III. A. 3. MCH Success Story

Congenital Syphilis Point of Care Tests Survey Results

To evaluate the uptake of these recommendations in hospitals, the Tennessee Department of Health (TDH) conducted a survey of Tennessee hospitals. Of the 46 hospitals that responded, 8 hospitals were not aware of Tennessee Health Alert Network (TNHAN) and 5 of which wanted to connect with TDH to gain awareness. Of the 46 hospitals, the stages of readiness for implementation varied (5 in pre-contemplation, 21 in contemplation, 2 in preparation, 8 in action, 7 in maintenance, 0 in lapse, and 12 were unsure.) Of the 8 hospitals in the action stage of readiness, 4 had unit specific changes and 4 have system wide changes. Finally, 12 hospitals had a policy for immediate treatment and 43 did not. Hospitals that were not aware have been provided a copy of the TNHAN and new TDH congenital syphilis recommendations. Additional outreach has been offered to these hospitals to evaluate their protocols, make recommendations for changes, and assist with education.

PROTOCOL FOR POINT OF CARE SYPHILIS TESTING USING SYPHILIS HEALTH CHECK

Draft Protocol as of June 2024

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Syphilis FAQs

What is Syphilis?

Syphilis is a sexually transmitted infection (STI) caused by the bacteria *Treponema pallidum* that can cause serious health problems without treatment. Syphilis can be cured with treatment with antibiotics, but that might not reverse damaged already caused from the disease. That's why timely testing and treatment is very important.

Syphilis infection develops in stages and each stage can present with different signs and symptoms. These stages are primary, secondary, latent, and tertiary.

Syphilis Stages

Primary syphilis means the person has a lesion(s) (known as a 'chancre') at the site of infection. The chancre develops around 10 days to 3 weeks following exposure.

Secondary syphilis occurs when the person has a rash or sores on mucus membranes, or other signs and symptoms of secondary syphilis. The rash can form all over the body, and often is on the palms of hands and the soles of feet. Other symptoms can include:

- Fever
- Swollen lymph glands
- Sore throat
- Patchy hair loss
- Headaches
- Weight loss
- Muscle aches
- Fatigue

Latent syphilis occurs without signs or symptoms. Latent syphilis can be classified as early (the infection was acquired in the last year) or late (the infection was acquired more than 1year ago). This difference is important to the length of treatment.

Tertiary syphilis is rare. In this stage, the patient will have various symptoms as the infection can affect many different organ systems.

Photos and additional information about syphilis staging are available at National STD Curriculum (uw.edu)

Who Should be Tested for Syphilis?

Routine testing is recommended for the following populations:

- All pregnant persons and their partners
- Men who have sex with men
- People diagnosed with HIV or other STI's
- People who use drugs
- People who have been incarcerated
- People in sex work
- People living in areas with a high prevalence of syphilis between the ages of 18-44

How Does a Person Contract Syphilis?

A person can contract syphilis from direct contact with a syphilis sore during vaginal, anal, or oral sex. Additionally, syphilis can pass to a fetus during pregnancy or at time of delivery.

Dispelling Syphilis Transmission Misconceptions

You cannot get syphilis from casual contact with toilet seats, doorknobs, swimming pools, or sharing clothing or eating utensils.

How does a person prevent syphilis?

Get tested and treated as recommended and encourage partner(s) to get tested
Consistent and correct condom use
If visible signs of syphilis are present or you have been told you have been exposed to syphilis, refrain from having sex

Is syphilis curable?

Yes, syphilis is treatable and curable with antibiotics.

Is it possible to get re-infected with syphilis?

Yes, it is possible to become re-infected if re-exposed or if all partners are not treated for infection.

Requirements for Testing using Syphilis Health Check

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 are classified as "waived" by the FDA when used with whole blood. 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 https://www.cms.gov/medicare/quality/clinical-laboratory-improvement-amendments.

OSHA Requirements
All sites must adhere to the OSHA Occupational Exposure to Bloodborne Pathogen standard (https://www.osha.gov/bloodborne-pathogens) 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 follow an exposure control plan and implement the bloodborne pathogen controls standard.

Establishing 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.

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

Compliance with all quality assurance (QA) activities detailed in the package insert and additional activities delineated by the Tennessee Department of Health STI Program.
Ensure quality testing by following all testing requirements detailed in the most current package insert.
Competence in conducting finger stick tests and blood draws and 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.
Documenting testing process and results.
Recording the storage temperature of test devices and external controls.
Communicating testing problems as identified and taking action to ensure that the test is providing valid and reliable results.

