Becoming Familiar with Self-collection and Self-testing for Sexually Transmitted Infections

This document defines key terminology associated with sexually transmitted infection (STI) diagnostic testing that involves self-testing and self-collection, and is intended to inform health departments and laboratories of the benefits and technical limitations associated with these processes. This document is primarily intended for public health laboratories and program managers responsible for evaluating, implementing or advising on STI self-testing or self-collection.

Overview

As health department programs and laboratories work to increase and ensure access to diagnostic services, various models to allow increased consumer control over components of the testing process (i.e., where and by whom samples are collected and/or tested) have piqued public interest. These different models are often non-specifically referenced under the umbrella of "self-testing" which includes a wide variety of collection and testing processes. We have included standardized definitions to distinguish between tests that are available directly to the consumer (over-the-counter (OTC) and direct-to-consumer (DTC)) versus tests that are provider-mediated, along with definitions of self-testing and the various methods of self-collection.

Currently, there are limited US Food and Drug Administration (FDA)-authorized home self-collection or self-testing options available. This document is intended to inform public health departments and laboratories of the technical and regulatory limitations that surround self-tested and self-collected specimens in clinical and non-clinical settings.

"Self-testing" models are intended to give individuals more options and control over where, when and how they are tested for STIs. Benefits may include:

- The ability to collect a specimen and/or perform a test from any location, at any time
- Enhanced privacy during various phases of the testing process
- Increased patient satisfaction

These benefits are not without risk, however, and limitations may include:

- Variable specimen collection and transport practices
- Difficulty assuring consumer adherence to material expiration dates and pre-analytical specimen requirements (i.e., temperature, transport and storage time)
- Lack of consumer understanding of and/or access to proper disposal methods for biohazardous waste or sharps
- Variability in test performance or interpretation
- Potential for insufficient clinical support with difficulties assuring linkage to treatment or supportive care for patients and their partners

- Challenges associated with reporting to providers, who may be left out of self-testing and even self-collection workflows
- Issues with reporting of nationally notifiable diseases to public health entities, which is a requirement placed on providers but not on patients
- Costs that may not be covered by health insurance.

Key Considerations for Laboratories

Availability

Currently available FDA authorized options for STI and HIV self-collection and/or self-testing are described in **Table 3**. While additional FDA authorized options are expected to come to market soon, laboratories should be aware that many of the currently marketed options for self-collection and self-testing are not authorized by the FDA. To verify whether a self-test or a self-collection kit is FDA-authorized, you can search for it by name in the FDA's *in vitro* diagnostics Over The Counter Database, Denovo database and/or CLIA database.

Regulatory Considerations

The FDA considers collection devices (swabs with collection tubes, urine containers, blood lancets, etc.) to be standalone medical devices, although they are often included as part of a test system. Laboratories may not validate a device for self-collection as laboratory-developed test (LDT), even if they intend to use the devices with an FDA-authorized test, unless the device's Indications for Use (IFU) allow for self-collection of specimens (e.g.,the Hologic Aptima® Multitest Swab Specimen Collection Kit can be used with the Aptima® Combo 2 Assay for self-collection of a vaginal swab in a clinical setting, but not for home collection of vaginal swabs). **Table 1** illustrates how FDA-authorized devices can vary in terms of laboratory applicability based off the submitted data and the IFU. Laboratories that want to use FDA-authorized products for self-collection or self-testing must use the products that are currently available or conduct their own studies and submit either a De Novo classification request, 510(k) premarket notification or premarket authorization submission to the FDA. Labs that are interested in pursuing authorization are encouraged to consult with the FDA before initiating studies to get advice on the regulatory pathway and the data required, using the presubmission pathway.[1] Public health laboratories may lack the capacity and resources to conduct the studies required by the FDA individually, but there is no cost for a presubmission.

Terms to Know

Over-the-counter (OTC) Medical Devices: Medical devices, including tests, that may be offered for sale directly to the consumer. A provider order may or may not be required.

Direct-to-consumer Testing (DTC): A consumer accesses testing without the involvement of a healthcare provider or prescription. Also known as Direct Access Testing and most often used to refer to genetic tests (e.g.: 23 and Me).

Healthcare Provider-mediated Testing: A consumer engages with a healthcare provider at one or more points in the testing process to access testing.

Clinical Setting: A site with a licensed healthcare worker on the premises.

Self-collection*: A consumer collects a specimen themselves, either at a non-clinical location of their choosing or in a clinical setting. Testing may be conducted elsewhere.

Home Collection*: A consumer collects the specimen themselves at a non-clinical location of their choosing. This may also be referred to as remote self-collection or self-collection in a non-clinical setting.

Self-testing: A consumer performs all phases of the testing process themselves in a location of their choosing. Sometimes referred to as "home-testing."

**Note: Though NOT synonymous, self-collection and home collection are often referred to under the umbrella of "self-testing."*

1 https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program

Table 1. Example accepted uses of FDA-authorized products

Product	Specimen	Who can use?	Which assay can be verified/validated?
Teal Wand™	Home-collected vaginal swabs	Any laborastory with appropriate CLIA certifications	• Any FDA authorized molecular HPV test that already includes vaginal swabs in the IFU • cobas® HPV test was used for FDA submission
simpli-COLLECT STI Test	Home-collected urine or vaginal swabs	Any laboratory CLIA-certified for moderate-complexity testing	Abbott Alinity m STI assay only
LetsGetChecked Simple 2 Test	Home collection of penile urine or vaginal swabs	Priva Path laboratories (dba LetsGetChecked, Inc.) only	Hologic Aptima® Combo 2 Assay

