

STI self-collection outside of a clinic setting in New York State (NYS) Question & Answer:

The purpose of this document is to communicate the permissibility for STI testing done by self-collection outside of a clinic setting to providers, vendors, community members, and other stakeholders. The New York State Department of Health (NYSDOH) supports STI self-collection as part of the NYSDOH's larger goal of broadening sexual health options for persons in NYS. Self-collection for STIs can be separate or part of in-person sexual health services.

1. Question: Is self-collection for STIs outside of a clinic setting allowable in NYS?

Answer: Yes, provided the following criteria are met:

1. The ordering provider must be NYS licensed and authorized to order tests and directly receive the results. For additional information, see: [Persons authorized to order tests and receive results](#)
2. A patient-provider relationship must be established at the time the test is ordered. Minimally, a medical history and/or a sexual health assessment (e.g., in person or through an online form to be reviewed by a provider) must be completed and/or reviewed prior to ordering a test. For additional information, see: [Education law for the professions](#)
3. Per Public Health Law § 587, Article 5, Title 6, the ordering provider cannot be directly employed or compensated by the testing laboratory. To access this law, follow directions through this link: <https://www.wadsworth.org/regulatory/clep/laws>
4. The testing lab must hold a clinical laboratory permit pursuant to Title V, Section 574 of the New York State Public Health Law. Appropriate permit categories (bacteriology, virology, diagnostic immunology etc.) must be included on permits.
5. Tests must be either
 - a. U.S. Food and Drug Administration (FDA) Approved Tests -OR-
 - b. Lab-developed tests approved by Wadsworth Center/Clinical Laboratory Evaluation Program (CLEP) - Laboratories seeking to add laboratory-developed tests not cleared or approved by the FDA for in vitro diagnostic use or FDA-approved tests that have been modified, must submit validation materials to CLEP for review by the department. Validation materials include, but are not limited to, a validation summary, validation data, standard operating procedures, test reports, and/or package inserts. Detailed requirements for test approval can be found at www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/test-approval
6. Where billing is applicable, billing of clients and/or the authorizing provider must occur directly and may not occur through a sub-contracted collection agent [Public health Law § sections 586(3) and 587 (6), volume A-1 (Title 10) Subpart 34-2-Laboratory Business Practices]. To access these laws, follow directions through this link: <https://www.wadsworth.org/regulatory/clep/laws>
7. Laboratory and disease reporting requirements of suspected or confirmed reportable STIs must be followed (Public health Law § 2102; [10NYCRR 2.10](#)). For HIV, this includes completion of the Provider Report Form (PRF) within 14 days of diagnosis as required by Public Health Law §, Article 21, Title III, Section 2130 using the [DOH-4189 Medical Provider HIV/AIDS and](#)

[Partner/Contact Report Form \(PRF\)](#) or completed electronically using the Provider Portal on the NYSDOH Health commerce System at: <https://commerce.health.ny.gov>. For all other reportable STIs collected outside of a clinic setting, this includes completion of the NYS [Communicable Disease Reporting Form \(Form Instructions\)](#) for residents of all counties outside NYC, and completion of [Universal Reporting Form](#) for New York City residents.

8. **Patient treatment services must be available. Patients diagnosed with HIV must be provided** post-test counseling and linkage to HIV medical care. Detailed requirements and additional guidance for follow-up actions for patients with diagnosed HIV infection can be found at: [HIV Testing Toolkit: Resources to Support Routine HIV Testing for Adults and Minors \(ny.gov\)](#). For all other STIs, treatment services must be available for any/all patients diagnosed with an STI through self-collection. If the provider or service does not offer STI treatment directly, a process must be in place to link the patient to treatment services (<https://providerdirectory.aidsinstituteny.org/>) prior to offering testing.

2. Question: What STIs are considered permissible for self-collection outside of a clinic setting?

Answer: Any condition recognized by the NYSDOH as an STI per [NYCRR § Title 10, Section 23.1](#) is permissible for self-collection outside of a clinic setting.

3. Question: Are there specific vendors that the NYSDOH AIDS Institute can recommend?

Answer: No. If you are an AIDS Institute-funded provider, please reach out to your contract manager to discuss how to implement self-collected STI testing. If you are not an AIDS Institute-funded provider, you can email stdc@health.ny.gov and include “STI self-collection” in the subject line.

4. Question: Does STI self-collection outside of a clinic setting require specific CLEP approvals?

Answer: For questions about CLEP approvals, please contact CLEP at clep@health.ny.gov.

5. Question: Where can I go if I have additional questions about STI self-collection outside of a clinic setting?

Answer: If you have additional questions, please email stdc@health.ny.gov and include “STI self-collection” in the subject line.

6. Question: Is STI self-collection permissible inside of a clinic setting?

Answer: Yes.