency ☐ Other	Date: Provided by: ☐ State ☐ Manufacturer ☐ Internal Agency ☐ Other	Date: Provided by: ☐ State ☐ Manufacturer ☐ Internal Agency ☐ Other	Date: Provided by: ☐ State ☐ Manufacturer ☐ Internal Agency ☐ Other	Date: Provided by: ☐ State ☐ Manufacturer ☐ Internal Agency ☐ Other	Date: Provided by: ☐ State ☐ Manufacturer ☐ Internal Agency ☐ Other	Date: Provided by: ☐ State ☐ Manufacturer ☐ Internal Agency ☐ Other
	Date: Provided by: ☐ State ☐ Manufacturer ☐ Internal Agency ☐ Other	Date: Provided by: ☐ State ☐ Manufacturer ☐ Internal Agency ☐ Other	Date: Provided by: ☐ State ☐ Manufacturer ☐ Internal Agency ☐ Other	Date: Provided by: ☐ State ☐ Manufacturer ☐ Internal Agency ☐ Other	Date: Provided by: ☐ State ☐ Manufacturer ☐ Internal Agency ☐ Other	Date: Provided by: ☐ State ☐ Manufacturer ☐ Internal Agency ☐ Other	Date: Provided by: ☐ State ☐ Manufacturer ☐ Internal Agency ☐ Other
	Date: Provided by: ☐ State ☐ Manufacturer ☐ Internal Agency ☐ Other	Date: Provided by: ☐ State ☐ Manufacturer ☐ Internal Agency ☐ Other	Date: Provided by: ☐ State ☐ Manufacturer ☐ Internal Agency ☐ Other	Date: Provided by: ☐ State ☐ Manufacturer ☐ Internal Agency ☐ Other	Date: Provided by: ☐ State ☐ Manufacturer ☐ Internal Agency ☐ Other	Date: Provided by: ☐ State ☐ Manufacturer ☐ Internal Agency ☐ Other	Date: Provided by: ☐ State ☐ Manufacturer ☐ Internal Agency ☐ Other

RAPID TEST KIT INVENTORY

(to be completed on the last business day of every month)

Agency Name:

Name of Staff:

Completed for (Month/Year):

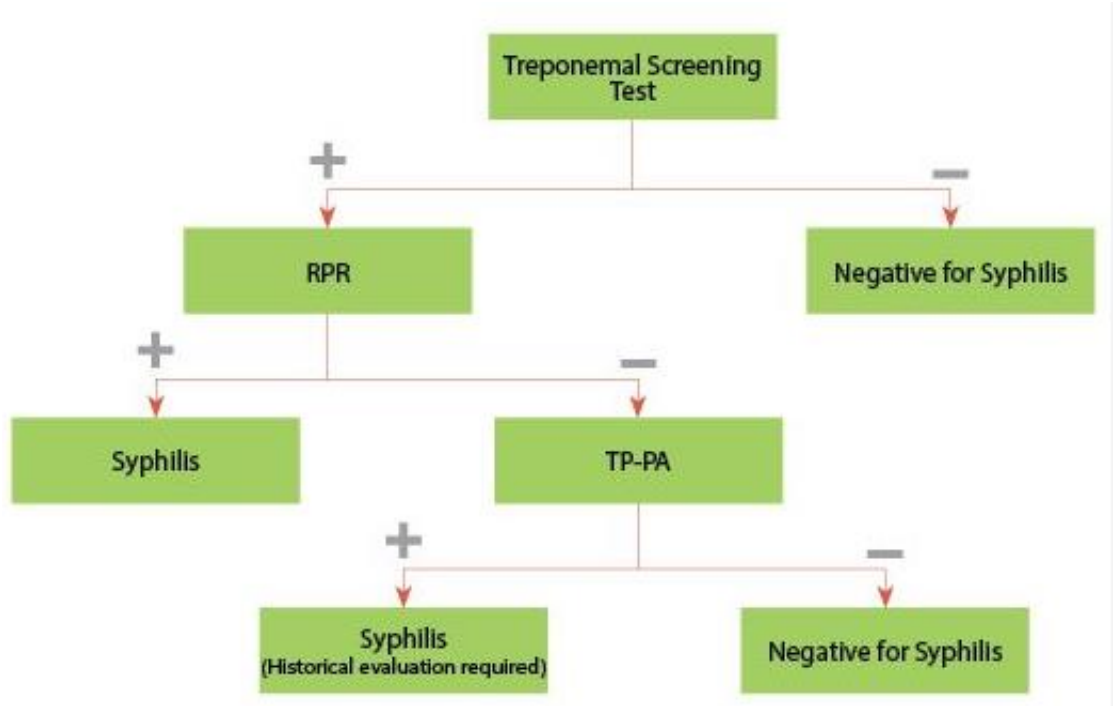
Date Completed:

