Rapid Syphilis Testing Protocol

WISCONSIN DEPARTMENT of HEALTH SERVICES

Division of Public Health

P-01832 (11/2023)

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A. Bureau of Communicable Diseases (BCD) Staff Contact List

Name and Title	Contact	Program Unit	Roles and Responsibilities
Stacy Clark *HIV Testing Coordinator*	(608) 266-8427 stacy.clark@dhs.wisconsin.gov	HIV Prevention	• Ordering tests • Provides training
Jacob Dougherty *HIV Prevention Unit Supervisor*	(608) 261-9429 Jacob.Dougherty@dhs.wisconsin.gov	HIV Prevention	• Rapid Syphilis Technical Questions
Craig Berger *Syphilis Surveillance Coordinator*	(608) 266-1323 Craig.Berger@dhs.wisconsin.gov	STI Unit	• General syphilis questions • Disease investigation
Brandon Kufalk *STI Unit Supervisor*	(608) 261-6390 Brandon.Kufalk@dhs.wisconsin.gov	STI Unit	• General STI Questions
Kailynn Mitchell *Hepatitis Prevention Coordinator*	(608) 261-6731 Kailynn.Mitchell@dhs.wisconsin.gov	HCV Unit	• Rapid HCV testing questions • General hepatitis questions, trainings, disease investigation

B. **Common Acronyms and Terms**

ASO - AIDS Service Organization

CLIA - Clinical Laboratory Improvement Amendment

DHS - Or WDHS - Wisconsin Department of Health Services

DPH – Or WDPH - Wisconsin Division of Public Health

CDC - Center for Disease Control and Prevention

CTR - Counseling, Testing, and Referral

HIV - Human Immunodeficiency Virus

IM - Intramuscular. Medication administered through needle injection into the vascular muscle tissue for absorption in the body.

LTHDs - Local and Tribal Health Departments.

MOU - Memorandum of Understanding

MSM - Men who have sex with men, or males who have sex with males, are male persons who engage in sexual activity with members of the same sex, regardless of how they identify themselves. They may identify as gay, homosexual, bisexual, pansexual, or heterosexual; or dispense with sexual identification altogether.

Nonreactive - Syphilis test showing no signs of antibodies in the blood stream.

PPE - Personal Protective Equipment

PT - Proficiency Testing

QA - Quality Assurance

QC - Quality Control

Reactive - The syphilis test showed signs of syphilis antibodies/antigens in the blood.

RPR - Rapid Plasma Reagin – A type of non-treponemal test that looks for antigens that syphilis causes in the blood stream. The results for this test can be qualitative (reactive or non-reactive) or quantitative (non-reactive or titers 1:1, 1:2, 1:4, 1:8, 1:16….). Results need to be confirmed with a treponemal test that looks for syphilis antibodies. RPR results tend to be higher than VDRL results even using the same specimen.

RST - Rapid Syphilis Testing

SGL – Same gender loving men (see also MSM) or women

STD - Sexually Transmitted Disease

STI - Sexually Transmitted Infection

STS - Serologic (blood) test for syphilis. A generic term for any type of blood testing to determine the presence of syphilis.

TPPA - Treponema Pallidum Particle Agglutination Assay A lab based test used to confirm a reactive test, when the VDLR contradicts the screening test

Treponema pallidum – Spirochete bacteria causing syphilis infection. Transmitted between humans through sexual activity.

VDRL - Venereal Disease Research Laboratory. Non-treponemal test identifying antigens caused by *T. pallidum*. Results can

be qualitative (reactive/non-reactive) or quantitative (titers 1:1, 1:2, 1:4, 1:8, etc.) VDRL results tend to be lower on same specimen than the similar RPR test.

WHO - World Health Organization

WSLH - Wisconsin State Lab of Hygiene

C. Introduction and Background

Intended Audience for this Protocol

This protocol is intended for agencies funded by the Wisconsin Division of Public Health-AIDS/HIV Unit and Sexually Transmitted Infection (STI) Unit to provide rapid syphilis testing (RST) services. These agencies include local and tribal health departments (LTHDs), community-based organizations (CBOs), and AIDS Service Organizations (ASOs). Agencies are generally funded through a grant to provide RST services.

Purpose of the Protocol

This protocol was developed to provide an overview of the Wisconsin Rapid Syphilis Testing (RST) Program, identify requirements of agencies contracted to provide RST services related to counseling, testing, referral, data collection, and record keeping. RST sites are required to adhere to this protocol and the terms and conditions of contractual agreements and memoranda of understanding (MOUs) with the Wisconsin Division of Public Health (WDPH).

Purpose of the RST Program

The WDPH AIDS/HIV Unit and the STI Unit coordinate a statewide program of designated RST sites to provide the following critical services:

- Readily accessible rapid syphilis testing and conventional, lab-based syphilis testing for individuals at increased risk for syphilis.
- Syphilis testing at low or no cost to individuals who would not otherwise be able to afford testing.
- Client-centered counseling designed to reduce client risk of acquiring or transmitting syphilis.
- Appropriate referrals for follow-up and care to treat identified syphilis cases and to refer to partner services to reduce the spread of the infection.

Philosophy of Service

RST services should be provided in a manner consistent with community and consumer norms and values. The qualities of services (reflecting an understanding of culture, gender roles and inequalities) and the ability to provide services to persons and groups at increased or disproportionate risk for syphilis is more important than the number of tests conducted. Services should be provided in a collaborative, cooperative manner among local agencies in a community.

D. Syphilis FAQ

What is syphilis?

- It is an STI caused by the bacteria *Treponema pallidum*
- Syphilis is a systemic infection; it affects the whole body after the initial inoculation site. Sores may appear on the penis, rectum, throat, and cervix initially. The bacteria enters the blood stream and then affect other parts of the body such as a body rash, palmer/plantar rash (rash on palms of hands and bottoms of feet) and it may affect other bodily organs as it progresses.

Who should be tested for syphilis?

Routine testing is recommended for the following populations:

- Same Gender Loving (SGL) Men
- People living with HIV
- People who are pregnant
- People who have been diagnosed with a gonorrhea or Chlamydia infection
- Partners of people who have tested positive for syphilis
- People who are sexually active and live in areas with high syphilis rates
- People who are taking PrEP for HIV prevention
- People in correctional facilities

How does a person contract syphilis?

- If a person comes in contact with a chancre (painless syphilis sore), which is highly infectious and commonly located in/near the mouth, anus, vagina or on the penis, *T. pallidum* (syphilis causing bacteria) can be transmitted from one person to another causing risk of infection.
- A pregnant woman can pass syphilis to her fetus during pregnancy.
- Secondary syphilis symptoms such as a rash, condylomata lata, and mucous patches can harbor *T. pallidum* microorganisms. It is possible that the infection can be transmitted through skin-to-skin contact with these symptoms, but are less likely to spread syphilis in this way.
- It is also possible, yet not likely, to contract syphilis from sex toys that have not been disinfected in between uses and between people, if one of the persons has a primary or secondary syphilis infection.

How is syphilis different from HIV?

- Syphilis is a bacteria and HIV is a virus.
- Syphilis can be cured with antibiotic therapy with a certain type and dose of penicillin; while HIV is not curable, but the infection can be brought to a state of undetectable, and unlikely to spread in that case.

How are syphilis and HIV connected?

- A person living with HIV who acquires syphilis may develop symptoms that are very different from the standard symptom type and range associated with syphilis alone.
- A person living with HIV is more likely to develop later stages of syphilis that are more severe, such as neurosyphilis and ocular syphilis.
- A person with a chancre (genital sore) from syphilis is at greater risk to contract HIV through sexual transmission when exposed to someone living with HIV.

What are symptoms of syphilis?

Primary Stage

- The appearance of one single chancre (syphilis sore). They are sometimes hard to notice because they are firm, round, and painless and might be hard to find in or around the vagina and cervix, in the foreskin of the penis, anus, and the throat. The sore will arise where syphilis entered the body and marks the primary stage. This sore will heal in approximately 1-5 weeks, even if the person does not receive treatment, however the syphilis infection will continue to progress to the secondary stage.

Secondary Stage

- Key symptoms: skin rashes and/or sores in the mouth, vagina or anus (mucous membrane lesions and condylomata lata).
- Rashes that are rough and red may appear on the palms of the hand and the bottom of the feet (the palmar and plantar surfaces of the skin).
- Rashes may develop in other areas of the body that could easily be mistaken for a rash associated with other infections.
- Sometimes rashes are so faint they aren't easily noticeable.
- Sores may develop in warm moist areas, such as the mouth, vagina, anus, or near the penile opening.
- Other symptoms during the secondary stage may include: sore throat, fever, swollen lymph glands, headaches, patchy hair loss on head or loss of eyebrows/eyelashes, weight loss, muscle aches, and fatigue.
- These symptoms will go away even without treatment within 2-4 weeks, yet if left untreated, the infection will progress to the latent or late stages of the infection.

Latent Stage, Tertiary Stage, and Neurosyphilis

- After symptoms from the primary and secondary stages resolve, the latent stage begins. A latent stage is characterized by having NO symptoms of disease. This period of time is call the Non-Primary, Non-Secondary Stage, and occurs within 1 year of acquiring syphilis infection.
- *Early Latent Syphilis:* when the infection occurred within the past 12 months
- *Late latent Syphilis:* when the infection occurred more than 12 months ago

- Late latent stage syphilis can last for years
- *Late Stage*: develops in about 15% of people who contract syphilis and may arise 10-20 years after the person was first infected. If the infection reaches the late stage it can damage internal organs, cause difficulty coordinating muscle movements, paralysis, numbness, gradual blindness, and dementia. It can even lead to death.
- *Neurosyphilis*: When the syphilis infection invades the nervous system, it is referred to as neurosyphilis. This can happen at any stage of the infection, and can cause a variety of symptoms that look similar to other neurological diseases, such as Parkinson's and Huntington's disease.
- Complaints about visual impairment might also be a sign of *ocular syphilis.*

How does one prevent syphilis?

