Community Based Organization Rapid Syphilis Test Quality Assurance (QA) Manual

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Revision History

Version	Date	Description of Changes
1.0	12/23/15	Original document
1.1	2/26/16	Added Syphilis Information and Testing Agreement form to Appendix
1.2	3/23/16	Updated counseling messages
1.3	4/11/16	Updated Epi-1 sample form
1.4	9/7/16	Added Conflict of Interest statement

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Acknowledgements

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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 simple 10 minute, 2-step procedure utilizing a finger-stick, which affords the following features and benefits:

- 98% agreement with reference treponemal assays;
- 100% 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;

Recommended Use

The Syphilis Health Check is ideal for use in outreach and other venues where syphilis testing is being offered to high-risk individuals and where the follow-up with those individuals who test positive is difficult. Specific venues include:

- Outreach to at-risk women who are pregnant
- Clinics designated for men who have sex with men (MSM);
- Outreach to commercial sex workers;
- Outreach to MSM venues;
- Testing sites performing rapid HIV testing; and
- Community-based testing in areas of high syphilis morbidity

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

Target Populations

- The Syphilis Health Check is not a test that should be offered to everyone. It is important that a detailed risk assessment be conducted prior to the offering of the test.
- 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 (i.e. rapid plasma regain or RPR) 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 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.

Conflicts of Interest

Agencies should not provide testing to persons who are employed by the agency providing testing. Additionally, if the client to be tested is a friend or associate of the test counselor, and either the client or the test counselor is uncomfortable with the situation, the test counselor shall immediately locate another staff person to provide services to the client. The counselor should verify that that the client is comfortable with the test counselor performing the counseling and knowing their test result. Test counselors should not provide syphilis testing to their co-workers. Agencies should assist their staff in locating another test site for services.

Adherence to Manufacturer's Instructions

Certain steps need to be taken even before a test is 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.

Shelf Life

Syphilis Health Check (both cassettes and controls) has a 2-year shelf life from the date-of-manufacture.

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.

- Check inventory regularly to ensure enough reagents and supplies are on hand for testing.
- Check and record expiration dates of reagents/kits, and discard any reagents or tests that have expired.
- Check and record temperatures of the testing and reagent storage areas. See Appendix A for samples of daily temperature logs.
- Check that all kit reagents came from the same kit lot. Do not mix reagents.
- Inspect reagents for damage, discoloration, or contamination; discard if found.
- Prepare reagents according to manufacturer's instructions.
- Allow time for refrigerated reagents/samples to come to room temperature prior to testing
- Perform equipment calibration checks, as needed, following the manufacturer's instructions.

- Perform testing in a well-lit area.
- Inspect equipment and electrical connections to be sure they are working.
- 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:

- Read and understand the manufacturer's instructions and/or site specific procedure.
- Keep a copy of the manufacturer's instructions on hand for easy reference.
- 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.
- File the current manufacturer's instructions and replace with an update if there are changes.
- Communicate all changes in the manufacturer's instructions to other testing personnel and to the person who directs or supervises testing.
- Follow safety precautions including Occupational Safety and Health Administration (OSHA) guidelines: http://www.osha.gov/SLTC/bloodbornepathogens/index.html
- Practice all tests, while an experienced person watches, before testing patient samples and reporting patient results.
- Document training on all tests in staff personnel files.

Syphilis Health Check Materials Supplied

Each kit contains everything needed to perform 20 tests.

- 20 test devices
- 20 disposable plastic fixed volume pipettes
- 5 mL diluent
- 1 Package insert

Additional Materials Needed

- Timer or watch
- Biohazard waste container
- Sharps container
- Disposable, absorbent workplace cover
- Disposable gloves
- Antiseptic wipes
- Sterile gauze pads
- Band-Aids
- Materials required to collect a venous whole blood specimen, or a sterile lancet to collect a fingerstick specimen producing a 50µl bleed

Quality Control (QC) Testing

Quality control (QC) testing gives confidence that your results are accurate and reliable. The manufacturer's instructions or site specific procedure 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

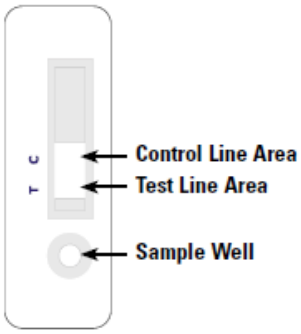
Internal Controls (also referred to as built-in or procedural controls) evaluate whether:

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

External Controls evaluate whether:

- The entire testing process is performed correctly, and
- 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 correctly. 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.

