



POLICY AND PROCEDURE	
SUBJECT/TITLE:	Syphilis Health Check – Rapid Testing of Syphilis in SWAP
APPLICABILITY:	Nursing Department – Harm Reduction Programming/Laboratory Department
CONTACT TITLE & DIVISION:	Director of Nursing/Laboratory Manager
ORIGINAL DATE ADOPTED:	02/19/2025
LATEST EFFECTIVE DATE:	11/26/2025
REVIEW FREQUENCY:	Every 3 years and as needed
BOARD APPROVAL DATE:	N/A
REFERENCE NUMBER:	400-006-P Policy Development for numbering policies.

A. PURPOSE

The purpose of this policy is to integrate the Syphilis Health Check, a point-of-care rapid test for syphilis, into the Syringe Service Program, SWAP (Stark Wide Approach to Prevention). The policy outlines the procedures for administering the syphilis test and ensures proper care, confidentiality, and follow-up for individuals accessing services at the syringe exchange site. The Syphilis Health Check will be administered by the HIV testing clinician and is aimed at early detection, improving health outcomes, and reducing the transmission of syphilis in at-risk populations.

B. POLICY

The Syphilis Health Check will be offered as a routine service at SWAP, where it will be conducted by trained HIV testing clinicians. The program will follow the guidelines outlined in the Diagnostic Direct Protocol for Syphilis Health Check and will maintain the confidentiality and privacy of all participants. The test will be performed as a point-of-care rapid test, with results provided on-site. Positive results will be followed by immediate referral for confirmatory testing and treatment, as appropriate.

C. BACKGROUND

Syphilis is a bacterial infection that can lead to severe health complications if left untreated, including neurological and cardiovascular damage. People who inject drugs, especially those sharing needles and engaging in unprotected sex, are at a higher risk for syphilis transmission. The integration of the Syphilis Health Check into syringe service programs aims to address the gap in syphilis testing among people who inject drugs, promoting early detection and facilitating prompt treatment to prevent further transmission.

Rapid testing technologies like Syphilis Health Check provide a timely and efficient means to detect syphilis at the point of care, ensuring that individuals can receive immediate guidance on next steps. As part of a comprehensive harm reduction strategy, this protocol helps improve the overall health outcomes of participants in SWAP by identifying and addressing syphilis early.

D. GLOSSARY OF TERMS

- **Syphilis Health Check:** A point-of-care, rapid diagnostic test used to detect syphilis antibodies in blood samples.
- **Stark Wide Approach to Prevention (SWAP):** A harm reduction service that provides clean needles, syringes, and other supplies to individuals who inject drugs to reduce the transmission of bloodborne infections like HIV and Hepatitis C.



- **HIV Testing Clinician:** A health Department employee trained to conduct HIV and syphilis tests, offer counseling, and provide referrals.
- **Point-of-Care Test:** A medical test conducted at or near the site of patient care, allowing for rapid results without requiring laboratory processing.
- **Confirmatory Testing:** Follow-up testing conducted to verify the results of initial screening tests, typically in a laboratory setting.
- **Harm Reduction:** A public health approach aimed at minimizing the negative consequences of behaviors that may lead to adverse health outcomes, particularly for people who inject drugs.

E. PROCEDURES & STANDARD OPERATING GUIDELINES

- **Eligibility and Screening:**
 - The HIV testing clinician will offer the Syphilis Health Check to participants of the syringe service program who are at risk for syphilis, including individuals who inject drugs, engage in unprotected sex, or have a history of STIs.
 - Prior to testing, a brief screening for syphilis risk factors will be conducted, including an assessment of sexual and injection practices.
- **TEST ADMINISTRATION:**
- **TRAINING & COMPETENCY**
 - <https://diagnosticsdirect2u.com/course/syphilis-health-check-on-demand-training/>
- **MATERIALS SUPPLIED**
 - Each kit contains everything needed to perform 20 tests.
 - 20- SYPHILIS HEALTH CHECK Test devices
 - 2 - 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
- **STORAGE** All SYPHILIS HEALTH CHECK kit components should be stored at (4° - 30°C). Test cassettes should be stored in their sealed pouches.
 - **Do not freeze the test kit.**
 - The SYPHILIS HEALTH CHECK- kit is stable until the expiration date stated on the package label.
- **MATERIALS REQUIRED BUT NOT PROVIDED**
 - Timer - 20 min.
 - Syphilis Health Check Control Set, order from Diagnostics Direct LLC at (866) 358-9282.
 - CCPH laboratory will order all required controls.
- **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 nontreponemal 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 tested for colorblindness before performing the test.
- **QUALITY CONTROL**
 - Built-in 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.
 - 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:
 - 1) The Positive and Negative Controls, which are sold separately by the manufacturer, should be run according to the laboratory requirements.
 - 2) These controls should be run like an unknown patient specimen, and as required by your laboratory's standard QC procedures or Medical / Lab Director selected from any of the following examples
 - Each new lot
 - Each new shipment (even if from the same lot previously received)
 - Each new operator
 - Monthly, as a continued check on storage conditions
 - Whenever problems (storage, operator, or other) are identified