- If visible signs of syphilis are present, refrain from having sex.
- If you have been told you have been exposed to syphilis, avoid having sex with someone else to protect them from infection. Get tested and treated as appropriate per current CDC STI Treatment Guidelines.
- Consistent and correct condom use when the infected area is covered by the condom is very effective in preventing transmission of syphilis. Sores may exist outside the area covered by the condom, and the infection can still be spread even if condoms are used. This is especially true with oral sex because of the infrequency of condom use.
- Get tested and encourage your partner(s) to get tested.
- Partner notification and referral can be done by your LTHD trained staff, and is important if someone is positive for syphilis.
- Refrain from sex if a partner is exhibiting symptoms of any kind.

What activities DO NOT prevent syphilis?

- Washing the genitals
- Urinating
- Douching after sex
- PrEP

Is syphilis curable?

- Yes, a person with primary, secondary, or early latent syphilis can be cured by one injection of Benzathine penicillin G administered intramuscularly (IM).
- A person with late latent syphilis or latent syphilis will need 1 weekly shot (IM) of Benzathine penicillin G for a period of three weeks. Treatment for neurosyphilis or other late manifestations may include intravenous (IV) administration of specific types of penicillin. Please make sure your clinician uses the STI Treatment Guidelines for details on specific treatment regimes.
- Treatment will stop future damage done by the infection, but cannot repair any damage already done to the body.

Is it possible to get re-infected with syphilis?

- Yes, it is possible to become re-infected and in that case the person should be treated again, and sex-partners should be re-treated as well.

Where can someone get more information about syphilis?

- CDC: Syphilis Information
- Wisconsin DHS STI Unit: Syphilis Information

What kind of confirmatory testing should my laboratory perform?

There are two ways laboratories will perform syphilis testing. There is the traditional sequence testing and the reverse sequence testing. In the traditional method the laboratory would first perform a non-treponemal test and then use a treponemal test to confirm the results. The reverse sequence testing performs a treponemal test first. Then if the test is reactive performs a non-treponemal test. Only if you have discordant results (the treponemal reactive, non-treponemal test non-reactive) would you perform a TPPA.

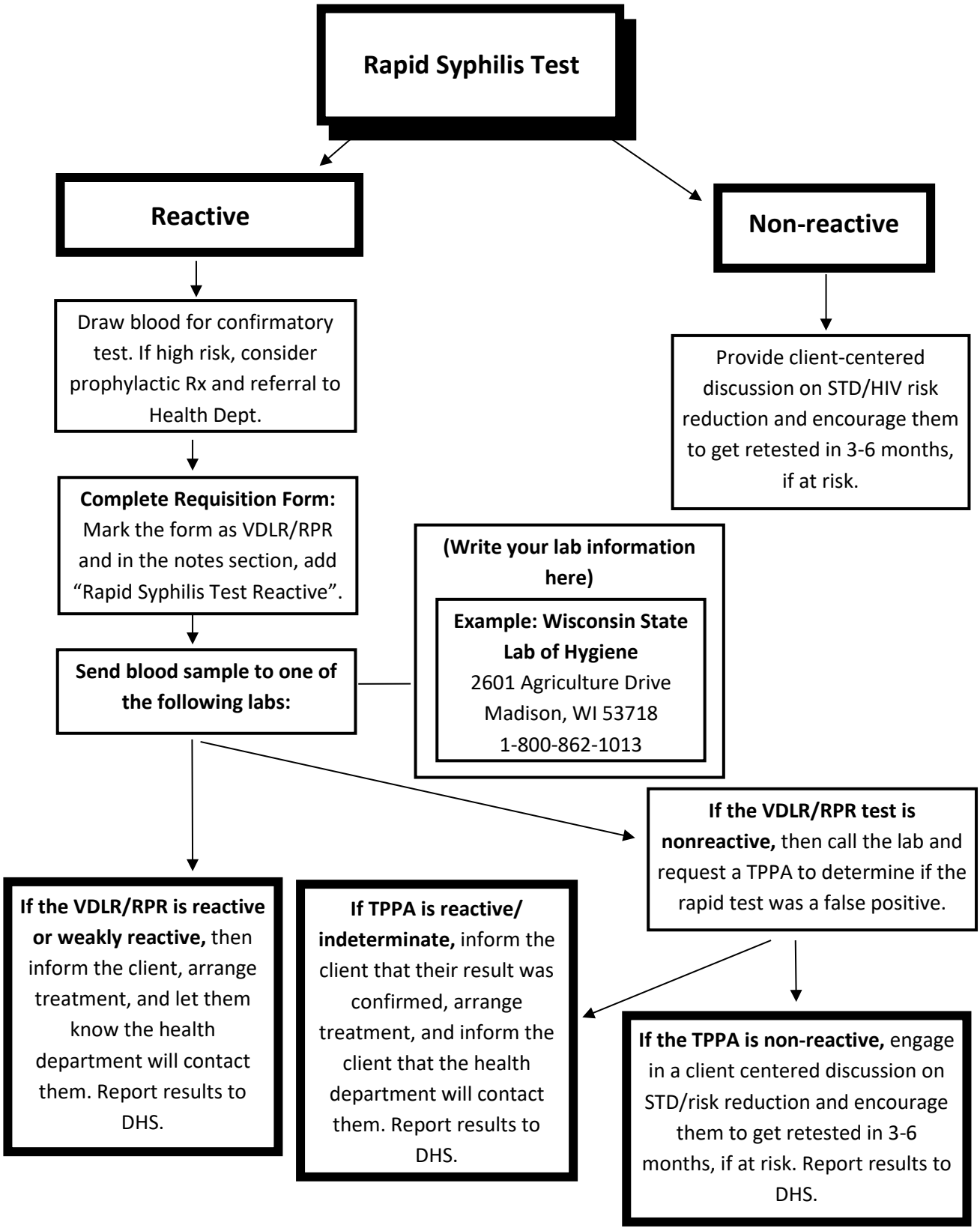
The reason for the additional TPPA which is a type of treponemal test is that all testing has sensitivity and specificity. Some initial syphilis tests like the rapid syphilis test are very sensitive, but they are not as specific as other tests. This can lead to some false positives in some patients. This is also true of non-treponemal syphilis tests. The test which has the best sensitivity and sensitivity is the TPPA. Unfortunately, the TPPA takes longer to perform and costs more which is why it is not used as the initial test.

Only the non-treponemal test has the benefit of helping diagnose re-infections after a person has already been exposed to syphilis. This is why a person who has previously been exposed to syphilis should not get a rapid syphilis test or any other treponemal test performed as it will not detect re-exposure. Once a person has had syphilis the treponemal test should always be reactive even after cure as the body continues to keep the antibodies the tests look for.

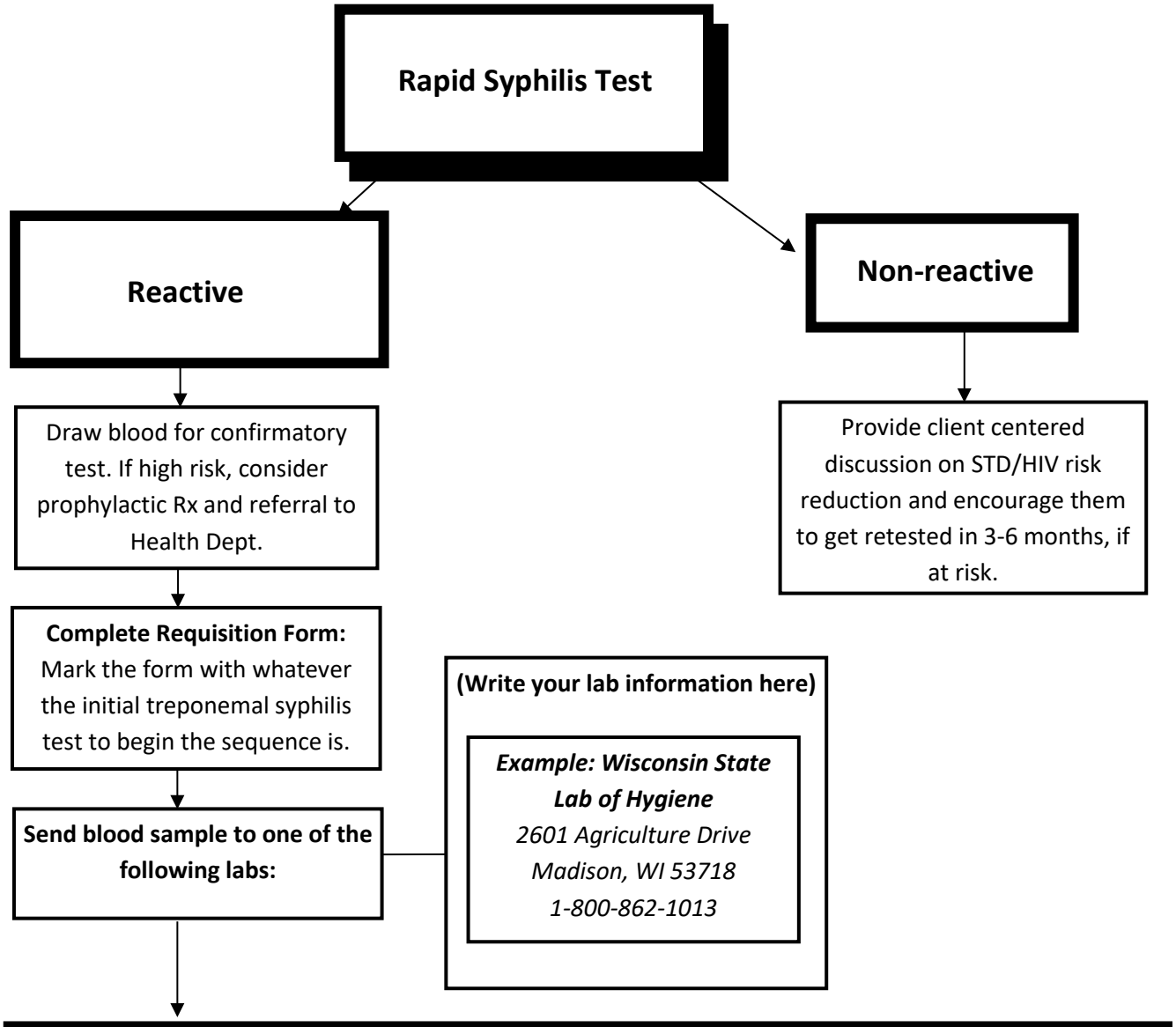
Below is an example of each of the algorithm laboratories use. You will want to first find out which sequence your laboratory is using before you send them specimens. Then you will want to ensure you are marking the correct test on the form so the lab reflexes automatically to the test it is supposed to go if a test is reactive/nonreactive depending. For instance, the WSLH currently has a test labeled syphilis diagnostic algorithm for their syphilis testing. They are currently a reverse sequence testing facility and therefore you would use the reverse sequence testing algorithm.