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, contact Trinity Biotech Technical Services at 866-358-9282.

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 non-treponemal assay with titer, such as RPR, along with a clinical evaluation, for diagnosis of syphilis. Patients with a positive treponemal test must be linked to a medical provider able to order the RPR and conduct a clinical evaluation.
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.

Tracking Quality Control

Documenting and tracking QC results can show whether a test is being performed correctly and if the test is working correctly. A periodic review of QC records can show whether the QC results are changing over time. This information can help identify problems that may be affecting patient testing and need to be addressed.

Actions for Unexpected QC Results

If controls do not give the expected results, patient results should not be reported until the problem is identified and corrected.

- Check to see if the manufacturer's instructions were followed correctly.
- Look for possible sources of error such as outdated reagents or test devices.
- Check to see if reagents were stored correctly.
- Make sure controls or reagents were not cross-contaminated by accidentally switching caps.
- Follow the troubleshooting steps in the manufacturer's instructions or site-specific procedure.
- For additional assistance, contact the manufacturer, technical representative, and/or the person(s) who directs or supervises the testing.

Once the problem is identified and corrected, repeat QC testing. If the QC results are acceptable, re-test patient sample(s) and report the final acceptable results.

Storage

All Syphilis Health Check kit components should be stored at (4º - 30°C). Test cassettes should be stored in their sealed pouch and are stable until the expiry date stated on the package label.

All Syphilis Health Check Control sets should be stored at (2º - 8°C).

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. 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.

Collection and Storage of Specimens

Video procedure can be found at: http://www.trinitybiotech.com/products/syphilis-health-check/

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.

Sample Selection and Addition to Device

A. Finger Stick Whole Blood for CLIA Waived samples

Sample Collection

- Using an alcohol wipe, clean the finger of the person being tested. Allow the finger to dry thoroughly or wipe dry with a sterile gauze pad as alcohol will affect the test.
- Using a sterile lancet, capable of producing a 50µl bleed, puncture the skin just off the center of the finger pad. (See picture 1)
- Apply gentle pressure beside the point of the puncture. Wipe away the first drop of blood with a sterile gauze pad. Allow a **second** drop of blood to form. If blood flow is inadequate, the subject's finger may be gently massaged to produce two droplets of sufficient volume.
- Collect the blood into the disposable plastic fixed volume pipette provided in the kit, following the procedure presented below. (See picture 2)
- Hold the pipette bulb gently in a horizontal position to the sample being collected. **This is important, as the specimen may not be adequately drawn in the pipette if the pipette is held in a vertical position.**
- Place the tip of the pipette into the sample, taking care not to squeeze the bulb. Allow the blood to flow into the pipette on its own. Making sure that there are no airbubbles, empty spaces, or gaps in the specimen. Maintain this position until the flow of sample into the pipette has stopped. The sample should fill to the mark on the pipette. (See picture 2) If sample is not collected to the mark, or if air bubbles, empty spaces or gaps are present, the pipette should be safely discarded and another specimen should be collected from another finger by repeating the sample collection process.

Sample Addition

- Holding the pipette vertically, squeeze the bulb until the sample is fully dispensed in to the sample well. If the sample does not fully dispense, cover the small opening at the mark on the pipette with gloved fingers and squeeze the bulb until the sample is fully dispensed. (See picture 3) Allow the sample to absorb into the paper in the sample well. Ensure air bubbles are not introduced into the sample port. Dispose of the pipette in biohazard waste.

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). If testing is NOT performed within 8 hours, the sample must be converted to serum or plasma and can be stored refrigerated (2 - 8ºC) up to 5 days. If testing is delayed more than 5 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 the patient's name or control number.
- 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 4 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 - 26ºC) for 10 minutes.
- Read the results after 10 minutes. The result can be read up to 15 minutes. Do not read after 15 minutes.

