

At-home Self-collection Lab Testing for Sexually Transmitted Infections

National Coalition of STD Directors
Technical Assistance Brief – Updated May 20, 2020

I. Background: Home-based STI Testing with Digital Health Support

Since the advent of COVID-19 in the U.S. in January 2020, STD facilities and program/clinic staff have been frequently repurposed and redeployed substantially in an effort to scale up SARS-CoV-2 testing, contact tracing, and build infrastructure and response to this expanding epidemic. Digital health platforms can work hand-in-hand with their traditional clinician counterparts, achieving better health outcomes by breaking down access barriers to healthcare. Home-based sample collection followed by lab-based testing can facilitate patient care without the patient having to leave home.

Telehealth is a tool for delivering medical services rather than a distinct medical service itself. Digital health platforms are able to deliver public health outcomes not readily achievable via a traditional brick-and-mortar clinic model. Rather than replace in-person providers, digital health platforms can work hand-in-hand with their traditional clinician counterparts, achieving better health outcomes by breaking down access barriers to healthcare.

Digital health includes more conventional “synchronous” models of patient care that involve scheduled, time-limited meetings of providers and patients by phone or video conference. Effective consultation can also be achieved through an “asynchronous” model in which the patient communicates by messaging with the health care team that may include physicians, nurse practitioners, nurses, and other supporting providers.

Digital health platforms allow patients to connect with compassionate and skilled providers regardless of where the patient resides. Through high-quality digital health, patients participate in an interactive subjective and objective examination process and are provided with evidence-based care. The process is very similar to an in-person exam or consultation, but with greater efficiency and the benefit of remote engagement that eliminates infection exposure risks. Furthermore, especially through asynchronous care, stigma concerning sensitive health issues is often overcome, with patients willing to share necessary yet potentially embarrassing subjective information with digital health providers. The asynchronous model of care also facilitates ongoing, longitudinal communication with the health care team and facilitates efficient triaging of requests to the team member most appropriate to respond to particular patient requests.

Similarly, home-based sample collection for lab-based testing allows collection of objective data to facilitate patient care without the patient having to leave home. Sample collection at home is straightforward and safe, validated to ensure accuracy consistent with traditional lab testing, and provides patients with an enhanced sense of privacy. An increasingly wide range of sample types can now be collected in the home setting, from non-invasive specimens such as saliva and urine, to swabs for direct testing of mucosal surfaces, to dried blood spots for a broad range of serologic testing. Solving for the logistical barriers of testing can be especially helpful for people who reside in remote areas where they may live hours from the nearest lab or clinic. Home testing also overcomes stigma insofar as

patients may be reluctant to seek certain types of testing that they imagine reflect on perceived risk-taking behaviors.

Finally, in the era of COVID-19, involving widespread social distancing imperatives, acute infection control concerns, and critical shortages of personal protective equipment, home-based testing and consultation for STI care and conditions makes absolute sense. The most significant challenges are the persistent technology gaps and bandwidth limitations of clinic staff necessary to integrate service delivery with available services, which include digital healthcare providers and labs with requisite expertise in home testing. There also remains a troubling gap in reimbursement for innovative digital health and home-based testing services, with existing payment rates governed by traditional care and testing standards that fail to accommodate some of the fundamental elements of digital health, such as platform use requirements, digital provider effort that is not face-to-face or exam-based, specimen shipping costs, and accrued laboratory costs associated with validating tests for home-based collection.

II. Regulatory Overview: Home-based Testing

The Food and Drug Administration (FDA) reviews diagnostic devices for clearance and approval. Device manufacturers submit a 510(k) application to FDA to demonstrate that a device is at least as safe and effective as a legally marketed device that is not subject to premarket approval (PMA). In the case of diagnostic assays that are most commonly in use to test for sexually transmitted infections (STIs), assays are 510(k) cleared or PMA cleared; however, the alternative collection methodology of self-collection of samples in the home is not cleared by the FDA. In fact, the vast majority of diagnostic tests in the U.S. are not “FDA-approved” as such, but rather fall into the category of Laboratory Developed Tests (LDTs).

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) establishes quality standards for laboratory testing and an accreditation program for clinical laboratories. Laboratories performing moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

Such laboratories can validate alternative collection methodologies, such as home collection, as LDTs subject to review of the validation methods and outcomes by their prevailing CLIA authority, typically a state that has local jurisdiction over such regulation, which is ultimately governed by Centers for Medicare & Medicaid Services (CMS) oversight. Since clinicians must order the provision of laboratory tests – FDA approved or otherwise – in the home testing arena, numerous digital providers of clinical care and/or lab testing have emerged to offer validated self-collection of samples that are then transported to and tested in the lab, using FDA cleared assays.