E. Rapid Syphilis Testing Algorithm

Rapid Syphilis Testing for Traditional Sequence Testing Laboratories



Syphilis Testing Algorithm for Reverse Sequence Testing Laboratories



If the initial treponemal test is non-reactive, engage in a client centered discussion on STI/risk reduction and encourage them to get retested in 3-6 months if at risk. Report to local health dept.

If the initial treponemal test is reactive a non-treponemal test should be performed. If the non-treponemal test is reactive/indeterminate, inform the client that their result was confirmed, arrange treatment, and inform the client that the health department will contact them. Report results to DHS.

If the initial test is reactive a non-treponemal test should be performed. If the non-treponemal test is non-reactive, perform a TPPA. If the TPPA is nonreactive, engage in a client centered discussion on STI/risk reduction and encourage them to get retested in 3-6 months if at risk. Report to local health dept.

If the initial test is reactive a non-treponemal test should be performed. If the non-treponemal test is non-reactive, perform a TPPA. If the TPPA is reactive/indeterminate, inform the client that their result was confirmed, arrange treatment, and inform the client that the health department will contact them. Report results to DHS.

F. **Program Requirements**

To provide rapid syphilis testing with the Syphilis Health Check test, sites must meet the following requirements (a listing of core requirements is at the end of this section):

1. **Compliance with all government and regulatory requirements including the Clinical Amendments Improvement Act of 1988 (CLIA) and Occupational Safety and Health Administration (OSHA) Bloodborne Pathogen Standards**.

CLIA Requirements

The rapid tests used by the Wisconsin AIDS/HIV Unit and the STI Unit are classified as "waived" by the FDA when used with whole blood or oral fluid specimens. CLIA requires that all sites offering these tests have laboratory certification allowing them to conduct waived testing.

Sites must minimally hold a CLIA Certificate of Waiver or Provider Performed Microscopy Procedure (PPMP) certificate. For more information on CLIA and how to apply for a certificate, view the federal Centers for Medicare and Medicaid Services website at www.cms.gov/clia/. Staff in the Clinical Laboratory Section of the Wisconsin Division of Quality Assurance (see below) are also available to answer questions.

The CLIA application should be mailed to:

Clinical Laboratory Section
Division of Health Services
1 W. Wilson
PO Box 2969
Madison, WI 53701-2969
Phone: (608) 261-0653

When submitting the application, please add the e-mail address for the person who is completing the application, and identify the State of Wisconsin License Number (e.g. MD, RN, Certified Social Worker, etc.) for the person who will be the laboratory director.

OSHA Requirements

All sites must also adhere to the OSHA *Occupational Exposure to Bloodborne Pathogen* standard.

OSHA published this standard to prescribe safeguards to protect workers against health hazards related to bloodborne pathogens. Under the OSHA standard, an employer must develop and implement a worksite exposure control plan that describes detailed steps to protect employees.

Since the external controls used with rapid tests are derived from plasma, all sites must develop an exposure control plan and implement the bloodborne pathogen controls standard.

Exposure control plans are required to cover the following areas:

- Determination of employee exposure.
- Methods of compliance addressing exposure control (including standard precautions, engineering and work practice controls, personal protective clothing and equipment.)
- Vaccination and antibody testing for hepatitis B.
- Post-exposure evaluation and follow-up.
- Communication of hazards to employees.
- Utilizing biohazard signs, labels, and waste disposal methods.
- Keeping of records, including a sharps injury log.
- Annual training.

Resources for developing and implementing a bloodborne pathogen control plan and additional infection control information are available at WDHS Infection Control and Prevention Program.

Also available is a copy of a multiple-ply form entitled *Determination of Exposure to Blood/Body Fluids* (Form WKC-8165). This form is to be completed by a health care provider to certify that a staff person has been significantly exposed to the blood or body fluids of a patient or client. This form may also be used for the purpose of Worker's Compensation. Form WKC-8165 is available for purchase from the Bureau of Document Services at: 608-266-3358 (telephone), docsales@doa.state.wi.us(E-mail), https://docsales.wi.gov/(Internet web site).

For additional technical support and resources, agency staff may contact the HIV CTR Coordinator at 608-267-3583 or at the e-mail address provided in the contact list. These resources include:

- Policies and procedures related to bloodborne pathogen exposure control.
- A sample sharps injury log.

2. Establishment of policies and procedures describing all steps in the performance of the test, including description of site flow and activities in the various settings where the test is performed.

This protocol may serve as an agency's basic policies and procedures related to rapid syphilis testing. However, each agency should have site-specific policies and procedures that include a description of how the test is conducted in both clinic and outreach settings where agency staff conducts testing.

The following policies and procedures must be in place:

- Provision of syphilis risk assessment and test information related to providing client information regarding rapid testing.
- Use of gloves and other personal protective equipment.
- Safe disposal of biohazardous waste (e.g. used lancets, external controls).
- Maintaining sufficient inventory and checking new lots and shipments.
- Maintaining and documenting environmental temperature control.
- Describing testing steps and activities in both in-house and outreach settings.
- Collecting a specimen.

- Performing steps in the test procedure and reading results.
- Performing quality control testing and identifying what to do when controls fail.
- Participating in external quality assessment (proficiency testing) as required.
- Reporting results.
- Specimen collection and submission for confirmatory testing.
- Documenting client and control test results.
- Client centered discussion on STI/HIV risk reduction.
- Record review, storage, and disposal.
- Troubleshooting activities – what to do when things go wrong.
- Staff training, competency assessment, and documentation of training.

3. Utilization of personnel who are trained and competent in all components of rapid syphilis testing. Staff must participate in all training required by the Division of Public Health and have thorough knowledge of the package insert instructions for the rapid test prior to testing.

Personnel providing rapid testing should possess the following qualities:

- Commitment to following procedures and precision in work habits.
- Literacy – the ability to read instructions and document testing activities, including reading results.
- The ability to resolve problems and discern when further help is needed.
- Organizational skills.

All site staff intending to offer rapid syphilis testing must first attend the following foundation courses:

- Test training by Trinity Biotech.
- Syphilis Webinar by Department of Public Health.
- STD 101: Making the Connection with HIV.

An exception to the above requirement is for laboratory staff working in a moderate complexity laboratory. If these staff will not be conducting counseling, they may conduct the test by following the instructions in the package insert and program protocols without attending the core courses or rapid testing training. Typically, the HIV CTR Coordinator will meet with the lead staff person in a moderate complexity laboratory to review rapid testing procedures and forms for the program and to assure that the testing process is consistent in all CTR sites.

Prior to testing client specimens all staff **must** read and understand the rapid test's package insert, in addition to this protocol. Also, staff *should review the revision date* of the package insert, included with each test shipment, to find out whether the instructions have been updated, and to review them if they have been changed.

4. Compliance with all quality assurance (QA) activities detailed in the package insert and additional activities delineated by the Wisconsin AIDS/HIV Unit and STI Intervention Unit.

All sites must ensure quality testing by:

1. Assigning a lead staff person responsible for overseeing rapid syphilis testing and all QA activities on-site.
2. Ensuring that staff participate in state-sponsored trainings and successfully complete a competency assessment.
3. Following all testing requirements detailed in the most current package insert.
4. Using external controls as required in the protocol.
5. Documenting testing process and results.
6. Recording the storage temperature of test devices and external controls.
7. Participating in a state-sponsored proficiency testing program as outlined in this protocol.
8. Communicating testing problems to the on-site lead staff person (#1 above), the Wisconsin State Lab of Hygiene (WSLH), or the Wisconsin STI Intervention Unit, as appropriate and taking action to ensure that the test is providing valid and reliable results.