Run Sample

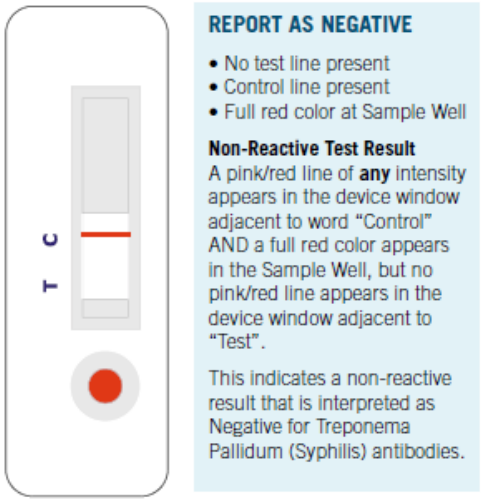
- Holding the dropper bottle of diluent in a vertical position, add 4 full drops (200 µl) in the sample well (small circle). One more drop can be added if the sample does not flow down the membrane. DO NOT USE WATER OR OTHER LIQUIDS. (See picture 4)

- Set timer for 10 minutes and set the cassette on a flat surface to incubate at RT (20 - 26ºC).
- Read the results after 10 minutes. The result can be read up to 15 minutes.
- PLEASE NOTE: Do not read after 15 minutes. (See picture 5)

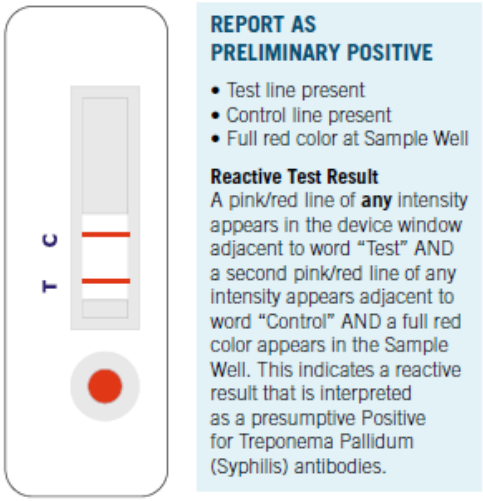
Interpretation of Results

The assay is calibrated against commercially available serum "standardized" against the WHO 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.

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.



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.



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.

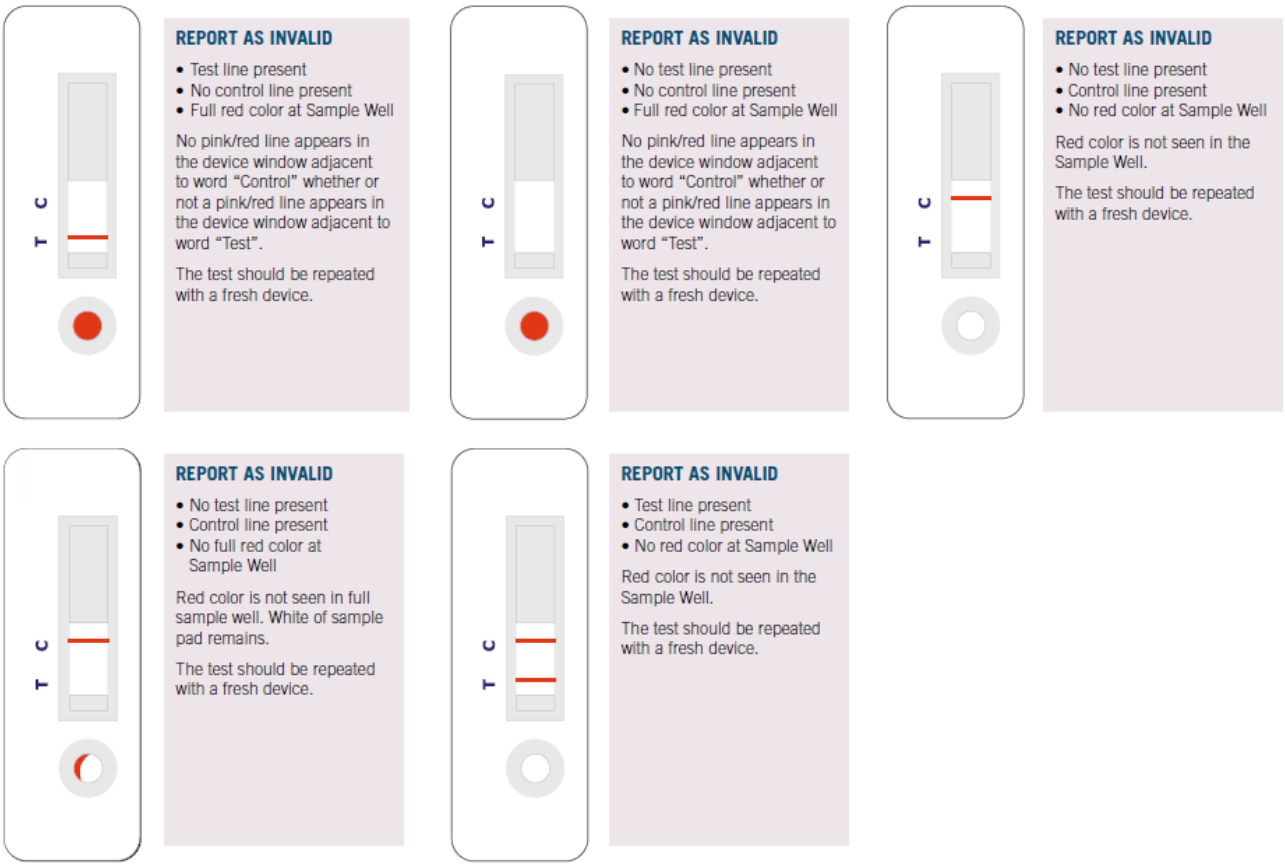
Contact Diagnostic Direct Technical Services at 866-358-9282 if you are unable to produce a valid result upon repeat testing.