III. STI Home Testing Landscape

Presently in the U.S., a very few high complexity laboratories have emerged to provide lab-based testing on self-collected samples collected in the home, using 510(k) cleared / PMA cleared assays.

The largest commercial labs (LabCorp and Quest) have involvement in this arena limited by heavy investment in brick-and-mortar draw stations and related infrastructure. Pixel by LabCorp offers home collection of a urine sample to test for three common STIs, including Chlamydia, gonorrhea, and

trichomonas. QuestDirect offers home collection for testing for chlamydia and gonorrhea, trichomonas, hepatitis B and C, syphilis and HIV. Both services integrate a remote clinician evaluation and order to initiate fulfillment of respective test kits.

Laboratories associated with NIH Centers for AIDS Research (CFAR) sites have innovated home collection methods for a limited number of LDTs, primarily HIV tests, such as through use of a dried blood spot (DBS) sample self-collection process.

In the LDT validation of at-home self-collection for STI testing, Molecular Testing Labs of Vancouver, WA (Molecular) has significant capabilities supplying a range of digital health providers. Molecular is a CLIA-licensed / CAP-approved high-complexity laboratory that has emerged to supply back-end lab services to a host of digital health care providers. Its LDTs for STIs – including three anatomic site testing for Chlamydia and gonorrhea (using urine or swabs) and syphilis EIA and 4th gen HIV Ab/Ag by DBS, and others – are fully validated with sensitivities and specificities near 100%. Molecular has established relationships with government and academic institutions to advance the profile and scientific rigor of at-home self-collection for STI testing. Molecular offers digital health care and traditionally based providers a continuum of end-to-end services integrated with its commercial lab services, including fulfillment, EHR API development, and integrated patient insurance billing.

Additional CLIA-licensed / CAP-approved laboratory providers exist providing similar back-end lab services.

IV. Home STI Testing Provider Landscape

There is a range of known digital health providers and labs (esoteric and other commercial) active in the home STI testing space in the U.S. NCSD may provide information in future about available providers and labs to facilitate efficient program/clinic linkages.

V. The COVID-19 Era: STI Program / Clinic Needs related to Home STI Testing

Post-emergence of COVID-19, NCSD's initial evaluation of the needs of U.S. STD clinics and programs, whose facilities and staff have largely been re-purposed or redeployed, has demonstrated that integration with digital providers and laboratory services to facilitate at-home STI testing is vitally needed.

Programs will need to perform a self-assessment of the at-home test integration pathway that best meets their needs. See Figure 1 for key considerations.

Figure 1: Comparing at-home STD integration options

	(1) In-house/ "Homegrown" Program	(2) Integration with a Lab Service	(3) Integration with a Digital Healthcare Provider	(4) Hybrid / other Solutions
<i>Examples</i>	<ul style="list-style-type: none"> JHH "I Want the Kit" (IWTK) Howard Brown Health 	<p><i>Program develops platform (API, other) to access at-home testing lab kits</i></p>	<p><i>Program integrates with digital healthcare provider to offer end-to-end care and testing solution to its patients</i></p> <ul style="list-style-type: none"> Colorado Dept of Public Health & Environment 	<ul style="list-style-type: none"> Building Healthy Online Communities (BHOC): TakeMeHome service
Potential Benefits	<ul style="list-style-type: none"> Seamless patient experience and management No loss of surveillance or disease investigation integration with care Greater control over cost variables Greater control over branding, kitting, user experience 	<ul style="list-style-type: none"> In some settings, as straightforward as building a new lab integration (to supplement existing lab order options) Outsources kitting, fulfillment, and specimen handling No loss of surveillance or disease investigation integration with care 	<ul style="list-style-type: none"> Outsourced lab/specimen logistics, clinician ordering, and patient support Least internal resources required for at-home test integration May require little tech enhancement 	
Potential Challenges	<ul style="list-style-type: none"> Requires close working relationship with PHL/other lab In-house kit fulfillment, shipping required Technology lift around electronic lab ordering, EHR integration Provider training and availability to support test delivery, results disclosure 	<ul style="list-style-type: none"> External at-home lab options may be limited, rendering less control over per-kit cost Technology lift around electronic lab ordering, EHR integration In-house provider availability for kit ordering, results disclosure, patient support 	<ul style="list-style-type: none"> Attention to roles & communication between in-house providers and digital HC providers Attention to surveillance / disease investigation integration Partner options will dictate per-kit and patient support costs Co-branding or white labeling may be needed / desired 	
<i>Notes</i>		<ul style="list-style-type: none"> Partner lab may be a public health lab, academic / CFAR lab, or commercial lab with experience in LDT validation of self-collected specimen use with 510(k)/PMA-cleared STD assays 	<ul style="list-style-type: none"> Available digital healthcare providers best described in KFF April 23, 2020 review (see Resources) 	

VI. Frequently-asked Questions (FAQ)

Regulatory questions

Q: For an at-home self-collect test to be “validated,” does the self/sample collection have to be validated specifically?