5. Adherence to all program record-keeping and data collection requirements.

Agency staff must document all testing processes, including receipt of inventory (Appendix 1); storage temperature of tests and controls (Appendix 2); and details related to conducting clinical tests and external controls. Testers must also complete the syphilis risk assessment with their clients (Appendix 3).

Reactive tests must be reported to the local health department within 72 hours by the tester using WEDSS or a physical reporting form. Physical reporting forms, called *F-44243*, can be found here*:* *https://www.dhs.wisconsin.gov/std/health-pros.htm*. Agencies must also keep track of the results of these tests for their records. Please refer to the state statutes chapter 252.05 and 252.11 for more details on legal reporting requirements: https://docs.legis.wisconsin.gov/statutes/statutes/252/05.

Core Requirements for Rapid Syphilis Testing/ Training Checklist

The requirements for rapid syphilis testing described in the previous section (#1-5 under Program Requirements) are listed with more detail below under the following categories.

Laboratory and Bloodborne Pathogen Requirements

- Valid CLIA certification for conducting waived tests.
- Refrigeration to store controls, and provision for monitoring refrigerator temperatures (per bloodborne pathogen standards – the refrigerator must not store food or beverages).
- Compliance with blood borne pathogen standard requirements listed below:
  - √ Exposure control plan including documentation of review and use by staff of safer devices
  - √ Exposure determination record
  - √ Initial and annual staff training in standard precautions
  - √ Availability of hepatitis B vaccine to all employees conducting testing, at no cost to the employee
  - √ Availability of post-exposure evaluation and follow-up, including prophylaxis, at no cost to the employee
  - √ Individual employee records documenting training, vaccination, post-exposure evaluation & follow-up - to be kept for duration of employment + 30 years
  - √ Training records to be kept for 3 years from the date of training
  - √ Sharps injury log
  - √ Warning labels affixed to all containers containing blood or other infectious materials, (including refrigerators) or red containers
  - √ Biohazardous waste containers, gloves, decontamination materials
  - √ Access to hand washing facilities or appropriate antiseptic hand cleanser as indicated
  - √ Arrangements for biohazardous waste disposal

Administrative Requirements

- Procedures describing activities and flow in various settings where testing is performed.
- Supervisor or lead worker assuring that procedures are being followed to ensure high quality testing.
- Supervisor or lead worker assuring that bloodborne pathogen control standards are being implemented.
- Confirmatory testing (serum) to confirm reactive rapid tests.
- Participation in the State's QA activities and compliance with its QA plan.
- Referral systems for reactive rapid results.

Staff Training and Quality Assurance Requirements

- Prior participation in the Trinity Biotech syphilis rapid test training, WDPH's syphilis webinar, and STD 101 training.
- Competence in conducting finger stick blood draws.
- Thorough knowledge of and adherence to package insert instructions for the rapid test.
- Successful completion of a competency assessment by testing samples and accurately reading the results prior to testing clients.
- Successful test administration and interpretation of test results for both positive and negative controls prior to testing clients.
- Agency participation in the state proficiency program to assure staff competency in testing.

Record-Keeping Requirements

- Maintenance of testing logs for a minimum of three years. Logs with personal identifiers on them must be shredded.
- Maintenance of temperature and inventory logs should be stored for two years.
- Individual employee records documenting training, vaccination, post-exposure evaluation and follow-up to be kept for duration of employment, plus three years.
- Training records to be kept for three years from the date of training.
- Sharps Injury Log.

G. Agency Flow of Services

Rapid syphilis testing may not feel "rapid" to the client being tested. Since the syphilis risk assessment, specimen collection, testing, and the client centered discussion on STI/HIV risk reduction all occur in one visit, a client can expect to be at an agency at least 30 – 60 minutes before receiving their test result. Some clients may feel this is too long and opt for laboratory syphilis testing.

Rapid testing typically requires more personnel for conducting the same quantity of tests since agency staff must now do the testing in addition to the counseling. Agencies should consider how to use their staff most effectively in order to provide efficient client services. Some agencies may use two or three staff to conduct rapid testing services – one or two to provide the counseling and referral and the other to process the test. Other agencies may decide to "overlap" clients: while one client is waiting for their test to develop, the staff person may begin counseling and testing another.

Each site will need to review how site flow is established based on their personnel resources and other logistics of their setting. Agencies should assure that staff members are available to assist and support the client receiving a reactive rapid test. Persons with reactive rapid results will typically require much more time for post-test counseling and referrals than those with non-reactive (negative) results.

H. Rapid Syphilis Testing in Non-Traditional or Outreach Settings

The Wisconsin AIDS/HIV Program and the STI Intervention Unit approves of conducting rapid syphilis testing in non-traditional or outreach settings as long as specific conditions are met.

The following conditions must be present for rapid syphilis testing in non-traditional settings:

- *Lighting*: Sufficient lighting to safely and accurately conduct the test and read the result. If the natural or room lighting is not bright enough to read the result, staff should use a lamp to improve the lighting – not a flashlight.

- *Temperature*: The temperature of the testing environment should be within the operating temperature for the test specified in the package insert and this protocol. Staff must use a thermometer in the field to assure that the temperature is within the proper range. The temperature during each test should be documented on the Testing Site Log (a sample of this form is at the back of the Determine section of this protocol). Test kits should be stored during transport and prior to testing within the storage temperature range listed in the package insert and this protocol.

- *Surface area*: The test must be performed on a level, clean surface. Consistent with bloodborne pathogen control procedures, no food or drink should be consumed in the area where testing is performed. Staff should set up their workspace as recommended under "Testing Steps" in the Determine section of this protocol.

- The psychosocial conditions associated with rapid testing in non-traditional settings are as important as the above technical conditions. Agency staff must maintain the following conditions to assure that clients who are being tested are able to receive their result in a confidential and emotionally supportive setting.

- *A confidential, private space for testing, counseling, and providing results*: Since the test is actually conducted in the outreach setting, staff must be certain that tests develop in a private place where only the testing staff can view results. A confidential space must also be used to provide STI/HIV risk assessment and a discussion on risk reduction to clients. Testing staff must be particularly conscious of the confidentiality issues of clients with a reactive result. For instance, if a client meets with staff for a longer period of time than those clients with a non-reactive result, this may inadvertently break their confidentiality, since others may assume the client had a reactive result. Staff must consider all the ways that confidentiality may be broken and develop strategies to protect the client's privacy.

- *Testing staff prepared to provide a reactive result*: A reactive rapid test result is provided in a short time frame which limits staff's ability to prepare for providing this difficult news. A reactive result also is not definitive, limiting the type of referrals the staff person can

provide and leaving the client in a state of uncertainty. In outreach, these difficulties are compounded by the inability of staff to access on-site agency resources and support that are usually available in the clinic setting.

For these reasons, staff providing rapid testing in an outreach setting must be adept at interpreting a reactive result, prepared to support a client through the confirmatory process, and ready to respond to a client in crisis. Staff must know what referrals can be immediately accessed for the client and be ready to link the client to these services. If outreach testing is being done late in the evening or on the weekend, staff must have a plan of how to emotionally support clients who receive a reactive result.

- If staff is not able to provide immediate confirmatory testing, treatment, and/or refer to the health department, then they should arrange for a referral to get these accomplished. A patient should always receive a confirmatory test with a reactive rapid test. If they are high risk they can be also be offered the prophylactically Rx. The patient should also be informed that the health department may contact them, and provide information on where they can call.

I. Syphilis Risk Assessment with Rapid Tests

Besides assessing risks, additional information that should be discussed during a syphilis risk assessment when offering a rapid syphilis test includes:

- The differences between laboratory-based testing and rapid testing.

- Procedures related to each of the testing options – how the test is done, how long the process takes, timeframes for getting results, meaning of test results, and repeat testing. Make sure the client understands that a previous syphilis infection will always be reactive with RST.

- Relevant information regarding the "window period" i.e. the time between possible exposure to syphilis and when the test is likely to identify a syphilis infection. (The window period for this test is three months, with a likelihood of four weeks. Some clients mistakenly believe that the term "rapid test" refers to identifying infection rapidly – that the test can accurately determine whether a risk exposure last night resulted in infection today.) Staff must be clear that rapid syphilis testing only refers to obtaining results rapidly, and should explain that the Syphilis Health Check test can detect infection that may have occurred prior to three months ago. If a client believes a possible infection occurred more recently than three months ago, the counselor should suggest re-testing in three months.

If the client decides to be tested with a rapid test staff should:

- Provide the client with the "Subject Information" pamphlet supplied by the manufacturer.
- Ensure that the client understands the meaning of test results, including that a reactive result requires that confirmatory testing be performed immediately.

- Assess client's potential reaction to receiving a reactive rapid test. Staff might ask "How would you feel if this test comes back reactive today? What would you do?" This discussion will help staff understand and plan for the client's support needs if their test result is reactive.

J. Syphilis Health Check Testing Kit

Intended Use

Syphilis Health Check is a qualitative rapid membrane immune-chromatographic assay for the detection of *Treponema pallidum* (syphilis) antibodies in human whole blood, serum or plasma. This product can be used as an initial screening test or in conjunction with a non-treponemal laboratory test and clinical findings to aid in the diagnosis of syphilis infection. This test is not intended for use in screening blood or plasma donors.