Adherence to all program record-keeping and data collection requirements.
Testing staff must document all testing processes, including receipt of inventory; storage temperature of tests and controls; and details related to conducting clinical tests and external controls. Testers must also complete the syphilis risk assessment with their clients.

Reactive tests must be reported to the local health department within 1 week by the tester using NBS or REDCap. Physical reporting forms, PH-1600, can be found here:
https://www.tn.gov/health/cedep/reportable-diseases.html
Tests and results must be documented as required in Electronic Health Record and/or NBS

Considerations Prior to Testing

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 the testing and counseling timeframe to be at least 30 – 60 minutes.

Each testing site or event will need to review how flow is established based on their personnel resources and other logistics of the setting. Staff should assure availability and time 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.

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 and the need for additional lab-based testing (non-treponemal test) with reactive results.

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 this test.

Relevant information regarding time between possible exposure to syphilis and when the test is likely to identify a syphilis infection. (The period for this test is three months, with a likelihood of four weeks). 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.

An assessment of the 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.

Rapid Syphilis Testing in Non-Traditional or Outreach Settings

The following conditions and considerations should be accounted for before conducting rapid syphilis testing in non-traditional or outreach settings.

Physical Considerations:

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 and throughout transport should be within the operating temperature for the test specified in the package insert and this protocol (68 to 78.8 ° F)

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 inthe area where testing is performed.

Psychosocial Considerations

A **confidential, private space for testing, counseling, and providing results:** staff must ensure tests develop in a private place where only the testing staff can view results. Clients should also be provided the STI/HIV risk assessment, sexual health education, and results in a confidential space.

- *Implementation consideration: If a client meets with staff for a longer period of time than those clients with a non-reactive result, this may inadvertently break confidentiality, since others may assume the client had a reactive result.*

Testing staff should be **prepared to explain a reactive result**: Staff providing rapid testing in an outreach setting must be adept at interpreting a reactive result, prepared to support a client through additional syphilis serology testing process, and ready to respond to a client in crisis.

Testing staff should be **prepared to collect additional blood samples and provide necessary treatment or link clients to additional syphilis serology testing, treatment, and other sexual health services.**

- *Implementation consideration: In outreach settings staff may have the inability to access on-site agency resources and support that are usually available in the clinic setting. Staff should know what referrals can be immediately accessed and be ready to link the client.*

Using Syphilis Health Check

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.

Features of the Syphilis Health Check

- Only rapid syphilis test with FDA Clearance and CLIA-waived
- Simple 2-step procedure utilizing a finger-stick
- Quick 10 minute processing time
- Ability to be stored at room temperature
- 98 percent agreement with reference treponemal assays
- 100 percent agreement with clinically diagnosed samples
- Detects both IgG and IgM to aid in the detection of early syphilis
- Utilizes multiple recombinant syphilis antigens (TP-15, TP-17, and TP-44 for optimized sensitivity and specificity)

When to Use Syphilis Health Check

The Syphilis Health Check should only be offered to clients who have no history of syphilis infection. Consider prioritizing the following individuals for testing:

- All pregnant persons and their partners
- Men who have sex with men
- People diagnosed with HIV or other (non-syphilis) STI's
- People for whom transportation to the health department or access to a healthcare setting is a challenge
- People who use drugs
- People who have been incarcerated
- People in sex work
- People living in areas with a high prevalence of syphilis and between the ages of 14-44

When Not to Use Syphilis Health Check

Since Syphilis Health Check is a treponemal assay it is not recommended as a screening test for individuals with a history of syphilis regardless of treatment history. If someone has been previously diagnosed with syphilis a serologic specimen should be drawn for standard lab-based testing.

What to do If Syphilis History is Unknown

If an individual is unsure whether they have a history of diagnosed syphilis, check NBS and PRISM to see if there is evidence the person has been previously diagnosed with syphilis and proceed accordingly.

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 requirements according to manufacturer's instructions. When storing test kits, the temperature of the area should be between 39.2 ° F to 86 ° F. The temperature that the testing environment should maintain is between 68° F to 78.8 ° F.

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

1. Check and record expiration dates of reagents/kits and discard any reagents or tests that have expired.
2. Check and record temperatures of the testing and reagent storage areas. See Appendix. Check that all kit reagents came from the same kit lot. Do not mix reagents.
3. Inspect reagents for damage, discoloration, or contamination, and discard if found.
4. Prepare reagents according to manufacturer's instructions. Quick Reference Guide. Allow time for refrigerated reagents/samples to come to room temperature prior to testing (68º F to 78.8 º F).
5. Perform equipment calibration checks, as needed, following the manufacturer's instructions
6. Perform testing in a well-lit area.
7. Clean work surfaces before and after testing.

