



Self-Testing Strategies for HIV Testing and PrEP Access

April 6, 2020

PARTICIPANT QUESTIONS

The following questions were posed by participants during the “Self-Testing: A Strategy to Improve Access to HIV, Viral Hepatitis, and STI Testing” webinar hosted on April 6, 2021.

Q: Could you clarify if self-collection for GC/CT amplified for rectal and throat swabs have been approved by FDA and if swabs are not a part of product insert, would each CLIA certified lab have to do for a validation study? Please elaborate on this issue.

A: The FDA-cleared GC/CT NAATs currently available do not include sample types that are self-collected outside of a healthcare setting. Some of the GC/CT NAATs are cleared for self-collected vaginal swabs in a healthcare setting. If the sample type is not included in the FDA-cleared method, then each laboratory must perform a validation for that sample type.

Q: Is the Self-Testing Toolkit available online?

A: The [toolkit and case studies](#) can be found on NASTAD’s website and [EHE Microsite](#).

Q: How frequently does verification testing need to be done?

A: The frequency and interval for verification varies. Typically, verification is performed when a laboratory implements a new test, or new test platform or system; when a modification is made by the manufacturer to a test or test platform/system; when a new method (e.g., sample type, collection method) is being adopted; or when a test is performed on multiple different machines/platforms.

Q: Do presenters have experience with contracting with a third party for self-collected tests such as MTL or [Take Me Home](#)? Would these tests be considered CLIA waved or validated?

A: The [OraQuick® In-Home HIV Test](#) is the only CLIA-waived test. A laboratory that conducts testing on self-collected samples acquired outside of a healthcare setting would need to validate each test for each sample type. Laboratories conducting tests on self-collected samples obtained outside of a healthcare setting should be able to provide health departments with information regarding validation of tests used by that laboratory.



Q: What tips do you have in encouraging populations to use self-testing via social media?

A: The [case studies](#) included with the toolkit provide details about the self-testing models employed by health departments, including recruitment and operational details, along with lessons learned that other health departments might find helpful.

Q: Does self-testing get reported into public health department clinic management systems?

A: Reporting of results to public health from self-testing strategies varies depending on the self-testing strategy employed. For samples that are self-collected and self-tested (i.e., the [OraQuick® In-Home HIV Test](#)) results will be known only to the consumer. Health departments implementing self-testing programs using this test method should consider implementing a mechanism to follow-up with consumers to ensure appropriate public health reporting.

For samples that are self-collected and tested at a laboratory, public health reporting could be accomplished by existing methods. Health departments should evaluate whether laboratories testing samples from self-testing programs are in compliance with jurisdictional reporting requirements. In either case, these considerations will need to be evaluated to ensure that the reporting of results meets the needs of the self-testing strategy. Please refer to the [Self-Testing Toolkit and associated case studies](#) for additional information.

Q: How are self-testing strategies utilized to gather data for rapid tests?

A: For samples that are self-collected and self-tested (i.e., the [OraQuick® In-Home HIV Test](#), a point-of-care rapid HIV test) information about the results will be known only to the consumer. Health departments implementing self-testing programs using this test method should consider implementing a mechanism to follow-up with consumers to ensure appropriate public health reporting.

Health departments implementing self-testing programs using this test should also consider mechanisms to gather information about consumers to whom kits are distributed to permit program evaluation and monitoring. Please refer to the [Self-Testing Toolkit and associated case studies](#) for additional discussion of considerations for data collection and examples of strategies for data collection.