Features of the Syphilis Health Check

The Syphilis Health Check is a very simple 10 minute, 2-step procedure utilizing a finger-stick; it affords the following features and benefits:

- 98 percent agreement with reference treponemal assays;
- 100 percent agreement with clinically diagnosed samples;
- Detection of both IgG and IgM, enhancing detection with early syphilis;
- Utilization of multiple recombinant syphilis antigens (TP-15, TP-17, and TP-44 for optimized sensitivity and specificity);
- Room temperature kit storage;
- Only rapid syphilis test with FDA Clearance and CLIA-waived; and
- CPT code: 86780.

Remember: The Syphilis Health Check should not be offered to everyone, but rather only to clients who meet specific risk factors, such as:

- **SGL Men,**
- **People living with HIV,**
- **People who are pregnant,**
- **People of partners who have tested positive for syphilis,**
- **People who are sexually active and live in areas with high syphilis rates,**
- **People who are taking PrEP for HIV prevention, and**
- **People in correctional facilities.**

Please use the Rapid Syphilis Test Risk Assessment form to determine client risk (Appendix 3).

Because the Syphilis Health Check is a treponemal assay, individuals with a previous known syphilis history should NOT be offered this test. Individuals with a previous known syphilis history should instead have a routine serologic specimen drawn for the standard lab-based syphilis testing.

When Not to Use

The Syphilis Health Check is not recommended as a screening test for individuals with a past history of syphilis, whether or not they were appropriately treated. It is important to specifically ask individuals if they were previously diagnosed with syphilis prior to using this test.

Adherence to Manufacturer's Instructions

Certain steps need to be taken even before a test has begun to be sure results are accurate. Most importantly, follow the manufacturer's instructions throughout the testing process. Problems found in testing sites that perform waived tests are most often the result of not following this critical step.

Testing Environment and Preparation

Testing should be performed in an area with adequate space to safely conduct testing while maintaining patient privacy. Testing and storage areas should be monitored to be sure they meet specific environmental requirements described in the manufacturer's instructions.

Equipment used for testing should be maintained and calibration checks should be performed as directed in the manufacturer's instructions.

1. Check inventory regularly to ensure you will have enough reagents and supplies on hand for testing.
2. Check and record expiration dates of reagents/kits, and discard any reagents or tests that have expired.
3. Check and record temperatures of the testing and reagent storage areas. See Appendix 2 for samples of daily temperature logs.
4. Check that all kit reagents came from the same kit lot**. Do not mix reagents**.
5. Inspect reagents for damage, discoloration, or contamination, and discard if found.
6. Prepare reagents according to manufacturer's instructions.
7. Allow time for refrigerated reagents/samples to come to room temperature prior to testing.
8. Perform equipment calibration checks, as needed, following the manufacturer's instructions.
9. Perform testing in a well-lit area.
10. Inspect equipment and electrical connections to be sure they are working.
11. Clean work surfaces before and after testing.

Testing sites that perform testing under a CLIA Certificate of Waiver must follow the current manufacturer's test instructions. The following steps should be taken to be sure the current test instructions are being followed:

1. Read and understand the manufacturer's instructions and/or site specific procedure.
2. Keep a copy of the manufacturer's instructions on hand for easy reference.
3. Check the manufacturer's instructions with each new lot and shipment of test kits to make sure there are no changes from the test kits being used.

4. File the current manufacturer's instructions and replace with an update if there are changes.
5. Communicate all changes in the manufacturer's instructions to other testing personnel and to the person who directs or supervises testing.
6. Follow safety precautions including OSHA guidelines: http://www.osha.gov/SLTC/bloodbornepathogens/index.html
7. Practice all tests, while an experienced person watches, before testing patient samples and reporting patient results.
8. Document training on all tests in staff personnel files.

Syphilis Health Check Materials Supplied

Each kit contains everything needed to perform 20 tests.

- Syphilis Health Check test devices = 20
- Disposable plastic fixed volume pipettes = 20
- Diluent in a dropper bottle containing saline buffer, detergent and sodium azide (NaN3, 0.1%) = 5 mL
- Package insert = 1

Materials Required but not Provided:

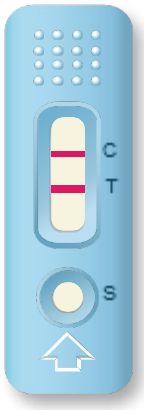
- Timer - 20 min
- Syphilis Health Check Control Set, order from Trinity Biotech (800) 325-3424
- Cotton swabs
- Alcohol pads
- Band aids

Quality Control (QC) Testing

Quality control (QC) testing gives confidence that your results are accurate and reliable. The manufacturer's instructions or site specific procedures explain what the controls are checking, the steps for performing QC testing, and when to do QC testing. Incorrect QC results alert the user to potential problems such as reagent/test kit deterioration, equipment failure, adverse environmental conditions, or human error.

Types of Controls

Two types of controls are generally found in waived tests:



Internal Controls (also referred to as built-in or procedural controls) evaluate whether:

- The test is working as it should.
- Enough sample is added.
- The sample is moving through the test strip correctly.
- The electronic functions of the instrument are working correctly.

External Controls evaluate whether:

- The entire testing process is performed correctly.
- The control results are in the expected ranges or values as found in the manufacturer's instructions.

Built-in Quality Controls

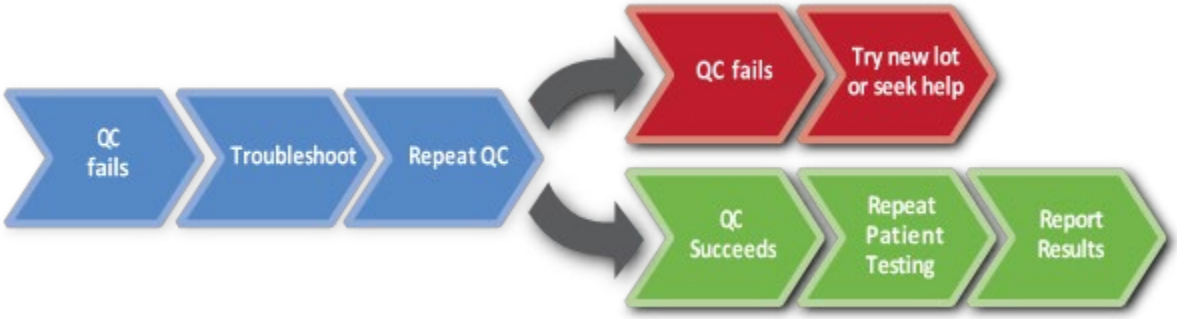
Syphilis Health Check contains built-in quality control features. A pink line in the Control Zone should always be seen and shows; 1) that enough volume is added, and 2) that proper flow is obtained. If this line is missing, the test was not run correctly or failed to function properly. The test is invalid and the test should be repeated using a new cassette.

External Controls

The Positive and Negative Controls, which are provided separately from the manufacturer, should be run according to the laboratory requirements. These controls should be run like an unknown patient specimen, at a minimum in the following circumstances:

- Each new lot.
- Each new shipment (even if from the same lot previously received).
- Each new operator (an individual who has not run the tests for at least two weeks).
- Monthly, as a continued check on storage conditions.
- Whenever problems (storage, operator, or other) are identified.
- Or other times as required by your laboratory's standard QC procedures.

If the controls do not give expected results (Positive or Negative), patient results must not be reported, and the test should be re-run.



Courtesy, Pennsylvania Department of Health

If your local or state regulations require more frequent testing of quality control material, quality control must be performed in compliance with those regulations.

If the test does not show any Control or Test line in the window or a smudged or partial line, the test cassette should be discarded. Do not report the results. Run the test again with a new cassette and follow the procedure exactly. If the second test does not show lines, please contact Trinity Biotech at (800) 325-3424. For any other concerns regarding Syphilis Health Check please contact BCD Staff on page 3.

Limitations

1. The results obtained from this assay are intended to aid in diagnosis only. As with all serological treponemal tests for syphilis, interpretation of results obtained with the Syphilis Health Check Treponemal Antibody test must be used in conjunction with a non-treponemal syphilis serologic test with titer, the patient's clinical symptoms, medical history and other clinical and/or laboratory findings to produce a diagnosis of syphilis by stage.
2. A positive treponemal test requires a reflexive second test with a nontreponemal assay with titer, such as RPR, along with a clinical evaluation, for diagnosis of syphilis.
3. Very early stage of infection could lead to false negative results, due to the low concentration of anti-*Treponema pallidum* antibodies in the serum, plasma or whole blood samples.
4. A positive result does not exclude the presence of other pathogens. A positive result can also be obtained in cases of other treponemal diseases such as yaws, pinta and bejel.
5. The Syphilis Health Check test is specific for detecting *Treponema pallidum* antibodies in serum, plasma or whole blood samples. It does not detect *T. pallidum* directly.
6. All treponemal tests tend to remain reactive following treatment and cannot be quantified; therefore, they should not be used to evaluate responses to therapy. Because of the persistence of reactivity, probably for the life of the patient, the treponemal tests are of no value to the clinician in determining relapse or re-infection in a patient who has had a treated infection.
7. Treponemal antibodies after treatment are not indicative of immunity to future syphilis infections.
8. Performance characteristics of this device have not been established for matrices other than whole blood, serum or plasma.
9. Assay performance characteristics have not been established for immunocompromised or immunosuppressed patients, cord blood, neonatal specimens, or infants.
10. Performance characteristics of this device have not been established with specimens containing heterophile antibodies which are known to cause false positive results in various immunoassays.
11. Treponemal tests are not recommended in neonates to diagnose congenital syphilis as passive transfer of maternal antibodies can cause false positive results.