Consultation

As experts in diagnostic testing, public health laboratorians may be asked to consult with public health programs and/or clinical and community-based providers regarding the performance of self-tests or tests conducted on self-collected samples. It is essential that laboratorians understand the FDA status and performance characteristics of tests that are being discussed. This may mean requesting further information regarding the sensitivity, specificity, comparator assays and limitations of test systems from commercial laboratories offering self-collection or companies marketing self-testing kits. Laboratories must also determine how they will treat specimens that arrive with results from self-tests documented; it is important to consider how those results will fit into or inform the laboratory's testing algorithms (e.g., for HIV and syphilis) and understand the limitations of the specific self-test that was used. Laboratories should work with programs implementing self-testing to prevent inefficient duplications of testing effort and resources and be mindful of any follow up testing requirements included in a test's instructions for use. When implementing self-testing or self-collection models, collaboration between laboratories, providers and health departments is essential to ensure appropriate workflow development and linkage to care. **Table 2** examines different collection and testing modalities and lists considerations, potential laboratory roles and example testing options.

Table 2. Sample collection and testing pathways

	Self-testing	Home-collection plus Laboratory Testing	Self-collection in a Clinical Setting plus Laboratory Testing

General Considerations	• Collection and testing instructions should be easy to understand
	• Laypeople may not follow (or read) the instructions, even when they are clearly written
	• Tests may lack sensitivity and/or specificity
	• Treatment, when necessary, may be difficult to receive or may require repeat testing
	• Testing limitations may not be understood by consumers, including those associated with:
	  ○ window periods
	  ○ immune status
	  ○ prescription medication (i.e., HIV PrEP)
	• Test packaging should be discrete, minimizing the potential for negative consequences if recognized (e.g.: domestic violence)
	• Reportable disease guidelines may not be followed
		• Specimen collection instructions should be easy to understand
		• Specific requirements for specimen labeling, volume, and time and temperature in transport must be included
		• Quality assurance checkpoints should be utilized with collection materials (i.e., temperature measurement devices)
		• How will collection supplies be paid for, especially given that they may be shipped out and not sent back
		• Packaging should be discrete, minimizing the potential for negative consequences if recognized (e.g.: domestic violence)
			• Specimen collection instructions should be easy to understand, and providers should be available to answer patients' questions during the collection process
			• Willingness and ability to access clinical settings varies across populations; some populations may experience stigma in seeking care

Laboratory Role	• Laboratories should help programs navigate sales tactics used by commercial vendors offering self-testing options • Laboratories should be prepared to request and ask questions about performance data (i.e.: 100% sensitivity as compared to what?) • Laboratories must be able to answer questions about self-testing results • Laboratories must determine the follow-up testing procedures when a patient reports a positive self-test	• Laboratories must ensure that all specimens meet pre-established acceptance criteria prior to testing • Laboratories should thoroughly consider specimen labeling requirements • Shipping of specimen collection kits may be managed by the laboratory or by a third party.	• Laboratories must ensure that all specimens meet pre-established acceptance criteria prior to testing • Laboratories should thoroughly consider specimen labeling requirements
Available Options	OraQuick In-Home HIV test, First to Know Syphilis test or Visby Medical Women's Sexual Health Test purchased by a consumer at a retail location, mailed to patient's home from primary care provider, distributed through community providers, or available by mail/delivery through health department programs	• LetsGetChecked Simple 2 Test • simpli-COLLECT STI Test • Visby Medical Sexual Health Test • Teal Wand™ plus validated HPV test	Many gonorrhea and chlamydia nucleic acid amplification tests (NAATs) and some NAATs for other STIs (e.g., HPV) are FDA-cleared for use with (or include) a provider-instructed specimen self-collection kit.

Table 3. FDA-authorized tests available as of 2/16/26

Test Name	Year Authorized	FDA Premarket Review Pathway; Regulatory Class	Test Type/ Complexity	Analyte	Specimen Types	Follow-up Testing Required?	Over the Counter?
Ora-Quick® In-home HIV TEST	2012	PMA; Class III	Home Test/Waived	HIV antibodies	Oral fluid	Yes	Yes
LetsGetChecked Inc. Simple 2 Test	2023	510(k); Class II	Home Collection/ Moderate	*C. trachomatis* and *N. gonorrhoeae* nucleic acid	Penile urine, self-collected vaginal swabs	No[1]	Yes
NOWDiagnostics First to Know® Syphilis Test	2024	De novo; Class II	Home Test/Waived	*T. pallidum* antibodies	Capillary whole blood	Yes	Yes
Abbott Molecular simpli-COLLECT STI Test	2024	510(k); Class II	Home Collection/ Moderate	*C. trachomatis, N. gonorrhoeae, T. vaginalis* and *M. genitalium* nucleic acid	Self-collected vaginal swabs or urine (note that for *M. genitalium*, only male urine is allowed)	No	No
bioLytical Laboratories, Inc. INSTI® HIV Self Test	2025	PMA; Class III	Home Test/Waived[2]	HIV Antibodies	Fingerstick whole blood	Yes	Yes
Visby Medical Women's Sexual Health Test	2025	De novo; Class II	Home Test/Waived	*C. trachomatis, N. gonorrhoeae* and *T. vaginalis* nucleic acid	Self-collected vaginal swabs	No[1]	Yes
Teal Health, Inc. Teal Wand™	2025	De novo; Class II	Home-collection device	Human Papilloma Virus nucleic acid[3]	Self-collected vaginal specimens	N/A[3]	No

1. Follow up testing is not required, but a healthcare provider is required in order to start, stop or change treatment.
2. Waived with fingerstick whole blood, but moderate if venous whole blood or plasma used.
3. The Teal Wand is a collection device only, but it can only be validated for use with FDA-approved HPV molecular assays. Whether follow up testing is required may depend on the test used.

Association of Public Health Laboratories

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