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 SHC 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.

Invalid Results

For a test to be valid a control line must be present and the sample well must contain full red color.



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.

OSHA Requirements

All sites that collect blood samples for traditional and/or rapid testing must meet the OSHA standards for blood-borne pathogens. Providers must establish a written Exposure Control Plan designed to eliminate or minimize employee exposures to occupational risks. Providers must provide PPE to employees at no cost. Examples of PPE are latex or vinyl gloves, eye protectors, and lab coats. If a problem arises with an article of PPE, the provider must repair or replace it at no cost to the employee. Providers must develop an Exposure Control Plan, which must be readily accessible to all employees who may encounter occupational exposure. Providers must provide hand-washing facilities, which are readily accessible to all employees. If hand washing facilities are not feasible, the provider must provide either an appropriate antiseptic hand cleanser or antiseptic towelettes.

Areas where there is a reasonable likelihood of occupational exposure include eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses. Food and drinks must not be kept in refrigerators, freezers, shelves, cabinets or on countertops or bench tops where blood or other potentially infectious materials are present.

The employer must ensure that all medical evaluations and procedures including the hepatitis B vaccination series, post-exposure evaluation and follow-up, including prophylaxis, are made available at no cost to employees. Following a report of an exposure incident, the employer shall immediately make available to the exposed employee a confidential medical evaluation and follow-up. Providers must contain and dispose of biohazardous waste in accordance with applicable regulations and develop a plan to ensure proper biohazardous waste and sharps disposal.

Information regarding OSHA standards can be found at: Blood-borne Pathogens Standards. https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=10051&p_table=STANDARDS

Clinical Laboratory Improvement Amendments (CLIA) Requirements

There is an important distinction between traditional syphilis testing and rapid testing. Sites that conduct traditional syphilis testing obtain a specimen and send that sample to a laboratory where testing is performed. Sites conducting rapid syphilis testing are considered to be a clinical laboratory and are held to laboratory standards. Rapid test sites must possess a CLIA waiver which designates the facility as authorized to perform waived rapid syphilis testing.

Prior to initiating a rapid testing program, sites must be issued a CLIA waiver and number from the U.S. Centers for Medicare and Medicaid Services (CMS). A CLIA Certificate of Waiver allows these sites to perform FDA approved waived rapid tests. For special events, and on a limited basis, sites may offer rapid testing at locations not on the CLIA waiver with the written approval of the area STD Program Manager. Email exchange for approval is acceptable. All rapid testing sites must adhere to the standards of a waived rapid testing venue.