A: FDA-cleared tests are intended to be ordered by a clinician, with samples obtained for patients in a clinical setting or draw station. When tests are used outside the clinical setting, a validation study must be performed to make sure that accuracy is maintained, and that new aspects of the testing methodology (such as shipping of samples, stability of specimens in transport devices) do not affect the integrity of the test. Self-collection also relies on individuals’ understanding of collection instructions, and human behavior that contributes to accurate collection of a sample, especially when collected by oneself, which may be inherently challenging and may contribute to inadequate collection. Therefore, a laboratory-developed test (LDT) must be validated such that every methodologic step of its use (i.e., self-collection, collection in a non-clinical setting, etc.) that differs from the 510(k) cleared or PMA cleared version of the same test must be validated.

Laboratory questions

Q: How accurate are at-home tests?

A: Sensitivity and specificity and other test performance characteristics are generated and documented in the validation study of the laboratory-developed test. At minimum, basic accuracy information should be provided for each test offered by the lab performing the validation.

Q: Are public health labs at departments of health sharing validation study protocols or results with other departments of health?

A: Validation study results may be shared by labs, though commercial labs may share only certain information if aspects of its validation process entails proprietary information. Public Health Labs often will share validation results, along with the protocol used to generate the results. However, since LDT validation and use is governed by the decentralized nature of local CLIA review, a validation study must be repeated by the laboratory newly wishing to deploy the test, and the laboratory director of this lab must attest to the performance of the study and results produced.

Q: Is there a list of labs who have completed validation studies?

A: Performing a validation study for at-home self-collection of specimens is a demanding exercise that many labs will not have the time and resources to complete, especially in the resource-constrained era of COVID-19. While there is no unified listing of labs that have completed at-home self-collected validations for STI assays known to NCSD, we can point you to select labs that have completed validations and have made their lab services available.

Q: If Quest or Labcorp or others have performed this validation, does that extend to all states or is it site-by-site?

A: Labs may process specimens from out-of-state patients, as long as a qualified prescribing clinician orders the test. States, however, may regulate the activity of out-of-state labs.

Procedural / operational questions

Q: Some clients are afraid to walk into any agencies or any facility. How do you reach out to clients at home to offer these self-collected tests?

A: To take advantage of at-home self-collected testing as an adjunct to traditional clinic-based testing, programs/clinics can reach patients effectively utilizing social media, advertisements, requesting clinic patients deliver at-home testing information to their partners, and/or word of mouth.

Q: Do STD clinic patients find home testing an acceptable alternative to in-person testing and care?

A: In a 2015 Cochrane Database review (“Home-based versus clinic-based specimen collection in the management of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* infections”; see Resources), the authors observed the following: “Qualitative data suggest that individuals who have undergone home-collected sampling prefer the simplicity, security, and privacy of self-collected specimens. Avoidance of anxiety and fear that might occur in clinical practice could also increase adherence to home-based sampling.”

Q: What about the at-home STD tests available from internet providers, e.g., myLab Box, others, etc?

A: The Kaiser Family Foundation reviewed digital health providers providing online STD care, some of which provide at-home testing. See “A Look at Online Platforms for Contraceptive and STI Services during the COVID-19 Pandemic,” Kaiser Family Foundation, April 23, 2020, in the Resources section.

Q: What is the turnaround time to receive results from home tests?

A: The answer depends on the lab/service and the shipping speed selected, and if specimens are being returned to a central lab for processing. A typical turn-around would entail 24-48 hours for return shipping, and 24-72 hours for results production, with a total time ranging between 2-5 days. An electronic, HIPAA-compliant patient portal facilitates communication of results to patients, minimizing delay in results disclosure. Certain digital health service providers offer varying degrees of patient counseling, support, and post-result care (i.e., remotely delivered treatment or referral to a local source of care).

Q: We provide rapid testing for HIV, so how would that work if a test kit is mailed to the client?