NOTE: 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 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 CCPH laboratory team and they will contact Technical Services at 866-358-9282.
- For any other concerns regarding Syphilis Health Check please call 866-358-9282 8am -6pm EST. Problems may also be reported using the MedWatch reporting system at <http://www.fda.gov/Safety/MedWatch/HowToReport/> or calling 1-800-FDA-1088 (1-800-332-1088).
- **COLLECTION AND STORAGE OF SPECIMENS** For Fingerstick 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. **See CDC finger stick Attachment.**
 2. Alcohol will affect the test. Let dry thoroughly to avoid contamination.
 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 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.
 10. Whole Blood samples collected by finger-stick should be used on the Syphilis Health Check test devices immediately after collection.
- **ASSAY PROCEDURE**
 1. Allow the Syphilis Health Check test device to come to room temperature prior to testing. Finger-stick whole blood samples should be used immediately after collection.
 2. Remove the reaction device from its protective wrapper by tearing along the notch.
 3. Label device with the patient's accession number.
 4. When whole blood from a finger stick is used, dispense two drops (50 µl) into the sample well.
 5. Allow sample to be absorbed into the pad.



6. Hold the diluent dropper bottle vertically and slowly add 4 full drops (200 µL) into the sample well (small circle) at an interval of 2-3 seconds between each drop. One more drop can be added if the sample does not flow down the membrane. **DO NOT USE WATER OR OTHER LIQUIDS.**
7. Set the cassette on a flat surface and incubate at room temperature (15 - 30°C) for 10 minutes.
8. Read the results after 10 minutes. The result can be read up to 15 minutes.

NOTE: Do not read after 15 minutes.

- The Syphilis Health Check will be administered by a trained HIV testing clinician. The test is to be conducted at the point of care using a blood sample from a fingerstick.
- **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 pink/red line 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 pink / red line in the test area is considered a negative result.
 - **POSITIVE** - A pink/red 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 pink/red only line is considered positive.
 - **INVALID** - If there is no color line 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.

NOTE: IMPORTANT: In addition to the pink / red line by the Control mark ANY pink/red only 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.

- All client information, including test results, will be stored securely and maintained confidentially per federal and state guidelines. No information will be shared without the client’s consent, except as required for follow-up care and reporting.

Nontreponemal	Treponemal Result	Report/interpretation for all except neonates or infants*
Nonreactive	Negative (Nonreactive)	No serologic evidence of infection with T. pallidum (incubating or early primary syphilis cannot be excluded).
Reactive	Negative (Nonreactive)	Current infection unlikely; probability of Biological False Positive (BFP) secondary to other medical conditions (febrile diseases, immunizations, intravenous drug use, autoimmune diseases, etc.). Recommend repeat testing (nontreponemal, and treponemal by other test method).



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Nonreactive	Positive (Reactive)	Probably past treated infection or untreated latent infection (e.g., if no history of previous treatment); rarely due to potential cross-reactivity with other spirochetes/related antigens. Recommend to treat (if untreated latent infection) or additional testing consistent with clinical findings/history.** Possibility of false negative NT due to incubating syphilis or prozone in secondary syphilis, late latent syphilis, or late neurosyphilis.
Reactive	Positive (Reactive)	Presumptive evidence of current infection or inadequately treated infection, persistent infection, reinfection, or serofast if prior history of treated syphilis). Recommend additional testing consistent with clinical assessment. **
Nonreactive	Not done	Current infection unlikely; effectively treated infection if previously treated; cannot exclude incubating or early primary syphilis; cannot exclude latent or neurosyphilis. Treponemal testing advised if clinical suspicion is present of latent or neurosyphilis. Recommend repeat testing if risks are present
Not done	Negative (Nonreactive)	Current or past treated infection unlikely unless treated early in the incubating or early primary syphilis stage; cannot exclude incubating or early primary syphilis. Recommend repeat testing if risks are present

*HIV-infected individuals may have delayed sero-reactivity or negative serology albeit very rarely.

**Nontreponemal testing with titer; clinical history; repeated (sequential) serological testing for changes in titer

- **Referral and Treatment:**
- Individuals with positive results will be referred to the DIS and CCPH’s STI clinic for treatment, including antibiotics as recommended for syphilis.
- The clinician will provide support and assist in connecting clients with additional healthcare resources, including STI and HIV care services.

F. CITATIONS & REFERENCES

Centers for Disease Control and Prevention (CDC). (2020). **Syphilis – CDC Fact Sheet**. Retrieved from <https://www.cdc.gov/std/syphilis>

U.S. Department of Health and Human Services (HHS). (2020). **Harm Reduction and Syringe Service Programs**. Retrieved from <https://www.hhs.gov>; <https://www.hhs.gov/sites/default/files/OASH-Syringe-Service-Programs-Webinar-07302019.pdf>; <https://www.hhs.gov/overdose-prevention/harm-reduction>

Diagnostic Direct. **Syphilis Health Check Protocol** (2023). Internal protocol and testing guidelines for Syphilis Health Check.

G. CONTRIBUTORS

The following staff contributed to the authorship of this document:

1. Diane Thompson, MSN, RN, Director of Nursing
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H. APPENDICIES & ATTACHMENTS

N/A

I. REFERENCE FORMS

Include a list of forms needed for this policy/procedure. If none, list as N/A.



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J. REVISION & REVIEW HISTORY

Revision Date	Review Date	Author	Notes
11/26/25		Mindy Groff, MLT(ASCP), BCLS	

K. APPROVAL

This document has been approved in accordance with the “800-001-P Policy Development” procedure as of the effective date listed above.