The CLIA of 1988 established quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results. A laboratory is defined as any facility that performs testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention, treatment of disease, or impairment of, or assessment of health. Federal law requires that all laboratories performing testing, no matter what type, must obtain a CLIA certificate and number. For more information about the CLIA waiver application process, visit CMS CLIA website.

Forms

For positive rapid syphilis tests the Rapid Syphilis Test Assessment form and the Epi-1 should be faxed together as one transmission to the local health department and to the Division of Disease Prevention (DDP).

For negative rapid syphilis tests the Rapid Syphilis Test Assessment forms should be sent via mail to DDP on a monthly basis (by the 10th of the following month).

Counseling Messages

The following are suggested counseling messages to discuss with your client.

Have you ever been diagnosed or treated for syphilis before? AND/OR
Has anyone you've had sex with told you that they had syphilis?

- **No:** "We will run both tests, and we will share your HIV information with you first before discussing the syphilis test results." Follow your normal messaging for pre-test counseling regarding rapid/rapid protocol.

    - "If the rapid syphilis test is positive today, you will need additional testing to determine if you have a new case of syphilis. We work closely with the local health department to arrange that."
- **Yes**: If you have had syphilis before, we can't use our rapid syphilis test with you because it would pick up that old infection. **If a sex partner has told you they have syphilis, we will refer you to the health department promptly for full evaluation and medical care**. Have you had any symptoms of syphilis since your last treatment? [Show pictures when appropriate]
    - **No**: Give information on how to get tested at the health department if they need to in the future.
    - **Yes**: Refer the client to the health department immediately for testing and follow-up.

Positive rapid syphilis test, negative rapid HIV test, DIS is available

- Give patient his/her test result. Explain the need to go to the health department for further follow up.
    - "Based on the result of the rapid syphilis test, it is very important for you to go to the health department for additional tests and further follow up to determine if you have a new case of syphilis. They will talk with you about your history, do further testing and a doctor will decide if you need treatment. I can take you to the health department right now."
    - If the patient asks about treatment for partners, explain that the health department will help them determine the best plan of action once they have met with the patient.

Positive rapid syphilis test, negative rapid HIV test, DIS not available

- Give the patient his/her test result. Explain the need to go to the health department for further follow up.
- Work with your LHD to coordinate linking the patient
    - "Based on the result of the rapid syphilis test, it is very important for you to go to the health department for additional tests and further follow up to determine if you have a new case of syphilis. They will talk with you about your history, do further testing and a doctor will decide if you need treatment. They are not open at this time, but I can schedule an appointment for you on _____. If you need assistance getting there, you can come here and I can take you over there."
    - If the patient asks about medication for partners, explain that the health department will help them determine the best plan of action once they have met with the patient.

Positive rapid syphilis test, positive rapid HIV test, DIS is available

- Give the patient his/her preliminary HIV test results.
    - Provide the result of the first HIV test. Explain process for second HIV test.
    - Do not address the syphilis result at this time
    - Once the second HIV test is completed, provide the result of the HIV test. Provide appropriate support for the HIV result, answer all questions and address all concerns, then provide linkage to care. The DIS will handle interviews for both infections.

    - If the patient asks about HIV testing for their partners, work with them to determine the best plan of action and explain that they can come into the CBO or the health department. We will be working with the LHD to determine the best plan of action once they have met with the patient.
- Once the HIV result has been addressed and the patient is comfortable with next steps, explain the next steps for syphilis testing.
    - "Based on the result of the rapid syphilis test, it is very important for you to go to the health department to determine if you have a new case of syphilis. They will talk with you about your history, do further testing, and a doctor will decide if you need medication. I can take you to the health department right now."
    - If the patient asks about medication for partners, explain that the health department will help them determine the best plan of action once they have met with the patient.

