Sexually Transmitted Infection Self-Collection Outside of a Clinic Setting in New York State

Frequently Asked Questions

The purpose of this document is to communicate the permissibility of Sexually Transmitted Infection (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 supports sexually transmitted infection/STI self-collection as part of the New York State Department of Health's larger goal of broadening sexual health options for persons in New York State. Self-collection for sexually transmitted infection/STIs can be separate or part of in-person sexual health services.

1. **Question: Is self-collection for sexually transmitted infections/STIs outside of a clinic setting allowable in New York State?**

   Answer: Yes, provided the following criteria are met:

   1) The ordering provider must be New York State licensed and authorized to order tests and directly receive the results. For additional information, see: Persons Authorized to Order Tests and Receive Results (Wadsworth, June 2023).
   2) In New York State, clinical laboratories can only test specimens when requested by a licensed physician or an authorized person. For at-home tests, the laboratory must wait for a healthcare provider to evaluate and issue a test order (e.g., in person or through an online form to be reviewed by a provider). For additional information, see: Information on Laboratory Developed Tests (LDTs) with at-home Collected Specimens (Wadsworth).
   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, see: 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) United States 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. For information about requirements for test approval, see: 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. They 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, see: https://www.wadsworth.org/regulatory/clep/laws.
   7) Laboratory and disease reporting requirements of suspected or confirmed reportable sexually transmitted infections/STIs must be followed (Public Health Law § 2102; 10NNYCRR Section 2.1(ny.gov)). For HIV, reporting is mandated under Public Health Law, Article 21, Title III, §2130, and New York Codes, Rules and Regulations Part 63 for laboratories, physicians, and other

authorized to order an HIV test. Submission of the Medical Provider HIV/AIDS and Partner/Contact Report Form (PRF), Form DOH-4189 is required within **7 days of a new HIV diagnosis and within 24 hours when acute HIV infection is diagnosed**. The PRF form can be completed electronically using the HIV/AIDS Provider Portal which is located on the New York State Department of Health, Health Commerce System (https://commerce.health.ny.gov) or via the paper form which can be obtained by contacting the Bureau of HIV/AIDS Epidemiology. Detailed reporting requirements for clinicians and laboratories are available at the New York State Department of Health's website.

For all other reportable STIs collected outside of a clinic setting, this includes completion of the New York State Communicable Disease Reporting Form (Form Instructions) for residents of all counties outside New York City and completion of the 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 sexually transmitted infections/STIs are considered permissible for self-collection outside of a clinic setting?**

   Answer: Any condition recognized by New York State as a sexually transmitted infection/STI per 10NYCRR Section 23.1 - List of sexually transmissible diseases (ny.gov, March 2023) is permissible for self-collection outside of a clinic setting.

3. **Question: Are there specific vendors that the New York State Department of Health 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 sexually transmitted infection/STI self-collection outside of a clinic setting require specific Clinical Laboratory Evaluation Program (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 sexually transmitted infection/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 sexually transmitted infection/STI self-collection permissible *inside* of a clinic setting?**
   Answer: Yes.

STI Self-Collection Utilizing Consumer-Controlled, Direct-Access Testing

1. **Question:** With respect to sexually transmitted infection/STI self-collection, what is direct access testing?

   Answer: Direct-access testing (DAT) [i.e., direct-to-consumer testing (DCT), patient-authorized testing (PAT), self-testing, and home testing] allows consumers to bypass a provider and initiate sexually transmitted infection/STI self-testing. Direct-access testing provides confidentiality and convenience, allowing consumers to take control of their health. For more information, see: direct-access-testing FAQs.pdf (cms.gov).

2. **Question:** What sexually transmitted infection/STI Self-collection tests are available and permissible in New York State as Direct-access testing?

   Answer: In November 2023, the Food and Drug Administration (FDA) approved the Simple 2 STD Test Kit from LetsGetChecked, which tests for chlamydia and gonorrhea. Meet our Lab | LetsGetChecked US operates a Clinical Laboratory Improvement Amendments (CLIA) and College of American Pathologists accredited laboratory.

   The Simple2 DAT is currently the only direct-access sexually transmitted infection/STI self-collection kit approved for use in New York State by vaginal swab and penile urine collected samples.

3. **Question:** How does the Food and Drug Administration-approved test flow from the consumer to getting results?

   Answer: Consumers purchase the test online, self-collect via vaginal swab or penile urine, mail the sample using the prepaid shipping label, and receive the results electronically or by phone call. For more information, see: Simple 2 STD Test Kit: Detects 2 Common Diseases - LetsGetChecked USA.

4. **Question:** Is there a requirement that sexually transmitted infection/STI Direct-Access testing results be reported?

   Answer: Yes. Per New York State and New York City Public health regulations, sexually transmitted infections/STIs, including chlamydia, syphilis, and gonorrhea, are reportable to the public health programs (including the county health department, state health department, and city health department) depending on the person's address of residence. As such, any positive test results will be transmitted electronically to these entities for further follow-up to ensure that all individuals receive timely treatment, including any sexual partner(s).

   Note: While New York State supports DAT/PAT, the New York State Department of Health does not expressly endorse any particular company that manufactures and distributes these FDA-approved tests.