Important Note: Testing sites under a CLIA Certificate of Waiver must follow the current manufacturer's test instructions which can be located here: Quick Reference Guide.

The following steps should be taken to be sure the current test instructions are being followed:

1. Read and understand the manufacturer's instructions.
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.

   Important note: if you find changes communicate all changes in the manufacturer's instructions to other testing personnel.

4. Follow safety precautions including OSHA guidelines. https://www.osha.gov/bloodborne-pathogens

All persons testing samples must have training and demonstrate competence in all components of rapid syphilis testing.

Quality Controls

The manufacturer's instructions 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.

        - 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.

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.

Test Limitations

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. 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. 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. 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.

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. 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. Treponemal antibodies after treatment are not indicative of immunity to future syphilis infections. Performance characteristics of this device have not been established for matrices other than whole blood, serum or plasma. Assay performance characteristics have not been established for immunocompromised or immunosuppressed patients, cord blood, neonatal specimens, or infants. 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. Treponemal tests are not recommended in neonates to diagnose congenital syphilis as passive transfer of maternal antibodies can cause false positive results.

Performing Syphilis Health Check Test

Syphilis Health Check Materials

Materials Provided:

- Syphilis Health Check test device
- Disposable plastic fixed column pipettes
- Diluent in a dropper bottle
- Package insert

Materials not provided but required:

- Timer – 20 minutes
- Syphilis Health Check Control Set
- Cotton Swabs
- Alcohol pads
- Bandaids

Collection of Specimens

For Finger stick Whole Blood Collection:

1. Allow device to come to room temperature prior to testing.
2. Label device with patient identifier.

Sample Collection:

3. 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.
4. Using a sterile lancet, capable of producing two drops of whole blood (50µl), puncture the skin just off the center of the finger pad.

5. 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.
6. Collect the blood into the disposable pipette provided in the kit.
7. 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.
8. 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 air bubbles, 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.
    a. 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 by repeating the sample collection process.

Sample Addition:

9. Holding the pipette vertically, squeeze the bulb one drop at a time until the sample is fully dispensed into 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. 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.

Run Sample:

10. 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.
11. Set the cassette on a flat surface to incubate at room temperature.
12. Set timer for 10 minutes.
    a. Read the results after 10 minutes. The result can be read up to 15 minutes.
        i. PLEASE NOTE: Do not read after 15 minutes.

Safety

Follow OSHA safety guidelines for occupational exposure to blood-borne pathogens: http://www.osha.gov/SLTC/bloodbornepathogens/index.html

Bloodborne Infectious Diseases: HIV/AIDS, Hepatitis B, Hepatitis C: https://www.cdc.gov/niosh/topics/bbp/

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.

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.

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.

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.

IMPORTANT:
In addition to the pink Control line ANY line that is seen near the Test line 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 venous whole blood specimen must be obtained for further testing.

STI Post Test Counseling

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 additional testing to be done.

Interpret the result and assess client understanding of the result.
Explain and arrange or perform additional syphilis testing. Both treponemal and non-treponemal testing is needed.
If additional blood testing not completed, obtain commitment from client to return for syphilis serology results.
Discuss what client intends to do during waiting time, including disclosure issues.
Encourage client to take precautions to avoid potentially transmitting infection to others.
Assess need for referrals.
Complete Partner Services interview or inform the client that a representative for the local health department will be contacting them confidentially to interview them about the infection.
Report to local health department.

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 a recent exposure or possibility of exposure within the last 3 months. If the client has a likelihood of recent exposure, 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 economic assistance, domestic violence services, housing, HIV testing, other STI testing and treatment, and hepatitis vaccination and testing in accordance with CDC guidelines.

Treatment

1. Prior to conducting any testing events, determine who will be receiving treatment in the event of a positive SHC.
2. For patients needing syphilis treatment in the field, ask about drug allergies prior to treatment. If the patient has no reported allergy to penicillin, treat with 2.4 million units of Bicillin IM X 1 (this may be divided in two 1.2-million-unit doses, one in each gluteus maximus).
3. Advise patient that if they have never tested before for syphilis, or they last tested more than 1 year ago, they will need two additional doses - one in 7 days and one in 14 days. They can obtain these doses at a local health department location. Please ask DIS on site for assistance with staging (i.e., how many doses need), scheduling follow-up doses and reminders. Please make sure we have good contact information for them.