ACCESS, FFC, CCS Only: Positive rapid syphilis test, positive rapid HIV test, DIS is available

- Give the patient his/her preliminary HIV test results.
    - Provide the result of the first HIV test. Explain process for second HIV test.
    - Do not address the syphilis result at this time
    - Once the second HIV test is completed, provide the result of the HIV test. Provide appropriate support for the HIV result, answer all questions and address all concerns, then provide linkage to care. Proceed with partner elicitation interview, prepare FR and IR for HIV, indicate rapid syphilis positive on both the IR and FR, and send originals to DDP, with copy to LHD.
    - If the patient asks about HIV testing for their partners, work with them to determine the best plan of action and explain that they can come into the CBO or the health department. We will be working with the LHD to determine the best plan of action once they have met with the patient.
- Once the HIV result has been addressed and the patient is comfortable with next steps, explain the next steps for syphilis testing.
    - "Based on the result of the rapid syphilis test, it is very important for you to go to the health department for further follow up to determine if you have syphilis. They will talk with you about your history, do further testing, and a doctor will decide if you need medication. I can take you to the health department right now."
    - If the patient asks about medication for partners, explain that the health department will help them determine the best plan of action once they have met with the patient.

Positive rapid syphilis test, positive rapid HIV test, DIS not available

- Give the patient his/her test results.
    - Provide the result of the first HIV test. Explain process for second HIV test. (Do not address the syphilis result at this time.)
    - Once the second HIV test is completed, provide the result of the HIV test and syphilis test. Provide appropriate support for the HIV result, answer all questions and address all concerns, then provide linkage to care for HIV. Agencies that conduct partner elicitation services can discuss that with client at this point.

- If patient is going to tell their own partners about HIV status and have them report to the same CBO for testing, explain the necessity of telling them about the syphilis test as well.
- Patient should explain to partners that they are positive for HIV, and that they may have syphilis as well, but further testing will need to be done to determine that.
- If the patient does not want to notify their partners of the syphilis result, discuss the process with the patient so they understand all the options. They may choose to have the DIS follow up on all partners for both infections if they are more comfortable with that.
- "Based on the result of the rapid syphilis test, it is very important for you to go to the health department for further follow up to determine if you have syphilis. They will talk with you about your sexual health history, do further testing, and a doctor will decide if you need medication. They are not open at this time, but I can schedule an appointment for you on _____. If you need assistance getting there, you can come here and I can take you over there."

Partners referred by a patient who is potentially dual infected

- Maintaining confidentiality
  - If a partner comes in and tells you that their friend sent them in and told them they need to be tested for HIV and syphilis, you should provide testing for both infections, and explain that regardless of the results of today's syphilis test, the person may need further evaluation and medication for syphilis.
    - Remember you *cannot* confirm anyone else's test result. You may only discuss syphilis evaluation based on what this patient tells you their partner told them.
    - "If your partner has syphilis, you may need medication even if today's result is negative. The health department may follow up with you regarding any additional evaluation you need."
  - If the partner comes in and tells you that their friend sent them in and told them they need to be tested for HIV but does not say anything about syphilis, you should introduce syphilis testing as you would to any patient of unknown status:
    - "Because anyone who has been exposed to HIV could also have been exposed to any other STD, we recommend also being tested for syphilis while you are here. We can run that test for you at the same time."

Ordering Information

Product	Part Number	Quantity	Storage
Syphilis Health Check™	VSC - 11 - 01	20 Test	4° - 30° C
Sphyilis Health Check Control Set	VSC - 11 - 02	1 positive 1 negative control	2° - 8° C

Test kits, controls, and lancets can be ordered directly through Trinity Biotech as they offer public health pricing to everyone.

Heidi Maxwell

Regional Account Manager

Trinity Biotech
2823 Girts Road
Jamestown, NY 14701
www.trinitybiotech.com

Phone: 800-325-3424 x 7212

Fax: 740-453-9870

heidi.maxwell@trinityusa.com

Appendix A – Temperature Log for Syphilis Health Check Controls

Refrigerator/freezer Location_____ Month/Year

Date	Temperature	Checked by:	Date	Temperature	Checked by:

Acceptable temperature range: (2º -8°C)

Corrective Action for Out of Range Temperature

Date	Action Taken	Initials

Reviewed by: _____Date: _/_____/___

Rapid Syphilis Test Assessment

Today's Date:_____/_____/_____ **Your age**: _____

City or County of Residence: _____ **State**: _____ **Zip**: _____

Gender: ☐ Male ☐ Female ☐ Transgender (Male to Female) ☐ Transgender (Female to Male)