K. Quality Assurance

Lead QA Staff

Each agency must designate a lead staff person responsible for assuring quality of their agency's rapid testing. This person will be responsible for assuring that:

- Storage and site temperatures are monitored and documented.
- Site testing log is completed accurately.
- Devices and controls are used prior to expiration.
- The agency has sufficient test devices and controls to provide efficient services to clients.
- Staff are trained and following the protocol.

The lead QA staff person will be the first person notified by other testing staff when a test is invalid or external quality controls fail. This person will work with agency testing staff to determine the basis of the problem and to notify additional agency personnel as needed. Some large agencies will have a hierarchy of administrative staff who oversee QA of testing. Each agency should develop communication mechanisms to assure that staff are made aware of testing problems and problem solving.

When problems arise, the lead QA staff or other administrative staff should contact BCD Staff on page 3. They will provide technical assistance on resolving problems regarding rapid syphilis testing. It may be necessary to contact the test manufacturer to report defective devices or controls.

Training

As stated previously, all staff conducting rapid syphilis testing must participate in the following training sessions conducted by the Wisconsin AIDS/HIV Program through the Wisconsin HIV/AIDS Training System:

- Trinity Biotech Rapid Syphilis Test Training
- WDPH's syphilis webinar
- STD 101: Making the Connection to HIV

The lead QA staff person should assure that staff is competent in rapid testing procedures by observing them in the various steps required for conducting a rapid test.

In addition, all staff must be trained annually in bloodborne pathogen control ("standard precautions") through their employer. Staff who conduct rapid testing with whole blood must be trained and competent in fingerstick collection of whole blood specimens. It is the responsibility of the agency to assure that staff are proficient and are using standard precautions.

To comply with OSHA standards, the agency should document training of staff in bloodborne pathogen control and fingerstick specimen collection. All relevant training and results of competency assessment should be documented in the personnel file.

Competency Assessment

In addition to the competency assessment, the Wisconsin AIDS/HIV Program and STI Intervention Unit recommends that the lead QA person at each agency complete the training checklist on page 14-15 to assure that staff accurately conduct rapid syphilis testing. Lead QA staff should observe the newly trained staff when initially conducting rapid testing with clients.

Proficiency Testing

Proficiency testing (PT) is another way to "test the tester." The WSLH sends agencies specimens to test and interpret results three times a year. Their performance is scored based on how many tests were interpreted correctly. The goal is for all sites to obtain a score of 100% for each PT event.

The Wisconsin AIDS/HIV Program/STI Intervention Unit enrolls sites in the WSLH PT Program and pays for its cost. Staff at the agency test the specimens and send WSLH the results which are scored on accuracy. Ideally, each staff person performing rapid testing will test and interpret at least some of the specimens each year. The lead QA staff at each agency will document that proficiency testing was completed and the name of the staff person who tested and interpreted each specimen. When completed, the specimens should be disposed of in a biohazardous waste container.

The results from each PT event will be sent to both the agency and the Wisconsin STI Intervention Unit. If an agency fails a PT event, BCD staff will contact the lead QA staff person to assess the situation. Rapid testing may be halted at the site until the problems with testing or interpreting test results are resolved.

Documentation

To assure that conditions and key elements of the testing process are in place to assure quality testing, each site is required to complete the following documentation:

1) Testing Log – documentation of key information related to each specimen and control run at the site.
2) Inventory Log – documentation of when test kits and control kits are received by the agency, their lot numbers, expiration dates, the number of tests within each box, and the date that tests from this box were first used.
3) Storage Temperature Logs – documentation of temperature where controls *and* tests are stored.

Examples of each of these logs are at the end of the protocol. Each log is described below.

1) *Testing Log (Appendix 4):* Each time a test is run on a client specimen or an external control the information regarding the test must be documented on a testing log. This documentation should occur at the same time the test is conducted. Staff should *not* wait to document tests on the log at a later time, (e.g. waiting until back in the office after an outreach event), since it increases the potential for error. For each test, the following must be documented:

   - Date of test.
   - Test ID number and client code/initials or positive or negative control.
   - Initials of staff performing test.
   - Current temperature of testing area.
   - When the test was started.
   - When the test was read.
   - Whether the internal control on the test device was valid.
   - Whether the result was reactive or non-reactive.
   - Whether a client specimen was sent for confirmatory testing.
   - Confirmatory test result.
   - Comments (e.g., why external controls were run; troubleshooting for invalid results; whether client received confirmatory results; venue where test was done).

   In addition, the lot numbers and expiration dates of both the tests and external quality controls must be documented at the top of the log.

   All specimens and controls must be logged chronologically, so that the log provides an accurate history of testing at that location. **A new log should be started every time a new lot of tests or external controls are used**. Logs should be submitted to the Syphilis Surveillance Coordinator via fax (608-261-9301) or scan/email on a monthly basis.

2) *Inventory Log (Appendix 1)* — Each time a shipment of tests or external quality controls is received by the agency, it should be documented on the log. The log should indicate when the item was received, the lot number; and expiration date. The log should also indicate the date when devices from this box were first used. Items with the earliest expiration dates should be used first.

3) *Storage Temperature Logs (Appendix 2)* — Staff must document storage temperatures of both test kits and the controls on each day tests are performed. The Sample Temperature Log specifies a column for the high and low temperatures since the last reading as indicated on a min/max thermometer. If the temperature falls out of the specified range, staff must document what corrective action was taken.

   When temperatures fall out of the required range for storing test kits, staff should run a set of external quality controls. If the expected results are obtained, the tests may be used. If either the tests are invalid or the expected results are not obtained, the tests should be disposed.

   When temperatures fall out of the required range for storing external control kits, staff should use that set of controls to run a positive and negative control on test devices that have been stored properly. If the expected results are obtained, the controls may be used. If not, the

controls should be disposed. This process should be done for each set of controls exposed to the out-of-range temperatures.

Troubleshooting

Troubleshooting is a problem-solving process. When a test fails, staff must attempt to determine the source of the problem. Staff must try to answer the question "What went wrong?" The problems may rest with the testing process or conditions, the test device, or the specimen.

The lead QA staff person should be involved in the problem solving process. If the testing process and conditions met all specified requirements, staff must assess if there was a problem with the test device. In a rare event, something about the specimen may have caused the failure. A process described on the next two pages can assist staff in evaluating reasons why an invalid test result occurred or external controls failed.

Whenever a site has an invalid result, this test should still be logged on the Testing Log. Staff should also e-mail BCD Staff on page 3, regarding the invalid result, possible reasons for it, and whether a repeat test yielded a valid result. If the invalid result does not seem to be due to human error, agency staff should contact the manufacturer.

Similarly, whenever a site has a discordant or false-positive result – a reactive rapid, but negative supplemental testing – staff should contact BCD Staff on page 3.

The External Quality Controls Failed…Now What?

1. Identify the problem using the following list of potential problem areas.

___Were the tests stored within the proper temperature range?

___Was the temperature of the testing area within the proper range?

___Were the controls stored between 35°F and 46°F?

___Were the controls brought to room temperature prior to use?

___Was the test used prior to the expiration date?

___Were the controls used prior to the expiration date?

___Was the test brought to room temperature prior to testing?

___Was the lighting in the testing area adequate for proper testing?

___Was the desiccant present in the test pouch?

___Was a new pipette used with each control vial?

___Were the devices labeled correctly? (i.e. positive on a positive control and negative on a negative control)?

___Was the buffer added to the test device?

2. If it is determined that any of the above conditions caused the external controls to fail, staff should document on the *Testing Log* in the "Comments" section - the troubleshooting process; actions taken; and how staff verified that corrective action taken addressed the problem. Staff should use the other side of the log if more space is needed.
3. If it is determined that none of the above conditions caused the external controls to fail, perform a second rapid test on another set of controls.
4. If the problem resolves with the second set of controls, dispose of the first set of controls.
5. If the problem remains with the second set of controls, contact the test manufacturer, (Trinity BioTech – 1-800-325-3424) and BCD Staff on page 3.

Record Review

The lead QA staff person should review all testing documentation at least once per month to assure that testing practices meet the requirements indicated in the manufacturer's package insert and this protocol. The lead staff should also review whether the number of test kits left in inventory is consistent with the number of tests used as documented on the *Testing Log*.

Wisconsin AIDS/HIV/STI staff will review testing documentation (testing logs, temperature logs, etc.) of grantee agencies at annual site visits.

Record Storage and Disposal

Testing logs should be stored in chronological order in a three ring binder or folder. Logs should be stored for three years, and then disposed. If the logs have patient identifiers on them, the logs must be stored in a locked file cabinet in a locked room.

Completed informed consent forms should be stored for three years and then disposed. Name associated forms should be stored in a locked file cabinet in a locked room.

Temperature and inventory logs should be stored for two years, and then disposed.

For disposal, any records with patient identifiers should be shredded. Otherwise, records may be disposed of in trash or recycling containers.

Storage

All Syphilis Health Check kit components should be stored at (4º - 30°C). Test cassettes should be stored in their sealed pouch.

All Syphilis Health Check Control sets should be stored at (2º - 8°C). The Syphilis Health Check kit is stable until the expiration date stated on the package label.