4. For patients with a positive SHC and a reported penicillin allergy, the alternative treatment for syphilis is doxycycline. Doxycycline should not be given to pregnant persons. If the individual is pregnant, or can become pregnant (that is, have reproductive potential and are NOT using highly effective contraception such as IUD, Nexplanon, tubal ligation etc.) and have not menstruated in >28 days, call doctor on call. These persons should **1)** be tested for pregnancy; and **2)** if pregnant, have penicillin allergy testing and will possibly need desensitization. These steps will need to occur in a clinical setting.
5. If the individual is not pregnant, or not capable of pregnancy and reports a penicillin allergy, they may be treated with 28 days of doxycycline 100 mg PO BID. Before providing medication, counsel patient about: - Taking pill with a full glass of water and sitting up for 30 minutes after taking pill (to avoid pill esophagitis) - To avoid the sun while taking this medication (ok to use sunscreen)

Testing and Treating Contacts to Syphilis

1. Persons who are a sexual contact to syphilis and have not been treated, should receive a single dose of 2.4 million units of benzathine penicillin (PCN) (Bicillin) IM xl. They also should have a blood draw for a quantitative RPR and TPPA. Testing may be negative in incubating syphilis, that is, very early syphilis.
2. Person with history of syphilis (meaning they cannot use the SHC test) and are a recent contact to syphilis also should be treated. Draw quantitative RPR and treat with 2.4 million units of bicillin IM x 1

Note: Local treatment recommendations may be adjusted during bicillin shortages to include doxycycline as an alternative during prioritization. Follow local recommendations and PHN protocol for treatment decisions.

Reporting Results

Reactive tests must be reported to the local health department within 1 week by the tester using NBS or REDCap. Physical reporting forms, PH-1600, can be found here: https://www.tn.gov/health/cedep/reportable-diseases.html

Tests and results must be documented as required in Health Department Electronic Health Record (EHR) and/or NBS.

Appendix

Additional Resources

To receive technical assistance with treatment guidelines, ocular syphilis, neurosyphilis or specific case consultations, please contact the Tennessee Department of Health STI Prevention Program at STD.Health@tn.gov or 615-741-7500.

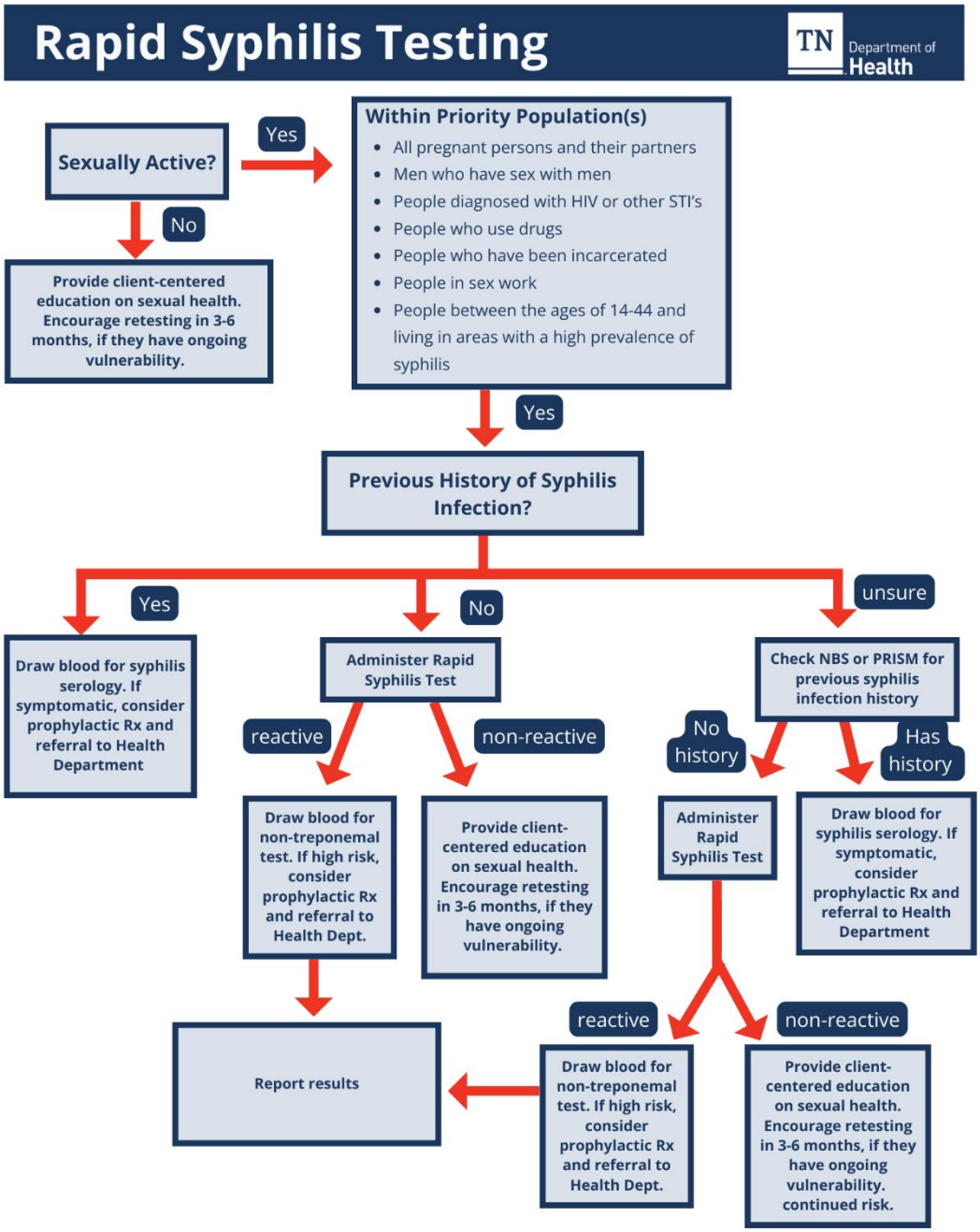
National Network of STD Prevention Training Centers Clinical Consultation Network: https://www.stdccn.org/render/Public