Race: ☐ White ☐ Pacific Islander/Hawaiian ☐ Asian
☐ Black ☐ American Indian/Alaska Native ☐ Other _____

Ethnicity: ☐ Hispanic or Latino ☐ Non-Hispanic

Have you ever been diagnosed with syphilis? ☐ Yes (If yes, you are not a candidate for the rapid syphilis test) ☐ No ☐ Not Sure

Sexual Health History in Past 12 Months (Check all that apply):
☐ Sex with male
☐ Sex with female
☐ Injection drug use
☐ Illicit drug use
☐ Met sex partner through internet or mobile app
☐ Sex with anyone you would not be able to contact again
☐ More than 1 sex partner
☐ Chlamydia or gonorrhea diagnosis
☐ Sex with someone who had syphilis
☐ Exchanged sex for money or drugs
☐ HIV positive
☐ Jail/prison
☐ Pregnancy

Symptoms in Past 12 Months (Check all that apply):
☐ Sore(s) in mouth/lips
☐ Generalized body rash
☐ Genital sore/ lesion
☐ Condyloma lata (wart-like lesions on genitals)
☐ Palmar/plantar rash (hands/ bottoms of feet)
☐ Sudden hair loss
☐ Swollen lymph nodes (groin)

For Office Use Only:

Test results: ☐ Positive (complete Epi-1 & attach) ☐ Negative ☐ Invalid

Site ID* of agency completing assessment: _____
*same ID used for HIV Testing

Mail or fax assessment forms to:
Fax: **(804) 864-7970**
Attention: DDP SODA

Virginia Department of Health
Division of Disease Prevention, 2nd floor
109 Governor Street
Richmond, VA 23219

VDH VIRGINIA DEPARTMENT OF HEALTH

Appendix C – Syphilis Information and Testing Agreement

A client signature indicating agreement to testing is not necessary when conducting rapid syphilis testing. However, suggested language is below for organizations desiring this documentation.

Testing provided by *(insert site name here)* is voluntary. By signing this form, you agree to take a test to determine if you have antibodies for *Treponema pallidum*, the bacteria that causes syphilis.

What kind of test is this?

You are receiving a **rapid test to determine if you have syphilis antibodies in your system**. Your immune system creates antibodies every time it is exposed to a new disease, which means that if you have antibodies for syphilis, you may be infected. Your tester is trained to conduct this test, and will use a fingerstick to collect blood. Your test results will be ready in 10-15 minutes.

How do people get syphilis?

Most often, people get syphilis by having unprotected sex with an infected person.

Is syphilis curable?

Yes. Syphilis infection can be cured with antibiotics.

Can I get syphilis more than once?

Yes. Having syphilis once does not protect you from getting it again. You can get re-infected.

What does my test result mean?

If your rapid syphilis test is negative, no antibodies for syphilis were found. However, if you recently had unprotected sex (within the last 90 days), there is a chance that you may be in the "**window period"**. This means that you may be infected, but your body has not developed antibodies yet. You should be tested again in three months.

If your rapid test is reactive or preliminary positive, you will need a follow-up laboratory test and medical evaluation to verify the result. Like many other communicable diseases, syphilis is a reportable condition in Virginia. Your tester will refer you to the local health department for follow up and medical care. Additional laboratory tests will be needed to confirm whether you have syphilis. You will need to return to the health department within 7-10 days to get your test results. The health department will protect your identity and your records.

Signature: _____ Date: _____

Printed Name: _____

Appendix D – Sample Epi-1 Form for Rapid Syphilis

Epi-1 form: http://www.vdh.virginia.gov/Epidemiology/documents/pdf/epi1.pdf

MAIL THE TOP TWO COPIES TO YOUR LOCAL HEALTH DEPARTMENT

VIRGINIA DEPARTMENT OF HEALTH
Confidential Morbidity Report

Patient's Name (Last, First, Middle Initial): Smith, John A.