Warnings and Precautions

1. Do not use test cassettes if foil pouches are opened or defective.
2. Make sure the materials in the kit are at room temperature before use.
3. Always wear gloves when performing Syphilis Health Check.
4. Place the device on a clean flat surface facing up.
5. Use the pipette included in the kit only.
6. This test is designed for "in vitro diagnostic" use.
7. Read instructions carefully before using this test.
8. A positive test must be followed by or reflexed to a laboratory non-treponemal syphilis assay with titer information.
9. Clinical judgment is necessary for interpreting the test results.
10. A positive result may not be useful for establishing a diagnosis of syphilis infection. In some situations, such a result may reflect a prior treated infection; a negative result can exclude a diagnosis of syphilis except for cases of incubating or early primary disease where syphilis antibodies are not yet detectable.
11. In general, blood specimens may be potentially infectious. Avoid contact with skin by wearing gloves and proper laboratory attire. Properly handle and discard all used test devices in an approved biohazard container.
12. Avoid any contact between hands and eyes or nose during specimen collection and testing.

13. Do not use the buffer or cassette after the expiration date printed on the outside of each foil pouch.
14. Test cassettes are single use only.
15. Adding sample and buffer in the wrong order will result in an incorrect result.
16. Test buffer and Controls contain sodium azide as preservative that is a poison and may be harmful if swallowed. Seek medical help if buffer is swallowed.
17. Persons performing the test must be screened for colorblindness before performing the test.

The Test Was Invalid…Now What?

1. Identify the problem using the following list of potential problem areas.

   ___Were the tests stored within the proper temperature range (39°F and 86°F)?

   ___Was the temperature of the testing area within the proper range?

   ___Was the test used prior to the expiration date?

   ___Was the test kit at room temperature prior to testing?

   ___Was the lighting in the testing area adequate for proper testing?

   ___Was the desiccant present in the test pouch?

   ___Was the first drop of blood wiped away and testing performed on the second drop?

   ___Was the test device properly seated?

   ___Was the buffer solution added to the test device?

2. If it is determined that any of the above conditions caused the invalid test result, staff should document on the *Testing Log* in the "Comments" section - the troubleshooting process; actions taken; and how staff verified that the corrective action taken addressed the problem. Staff should use the other side of the log if more space is needed.

3. If it is determined that none of the above conditions caused the invalid result, perform a second rapid test either with another client specimen or with a set of external quality controls.

4. If a client specimen was used and the second test is also invalid - run a set of external quality controls.

5. If the control tests come back invalid, discontinue testing. Report the problem to the test manufacturer, (Trinity Biotech – 1-800-325-3424) and BCD Staff on page 3.

6. When the invalid result is not due to human error, the agency should contact the manufacturer's technical services department to report the invalid result.

Collection and Storage of Specimens

For Finger stick Whole Blood Collection:

1. Rub the chosen finger towards the tip and wipe the end of the finger with an alcohol wipe and a sterile pad.
2. Alcohol will affect the test. Let dry thoroughly.
3. Two drops of whole blood (50 µL) is required to perform the test.
4. Stick fingertip with a lancet.
5. The first drop of blood should be wiped clean with a sterile pad. NOTE: It is important that the first drop should NOT be used to avoid any potential interference from the alcohol.
6. Rub the finger towards the tip for two more drops of blood.
7. Using the fixed volume pipette provided in the kit, touch the end of the pipette to the drop of blood.
8. Holding the pipette horizontally, allow the blood to flow into the pipette on its own, making sure that there are no air bubbles or empty spaces or gaps in the specimen. If air bubbles or empty spaces or gaps are present, collect another sample.
9. It may be necessary to rub the finger for an additional drop of blood to get two drops.

For Venous Whole Blood Collection:

The serum or plasma specimen should be collected aseptically under the standard laboratory conditions, avoiding hemolysis. Fresh samples should be used for testing.
If the test is to be run within 8 hours after collection, the specimen should be stored in the refrigerator (2° to 8°C or 35° to 46° F). If testing is NOT performed within eight hours, the sample must be converted to serum or plasma and can be stored refrigerated (2° to 8°C or 35° to 46° F) up to five days. If testing is delayed more than five days, serum and plasma specimens should be frozen. The frozen specimen must be completely thawed, thoroughly mixed and brought to room temperature prior to testing.

- Avoid repeated freezing and thawing.
- Draw venous whole blood sample into a syringe or a vacuum collection tube containing EDTA as an anticoagulant for plasma or a red top tube for serum.
- Remove tube cap and touch the end of the pipette included in the kit to the blood in the tube by slightly tipping the tube and holding the pipette so the tip is in the blood.
- Aspirate the blood into the end of the pipette (> 2 drops) making sure that there are no air bubbles or empty spaces or gaps in the specimen. If a whole blood (with red cells) sample is used, TWO drops of whole blood (50 µL) are needed for the assay. If the red blood cells are separated, then ONE drop of serum or plasma (25 µL) is required to perform this test. If air bubbles or empty spaces or gaps are present, collect another sample.
- Replace cap on tube.
- Assay procedure.
- Allow samples and the Syphilis Health Check test devices to come to room temperature prior to testing.
- Remove the reaction device from its protective wrapper by tearing along the notch.
- Label the device with Test ID stickers (A-number stickers).
- Fill the pipette with specimen (whole blood, serum or plasma).
- Hold the pipette vertically, dispense one drop (25 µl) of serum or plasma into the sample well (small circle). If whole blood is used, dispense two drops (50 µl) into the sample well.
- Allow sample to be absorbed into the pad.

- Add four full drops of Diluent (200 µl) to the sample well (small circle). One more drop can be added, if the sample does not flow down the membrane. DO NOT USE WATER OR OTHER LIQUIDS.
- Set the cassette on a flat surface and incubate at room temperature (20 º to 26º C or 68º to 78º F) for 10 minutes.
- Read the results after 10 minutes. The result can be read up to 15 minutes. **Do not read after 15 minutes.**

Interpretation of Results

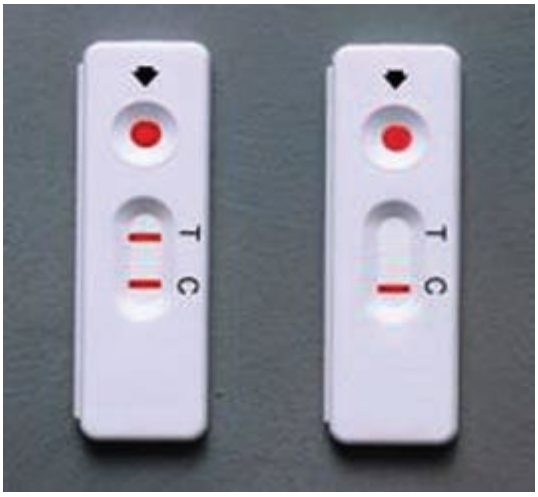
The assay is calibrated against commercially available serum "standardized" against the World Health Organization Reference Material and the cut-off confirmed with results obtained with uninfected patient samples and borderline treponemal positive samples diluted to assess the imprecision around the cut-off of the assay.

A. Negative: One colored band of any intensity appears in the "C" control area. This indicates a Non-Reactive result that is interpreted as Negative for Syphilis antibodies. No visible line in the test area is considered a negative result.

B. Positive: A line of any intensity appears in the device window adjacent to "T" Test and a second line of any intensity appears adjacent to "C" Control. This indicates a Reactive result that is interpreted as Presumptive Positive for Syphilis antibodies. Any visible red/pink line is considered positive.

C. Invalid: If there is no color band visible in the "C" control area, whether or not there is a line in the "T" test area, the test is invalid and cannot be interpreted. In this case, repeat the test with a fresh specimen using a fresh device.

Contact Trinity BioTech at 1-800-325-3424 and BCD Staff on page 3 if you are unable to produce a valid result upon repeat testing.



Positive: Two colored bands in test area AND control area,

Negative: One colored band in control area.

IMPORTANT:

In addition to the pink line by the Control mark ANY line that is seen near the Test mark of the cassette at the 10-minute time is considered a positive result. The intensity of the line does not matter.

A positive Syphilis Health Check result is not diagnostic of syphilis without additional non-treponemal serologic testing and a full clinical evaluation. A new venous whole blood specimen must be obtained for further testing.

Safety

- Follow OSHA safety guidelines for occupational exposure to blood-borne pathogens: http://www.osha.gov/SLTC/bloodbornepathogens/index.html and CDC's Exposure to Blood - What Health-Care Workers Need to Know: http://www.cdc.gov/ncidod/dhqp/pdf/bbp/exp_to_blood.pdf
- Wear appropriate personal protective equipment (PPE) such as gloves.
- Clean hands and change gloves between patients.

Follow work practices that reduce the risk of exposure including:

- handle all blood and body fluids as if they are infectious,
- use required PPE and safety devices,
- do not eat, drink, or apply cosmetics in the testing area,
- be cautious of exposure to mucous membranes such as eyes, nostrils, and mouth,
- wear goggles or face shields,
- avoid the use of needles and lancets if safe and effective alternatives are available,
- never re-use single-use devices such as needles and lancets,
- avoid recapping needles, transferring a body fluid between containers, and opening blood tubes,
- dispose of used sharps properly in puncture-proof sharps containers,
- report all occupational exposures promptly to ensure that you receive appropriate follow-up care,
- report any real or potential hazards you observe to the person who directs or oversees testing,
- participate in training related to infection prevention, and get hepatitis B vaccination.

Biohazardous Waste:
During the testing process, the biohazard bags and sharps containers used for disposal of contaminated materials should be:

- As close as possible to the immediate testing area,
- Upright throughout use,
- Replaced routinely, and
- Not overfilled.