General information about syphilis can be found at: http://www.cdc.gov/std/syphilis/

STI Treatment Guidelines can be found: https://www.cdc.gov/std/treatment-guidelines/default.htm

CDC Laboratory Recommendation for Syphilis Testing: CDC Laboratory Recommendations for Syphilis Testing, United States, 2024 | MMWR

Rapid Testing Algorithm



*

Rapid Test Storage Temperature Log

Test Kit Location:			
Acceptable Temperature Range: +4 º C to +30 º C (39.2 º F to 86 º F)			
Month/Year:			
Date	Time	Storage Temperature	Initials of Tester

Syphilis Testing Log

Agency: _____ Location: _____ Date Opened: _____
Device Lot Number (on box): _____ Device Expiration Date: _____
Control Lot No.(on box): _____ Control Exp. Date _____

Date	+/- Control	Start Time	Read Time	Results +/- /invalid	Staff initials	comments

Neurosyphilis, Otosyphilis, and Ocular Syphilis Screener

Patients who are suspected of having otic syphilis, ocular syphilis, or neurosyphilis should be referred for immediate evaluation of these symptoms. Evaluation for neurosyphilis symptoms will often require a lumbar puncture.

<u>Symptoms of Otosyphilis</u> 1. Have you recently had new trouble hearing? 2. Do you have new ringing in your ears?	 □ Yes □ No □ Yes □ No
Consider evaluation and treatment for otic syphilis in patients with new onset sensorineural hearing loss, tinnitus, and vertigo.	
<u>Symptoms of Ocular syphilis</u> 3. Have you recently had a change or blurring in vision? 4. Do you see flashing lights? 5. Do you see spots that move or float by in your vision? 6. Have you recently had pain or redness in one or both eyes?	 □ Yes □ No □ Yes □ No □ Yes □ No □ Yes □ No
Consider evaluation and treatment for ocular syphilis in patients with new changes in vision, including loss of vision, blurring, seeing spots or flashing lights and pain and/or redness in one or both eyes.	
<u>Symptoms of neurosyphilis</u> 7. Have you recently been having headaches? 8. Have you had recent problems with memory or confusion? 9. Do you have trouble concentrating? 10. Do you feel that your personality has recently changed? 11. Are you having new problems walking? 12. Do you have weakness or numbness in your legs?	 □ Yes □ No □ Yes □ No □ Yes □ No □ Yes □ No □ Yes □ No □ Yes □ No
Consider evaluation and treatment for neurosyphilis in patients with new onset of headaches (or headaches that are different from their usual headaches); new and persistent change in personality, memory or judgment; new numbness or weakness in the face, arms or legs; and/or new gait incoordination.	

When referring a patient for evaluation, please communicate to the evaluating provider the need to assess specifically for ocular syphilis and/or neurosyphilis.