SSN: 123 . 45 . 6789
Home #: (740) 123 . 4567
Work #: (740) 765 . 4321

Patient's Address (Street, City or Town, State, Zip Code): 123 South St, Norfolk, VA 23504

City or County of Residence: Norfolk

Date of Birth (mm/dd/yyyy): 05/20/1995
Age: 20
Race: ☐ American Indian/Alaskan Native ☐ Asian ☒ Black/African American ☐ Hawaiian/Pacific Islander ☐ White ☐ Unknown
Hispanic: ☐ Yes ☒ No
Sex: ☐ F ☒ M

DISEASE OR CONDITION: Syphilis
Pregnant: ☐ Yes ☒ No ☐ Unknown
Death: ☐ Yes ☐ No
Death Date:

Date of Onset: unknown
Date of Diagnosis: 11/20/15
Influenza: (Report # and type only. No patient identification)
Number of Cases:
Type, if Known:

Physician's Name: ACCESS AIDS Care
Phone #: (757) 625 . 6992
Address: 3309 Granby St. Norfolk, VA 23504

Hospital Admission: ☐ Yes ☒ No
Hospital Name:
Date of Admission:
Medical Record Number:

Laboratory Information and Results

Source of Specimen: blood
Date Collected: 11/20/15

Laboratory Test(s) and Finding(s): Rapid Syphilis Test

Name/Address of Lab: N/A
CLIA Number:

Other Information

Comments: (e.g., Risk situation [food handling, patient care, day care], Treatment [including dates], Immunization status [including dates], Signs/Symptoms, Exposure, Outbreak-associated, etc.)
patient reported ____ (risks/symptoms); referred/driven to _____ Health Department for RPR and follow-up on DD/MM/YY.

Name, Address, and Phone Number of Person Completing this Form:
Name of person who tested client
Clinic Name
Clinic phone #

Date Reported: 12/3/15

Check here if you need more of these forms, or call your local health department. (Be sure your address is complete.) ☐

For Health Department Use

Date Received:
VEDSS Patient ID:

Please complete as much of this form as possible

Form Epi-1, 10/2011

SAMPLE

VDH VIRGINIA DEPARTMENT OF HEALTH

Appendix E – External Control Log

The purpose of the External Control Log is to document performance of external positive and negative control tests.

Agency: _____ Site: _____ CLIA#: _____ Month/Year: _____/_____

Date	Site	Initials	QC Code	Test Kit		Control Kit			Non-reactive Control			Positive Control			Result Acceptable ?*	
				Lot #	Exp. date	Lot #	Closed vial exp	Open vial exp	Start time/ temp	End time/ temp	Result (circle one)	Start time/ temp	End time/ temp	Result (circle one)		
									: / °	: / °	**R N I**	: / °	: / °	**R N I**	Yes	No
									: / °	: / °	**R N I**	: / °	: / °	**R N I**	Yes	No
									: / °	: / °	**R N I**	: / °	: / °	**R N I**	Yes	No
									: / °	: / °	**R N I**	: / °	: / °	**R N I**	Yes	No
									: / °	: / °	**R N I**	: / °	: / °	**R N I**	Yes	No
									: / °	: / °	**R N I**	: / °	: / °	**R N I**	Yes	No
									: / °	: / °	**R N I**	: / °	: / °	**R N I**	Yes	No

Code (reason for running external controls)

1. New setting
2. New operator
3. New test kit lot
4. New test kit shipment
5. Environmental change-temperature outside range in storage area
6. Environmental change-temperature outside range in test area
7. Environmental change-low lighting
8. Scheduled, periodic test
9. Other (document reason on back of form)

Control Vial Expiration Dates

Closed vial expiration: expiration date printed on control unit package by manufacturer

Open vial expiration: eight weeks from the date vials are opened. This date should be written on the packaging when first opened and recorded above when used. Control unit may not be used if either open or closed expiration date has passed.

Result Codes:

R-Reactive
N -Non-reactive
I-Invalid

***Acceptable Control Results**

Both non-reactive and reactive control units must yield correct results. If either yields an incorrect result, result of external quality control procedure is unacceptable in this case. **DO NOT conduct client tests until problem is resolved.** Document problem and corrective action taken on back of this form.

Initial Review: _____ _____/_____/_____
Signature Date

Final Review: _____ _____/_____/_____
Signature Date