

**Syphilis Point-of-Care Testing Guidance**  
**State Health Department**  
**December 2024**

**Background:**

Point-of-care testing or POCT for syphilis offers a rapid and effective initial screening method for syphilis, particularly in settings where timely access to laboratory services is limited. These tests can provide results within 15 minutes, enabling immediate clinical decisions and treatment initiation.

**Objectives of Point-of-Care Syphilis Testing:**

- Improve early detection of syphilis to reduce transmission and complications.
- Facilitate timely treatment by providing rapid syphilis test results during the same visit.
- Enhance accessibility of syphilis testing in diverse settings, including clinics, outreach programs, and community health centers.

**Approvals Required for Testing Sites to Implement Point-of-Care Syphilis Testing:**

- Only the Food and Drug Administration's authorized point-of-care testing/over-the-counter tests for syphilis, which are validated for accuracy and reliability, may be used in New York State.
- Sites that are physician-owned practices must obtain a Certificate of Waiver from the [Physician Office Laboratory Evaluation Program | New York State Department of Health, Wadsworth Center](#), and add the approved test to the waiver.
- All other sites that do not fit the model of a Physician Office Laboratory must submit applications through the [Clinical Laboratory Evaluation Program | New York State Department of Health, Wadsworth Center](#), and adhere to the more stringent New York State regulations.

**Point-of-Care Syphilis Tests Available:**

Point of care, Clinical Laboratory Improvement Amendments waived Syphilis tests that meet the Food and Drug Administration approved and New York State requirements include:

- [Diagnostics Direct LLC Syphilis Health Check \(Fingerstick whole blood only\)](#) - A test for detecting Syphilis (Treponemal Pallidum Antibody) that provides results in about 10-15 minutes. Visit [diagnosticsdirect2u.com](#).
- [Chembio Diagnostic Systems, Inc., DPP HIV-Syphilis \(Fingerstick whole blood\)](#) - A test for detecting HIV and Syphilis (Treponemal Pallidum Antibody) in about 25 minutes. Visit [chembio.com](#).
- [NOWDiagnostics, First to Know Syphilis Test \(for use with fingerstick whole blood\)](#) - A test for detecting Syphilis (Treponema Pallidum Antibodies) in about 15 minutes—effective August 19, 2024. Visit [nowdx.com](#)

**Over-the-Counter Syphilis Tests Available:**

Over-the-counter, Clinical Laboratory Improvement Amendments waived Syphilis tests that meet the Food and Drug Administration approved and New York State requirements include:

- [NOWDiagnostics, First to Know Syphilis Test \(for use with fingerstick whole blood\)](#)- A test for detecting Syphilis (Treponema Pallidum Antibodies) in about 15 minutes. See [How To Perform the First To Know Syphilis Test - YouTube](#) for instructions.

**NOTE:** *The First to Know Syphilis Test is also approved as an “at-home test” for over-the-counter use. This can potentially be used in community settings by “handing” the test to the patient to take home or providing a safe space to self-conduct the test on-site. The Food and Drug Administration approved [Package-Insert-English.pdf \(SECURED\) \(firsttoknow.com\)](#) guidance expresses that a positive test result is inadequate for a diagnosis, and additional laboratory testing by a healthcare provider is needed to confirm a diagnosis of syphilis.*

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Given the ever-evolving nature of point-of-care testing and over-the-counter testing devices, **this list may not be all-encompassing**. The [Limited Service Laboratories | New York State Department of Health, Wadsworth Center](#) provides links to searching the FDA database for approved tests and over-the-counter lab test devices.

**Interpretation of Point-of-Care Syphilis Testing Results:**

- **Positive Result:** A positive Point-of-Care testing result should be followed by confirmatory testing to establish a definitive diagnosis. Test results are confirmed by performing a **lab-based serological test** and by **conducting a thorough medical evaluation**.
- **Negative Result:** A negative result in a high-risk individual should be interpreted cautiously and repeat testing may be necessary if clinical suspicion remains high.

**Best Practices for Point-of-Care Testing Implementation:**

- **Training:** Ensure providers and non-clinically trained testers are skilled in testing devices, infection control, biohazard waste disposal, and patient education on the risks and benefits of testing. Additionally, training and proficiency testing on utilization of the selected point-of-care and/or over-the-counter tests.
- **Quality Control:** Implement quality control procedures to maintain the accuracy and reliability of test results.
- **Counseling:** Sexual health is a key component of overall well-being. Provide patient-centered counseling, explaining the testing process and steps based on results. Counsel on the need for partner(s) testing and treatment to prevent reinfection and further spread of the disease.
- The AIDS Institute guidance on [Adopting a Patient-Centered Approach to Sexual Health - Clinical Guidelines Program](#) framework relies on open discussions about sexual identity, expressions, experiences, preferences, and care planning and delivery.
- **Feedback and Evaluation:** Collect feedback from staff and patients on the process and monitor the impact of Point-of-Care testing on patient care and outcomes. Make programmatic adjustments based on information collected, as appropriate.
- **Referrals:** Community-based organizations that cannot perform testing or confirmatory testing should set up a referral protocol for patients to receive testing. Agencies should work with providers ([Provider Directory Home Page](#)) or the local [County Health Departments](#) to streamline the process.
- **Documentation:** Record all negative, positive or inconclusive test results in the patient's medical record, including the date and type of test used. Document all referrals and patient follow-up plans.

**Billing for Point-of-Care Syphilis Tests:**

- CPT and LOINC Codes for Syphilis Testing: **CPT Code 86780QW LOINC Code 47236-5**

CPT Code 86780 is used to evaluate a patient's serum for antibodies to *Treponema pallidum*, the bacteria that causes syphilis<sup>123</sup>. LOINC Code 47236-5 refers to *Treponema pallidum* IgG+IgM Ab [Presence] in Serum by Immunoassay. The *Treponema pallidum* Antibody, Particle Agglutination test is designed to be used as an aid in the confirmation of antibodies to the treponemal organisms that cause syphilis.

**Providers are encouraged to contact their payors to determine appropriate coding and reimbursement rate prior to submitting claims.**

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**Public Health Reporting:** [Communicable Disease Reporting](#) of **confirmed positive syphilis** via laboratory-based serologic tests **must** be reported to local public health authorities as required. [Information on Partner Services](#) is available. Partner Services is a free, confidential service that links persons diagnosed with a communicable disease and their partners to medical and other appropriate support services.

**Considerations for pregnant persons:**

- Use **only** Food and Drug Administration-approved point-of-care Testing for syphilis that is validated for use in pregnant individuals.
- Syphilis testing is required in the third trimester. See [Interim Guidance for Public Health Law §2308 to require additional third trimester syphilis screening for pregnant persons: Chapter 57 of the Laws of 2023](#). Repeat syphilis testing during the third trimester or throughout pregnancy may be necessary, especially in high-prevalence areas or if the individual is at ongoing risk of infection. For additional information, visit [Congenital Syphilis Information for Providers](#).
- Point-of-care testing for syphilis can be a valuable tool in the early detection and management of syphilis, particularly in resource-limited settings. By providing rapid results, these tests can significantly improve patient outcomes and reduce the spread of infection. For additional information, visit the National Syphilis and Congenital Syphilis Syndemic Federal Task Force for [Considerations-for-the-implementation-of-syphilis-poc-tests.pdf](#)