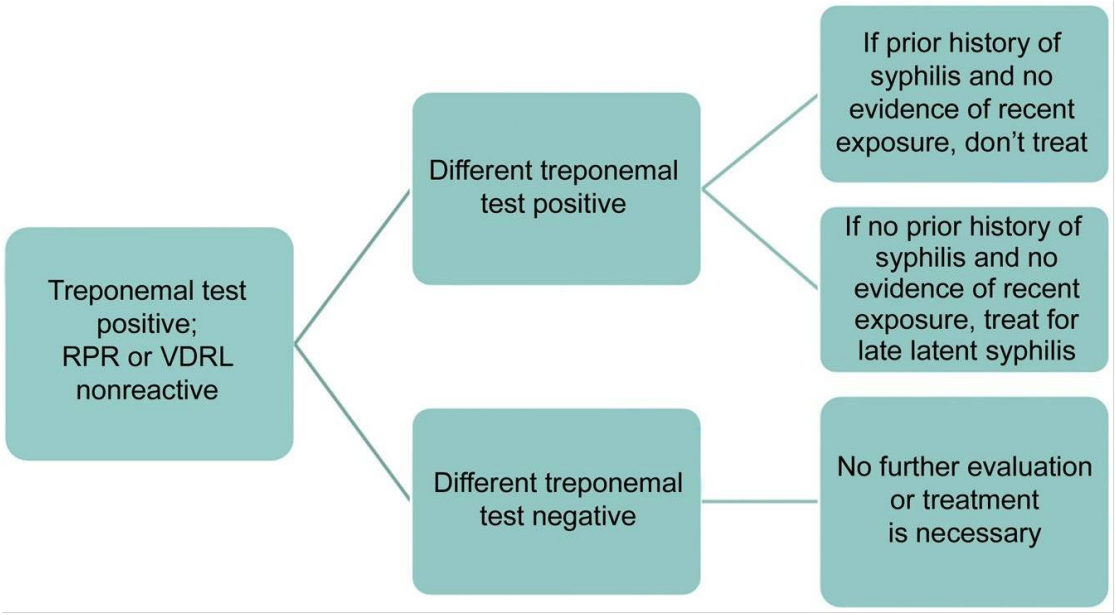
Brand Name	# Test Kits on Hand	Test Kits Expiration Date	# Controls on Hand	Controls Expiration Date
OraQuick HIV				
Chembio DPP HIV-Syphilis				
INSTI				
Syphilis Health Check				
OraQuick HCV				
Indicate Other Brands Below:				

NC DHHS Communicable Disease Branch Incentives Tracking Log

Date Issued to Agency	Card Tracking Number	Dollar Amount	Location Disbursed and/or Event Name	Date Disbursed to Participant	Disbursed by (Printed Staff Name)	Card Recipient Initials

Syphilis Reverse Testing Algorithms:





Sample Standing Orders for HIV Rapid Tests

{Physician Letterhead}

{Date}

{Agency Name and address}

To Whom It May Concern:

The following are Standing Orders for {Name of Agency} regarding HIV pre- and post-test counseling, and HIV rapid testing.

{Name of Executive Director} is appointed the sole person responsible for ensuring that these standing orders are carried out in full on behalf and in the authority of {Name of Physician}.

All HIV tests will be administered by and under the authority of {Name of Physician}. {Name of Executive Director} will ensure that assigned staff from {Name of Agency} have attended the Communicable Disease Branch approved HIV Counseling, Testing and Referral (CTR) training (www.whetstoneconsultations.com) and any Branch approved rapid HIV testing training.

Designated staff representing {Name of Agency} may collect appropriate specimens for HIV rapid tests and interpret rapid test results at specified nontraditional test sites in {Name of County} and during special targeted testing events.

{Name of Agency} must make post-test counseling available and all preliminary HIV-positive test results must be linked to confirmatory HIV testing. Per NC GS 130A-144(d), all clients with preliminary HIV-positive results must be given control measures. Designated staff will provide follow-up according to the agency's policies and procedures.

Signed by {Name of Physician}

Letter of Acknowledgement (340B Eligibility)

DHHS Communicable Disease Branch

The purpose of this letter is to acknowledge that the Communicable Disease Branch (CDB) provides support to (Agency X) through the provision of funding or in-kind support from the Strengthening Sexually Transmitted Disease Prevention and Control for Health Departments (STD PCHD) grant (grant # 1NH25PS005152). This provision of funding or in-kind support confers eligibility for HRSA's 340B drug pricing program. Application to and participation in the HRSA 340B program is not required. Should your agency choose to participate, please be aware that it is the responsibility of your agency to apply through HRSA and meet the requirements of becoming a 340B covered entity. Questions concerning 340B requirements should be directed to Apexus Answers (HRSA's contracted 340B management entity) and not the Communicable Disease Branch.

In the event that your agency wishes to participate in the 340B program, you agree to register with HRSA to become a 340B covered entity within nine months of receiving STD grant funds or in kind support and will abide by all requirements set forth by HRSA's Office of Pharmacy Affairs for the management and use of 340B funds. Signing this LOA indicates contractor acknowledgement and receipt of the 340B FAQs, the HIV Prevention Program 340B eligibility letter and Apexus Answers documents attached. It further constitutes acknowledgement that the agency is solely responsible for meeting all HRSA and Apexus requirements for 340B eligibility and maintenance.

Contractor

BY: _____ BY: _____
Program Administrator Witness

DATE: _____

Department of Health and Human Services, Communicable Disease Branch

BY: _____
Rapid Testing Program Coordinator

DATE: _____

MOA Revised 6/24

To find templates and tools that assist with 340B status please follow this link: 340B Tools (340bpvp.com)

NC DHHS Communicable Disease Branch Contact Information

HIV/STD/HCV Prevention Program

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Rapid Testing Team

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HIV/STD/HCV Prevention Program Data Team

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