Containers for contaminated waste must be:

- Constructed to contain all contents and prevent leakage of fluids during handling, storage, transport and/or shipping,
- Labeled or color-coded to indicate biohazard material, and
- Closed prior to removal to prevent spillage or protrusion of contents during handling.

L. STI/HIV Risk Reduction Post Rapid Results

What is discussed during the client centered discussion on STI/HIV risk reduction depends on whether the rapid test was reactive or non-reactive.

Reactive results:

The following information should be covered when counseling someone with a reactive result. Throughout this process, staff should provide emotional support to assist the client to cope while waiting for confirmatory testing to be done.

1. Interpret the result and assess client understanding of the result.
2. Explain and arrange or perform confirmatory testing.
3. Obtain commitment from client to return for confirmatory results.
4. Discuss what client intends to do during waiting time, including disclosure issues.
5. Encourage client to take precautions to avoid potentially transmitting the bacteria to others.
6. Assess need for referrals.
7. Inform the client that a representative for the local health department will be contacting them confidentially to interview them about the infection.
8. Report to local health department (refer to page 14 for reporting details)

1. *Interpret the result and assess client understanding of the result*: Reactive results are defined as "preliminary positives" by the CDC. However, this term may be confusing since some clients may not understand the word "preliminary," and "positive" has intense associations with it. By hearing the word "positive," clients may believe they are infected with syphilis, regardless of how the staff person describes this screening result.

   To more accurately convey that this result is an initial screen and requires confirmatory testing, staff should explain the result in the following manner:

   > *"Your test was reactive. It is important to do another test to find out whether you have a current syphilis infection."*
   >
   > *"Your test result shows that we need to preform another test to check whether you have syphilis."*
   >
   > *"Your test result indicated that you may have syphilis. Let's perform another test to confirm whether or not you are positive."*

Ideally, the client will understand the meaning of the result and the process of confirmatory testing based on your client centered discussion on STI/HIV risk reduction and explanation during the informed consent process. However, clients with a reactive result may require more explanation of the next steps in the testing process, referral for treatment if necessary, and why and how the health department is going to follow up with them.

Although the Syphilis Health Check is a screening test, reactive results generally results in a confirmed positive result that indicates a syphilis infection–especially when the client has been at risk. There is a 5% chance of a false positive among high risk populations. Therefore, although the client does not have a confirmed result, it is appropriate for the client to discuss their feelings and begin to deal with the possibility of infection. Staff should provide the client with written documentation of their result and explain how the treatment process works, if their infection is confirmed. In addition, staff should explain that if their infection is confirmed, then a health department will be following up with them confidentially to interview them about how they may have contracted syphilis.

2. *Explain confirmatory testing and prophylactic Rx*: A specimen for supplemental laboratory testing should be obtained immediately. If possible, a blood specimen should be drawn and prophylactic treatment given.

   Supplemental test results should be available from the WSLH, Kennan Health Center, or the Milwaukee City Health Department within one week.

3. *Obtain commitment from client to return for confirmatory result*: If the rapid test is reactive, staff should set an appointment with the client in one week to receive the confirmatory test result. You can call patient with syphilis test results if they come in sooner.

4. *Discuss what client intends to do during waiting time, including disclosure issues*: Waiting for the confirmatory result will create anxiety for many clients. Staff should discuss how clients intend to cope during this waiting period and whom – if anyone – they intend to tell about their rapid test result. As with someone who has just received a confirmed positive result, staff should discuss with the client who they will trust with the result, and the potential ramifications of disclosing their result widely. If their confirmatory result is negative, the client may also have to contend with people who mistakenly believe that he/she is truly infected with syphilis.

5. *Encourage client to take precautions to avoid potentially transmitting syphilis to others*: Staff should encourage and support the client in using risk reduction behaviors to avoid potentially transmitting syphilis to others. This includes examining the client's possible risk behavior during the waiting period and developing a plan with the client for modifying this behavior.

6. *Assess need for referrals*: The client may need emotional support during this waiting period. Minimally, staff should offer to be a support to the client by phone or in person. In addition,

the client may need referrals to a mental health counselor, risk reduction specialist, or crisis line.

Staff should also mention the services that are available to them if their confirmatory test is positive. A brief description of Partner Services, as well as access to medical evaluation and care, case management, risk reduction counseling, legal services, and the drug reimbursement or health insurance programs should be provided.

Non-reactive results:

The following information should be covered when counseling someone with a non-reactive result:

1. *Interpret the result and discuss possible need for re-testing*: A non-reactive result is interpreted as negative unless the client has engaged in risk behavior within the last 3 months. If the client has engaged in risk behavior during this time, staff should recommend a re-test 3 months after their last exposure.

2. *Assess need for referrals*: Staff should assess for additional services needed by the client, such as AODA treatment, economic assistance, domestic violence services, housing, HIV testing, other STI testing and treatment, and hepatitis vaccination and testing in accordance with CDC guidelines.

M. Obtaining Devices and Controls

Agencies should contact BCD Staff on page 3, or through e-mail to obtain more tests and external quality controls. Agencies should order needed tests and controls at least two weeks before current inventories run out.

Agency staff should maintain sufficient inventory of both tests and controls so that rapid testing services are not interrupted.

If an agency cannot use all of their tests prior to the expiration date:

The lead staff person should contact BCD Staff on page 3 to find out whether another site can use the tests prior to expiration so that these tests are not wasted.

Staff should maintain an *Inventory Log (Appendix 1)* documenting the following:

- shipment receipt dates of test kits and controls
- lot numbers
- expiration dates
- when devices from the box were first used

Shipments with the earliest expiration dates should be used first. Tests should be kept in a secure area, and inventory should be reviewed to assure that the number of tests that remain are consistent with the number of tests that have been used.

N. Appendix 1

Rapid HIV and Rapid Syphilis Inventory Log – Test and Controls

Log each box of tests or external controls received.

Item Received (Tests or Controls)	Date Received	Lot #	Exp. Date	Date when item first used

O. Appendix 2

Rapid HIV and Rapid Syphilis Test Temperature Log

Thermometer location _____

Acceptable temperature range* _____

Month/Year _____

Day	Initials	High Temp	Low Temp	Corrective action taken when temperature is out of range
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				
16				
17				
18				
19				
20				

* The acceptable range for test kit storage is 4 to 30° C or 36 to 86° F and the acceptable range for control storage is 2 to 8°C or 35 to 46° F.

Reviewed by _____

Date reviewed _____

P. **Appendix 3**

Rapid Syphilis Test Risk Assessment

Please complete the section below with some information about yourself. This information is confidential.

Date of Birth (MM/DD/YYYY)	**County Where You Live**	**State Where You Live**	**Your ZIP Code**
Your Ethnicity	**Your Race (Check All That Apply To You)**	**Your Sex at Birth**	**Your Current Gender Identity**
□ Hispanic or Latino □ Not Hispanic or Latino	□ American Indian/Alaskan Native □ Asian □ Black/African American □ Native Hawaiian/Pacific Islander □ White	□ Male □ Female	□ Male □ Female □ Transgender Male to Female (MTF) □ Transgender Female to Male (FTM)
Have you ever been tested for syphilis? □ No □ Yes □ I Don't Know		**If you have been tested for syphilis before, what was the result?** □ Negative □ Positive □ Don't Know	
What is your current HIV status? □ Negative □ Positive □ I Don't Know		**If you are HIV negative, are you currently on PrEP (pre-exposure prophylaxis)?** □ Yes □ No	

Please check the square to the right of each question to indicate No, Yes, or I don't know.

In the past 12 months, have you:	No	Yes	I don't know
Had oral sex with a male?			
Had vaginal or anal sex with a male?			
Had vaginal or anal sex with a male without using a condom?			
Had vaginal or anal sex with a male who is HIV+?			
Had vaginal or anal sex with a female?			
Had vaginal or anal sex with a female without using a condom?			
Had vaginal or anal sex with a female who is HIV+?			
Had vaginal or anal sex with a transgender person?			
Had vaginal or anal sex with a trans person without using a condom?			
Had vaginal or anal sex with a trans person who is HIV+?			
If you are female, have you had sex with a man who has sex with men?			

Q. Appendix 4

Syphilis Testing Log

Agency: _____ Location: _____ Date Opened: _____

Device Lot Number (on box): _____ Device Expiration Date: _____

Control Lot No.(on box): _____ Control Exp. Date _____

Date	Testing I.D. Sticker or +/- Control	Staff Initials	Temperature	Start Time	Read Time	Internal Control Valid?	Result Pos/Neg/Inv	Confirmatory Result pos/neg	**Comments:** -Indicate reason for running control -If test is invalid, indicate next steps -If rapid test is reactive, indicate whether client received confirmatory test results

R. **Appendix 5**

[Name]

[Organization]

Rapid Testing staff contact: [Name]

[Phone Number]

Syphilis Health Check Rapid Syphilis Test Result

Date of rapid syphilis test: _____

Client Name or Code: _____

_____ Your rapid syphilis test result was non-reactive. This result means that either you do not have syphilis infection or you have been exposed too recently to find out if infection has occurred. If you have had risk exposure in the last month, you should have a repeat test one month after your last exposure to be sure that you are not infected.

_____ Your rapid syphilis test result was reactive. A confirmatory test is required to determine whether you have a current syphilis infection or have ever been exposed to syphilis. A blood specimen from you will be submitted for confirmatory testing today and results of this test will be available within one week. While you are waiting for your confirmatory result, you should be sure to avoid transmitting the bacterium to others in case you are infected.

If you have any questions regarding your test result, please contact the person at the phone number listed above