A: There is a requisite delay in HIV testing using an at-home test – time delay for fulfilling the kit to the patient, and for tests that rely on a central lab for processing, a time delay for mailing the specimen back to the lab for processing and resulting. Clinical circumstances in which a rapid, point-of-care result is optimal are not those for which at-home self-collected testing is a good substitute; rather, at-home self-collected testing is an adjunct to traditional in-person clinical care for most settings.

Q: How do we offer PrEP labs at home without an in-clinic blood draw? This would be great for refills and routine follow ups as well.

A: In at least one case, at-home self-collected labs for PrEP includes a fingerprick to collect one or more spots on a dried blood spot (DBS) sample card, which is then mailed back to a central lab for processing. The DBS sample card can be used to perform a 4th generation HIV test, creatinine, as well as select other tests.

Q: Can you bill insurance for tests collected at home?

A: Some at-home testing labs and services will bill patient insurance for their at-home self-collected tests. Reimbursement does not always cover the amount billed, especially because reimbursement rates

for certain tests typically do not reflect the increased cost of deploying that test in an at-home mode (requiring shipping and, in some cases, wrap-around support during results disclosure, etc.)

Questions for BHOC (TakeMeHome service):

Q: Where can we find more info on TakeMeHome's STD service?

A: BHOC is building out its expansion to include STD testing. Further information will be available soon.

Q: What is the laboratory performing tests for BHOC?

A: At-home Oraquick testing is used, requiring no central lab for processing. For the expansion that will include STI testing, Molecular Testing Labs (MTL) of Vancouver, Washington, is the laboratory.

Q: Is there a limit on the number of tests that can be ordered monthly through TakeMeHome?

A: Presently there is no limit on the number of tests that can be ordered. Jurisdictions who may be paying for the testing can put limits on available test kits at their discretion and as budget allows.

Q: Will TakeMeHome be expanding for users under 18, in states with minor consent laws?

A: Since OraQuick is FDA approved for those 17 and older, BHOC has chosen to offer TakeMeHome to those 18 and older, for now.

Q: Can you provide an idea of costs for the current TakeMeHome HIV test kits?

A: Cost information appears on the BHOC site for HIV testing. \$46 includes all elements of the program, from administration, kit, fulfillment, shipping, promotion, to data access.

Q: How many tests has TakeMeHome run so far?

A: As of May 7, 2020, TakeMeHome has distributed 585 kits, which reflects the first month of the program.

Q: How many of the TakeMeHome tests distributed had positive results?

A: Because of the nature of the in-home, self-testing program, results are generated in the individuals' homes and are not reported or maintained centrally. However, BHOC works with local jurisdictions in an effort to capture self-reported positive results for re-testing and care. As BHOC has just completed the first month of the program, they are awaiting review by jurisdictional surveillance departments.

Q: Aside from the information provided with the kit to support those who test HIV-positive, are any warm follow-ups being done?

A: This is up to the participating health jurisdictions. Right now, this is not part of the TakeMeHome protocol, but BHOC has had conversations with some health departments who are thinking about adding this step.

Q: How can we become a community partner with Take Me Home?

A: Get more info here: <https://www.bhocpartners.org/home-testing>

Q: Where can more information on BHOC social media campaigns be found?

A: The BHOC social media campaign is specific to the TakeMeHome project, and is not designed as a general self-testing campaign. However, if your jurisdiction is participating, BHOC can share digital assets so that you can promote the program to specific communities you wish to prioritize in your area.

Q: How do we reach the organizers of TakeMeHome?

Jen Hecht can be reached at: jenhecht@bhocpartners.org or jhecht@sfaf.org.

Question regarding At-home HIV self-testing:

Q: Can patient insurance be billed (by the consumer, or other) for a self-collected oral fluid HIV test collected / performed at the patient’s home?

A: Currently there is no CPT code to support reimbursement of an at-home HIV test. Orasure, manufacturer of the OraQuick In-Home HIV Test, is actively working towards creation of a reimbursement mechanism, through a procedure outlined by CMS. Following an April 28 letter from CDC's DHAP on the topic of HIV self-testing (which can be found in our Resources section), Orasure is working with CDC, HRSA, and SAMSHA to help clear the way for current and future grant funds to be used for purchase and distribution of HIV self-test kits. Orasure has developed a series of webinars on HIV self-testing and testing during the COVID-19 crisis, and recordings are available. For more information, contact Kayla Coleman (kayla.coleman@dnagenotek.com).

VII. Resources

(1) Laboratory Developed Test (LDT) Validation Resources

Food and Drug Administration

Laboratory Developed Tests

<https://www.fda.gov/medical-devices/vitro-diagnostics/laboratory-developed-tests>

College of American Pathologists

Laboratory Developed Tests

https://webapps.cap.org/apps/docs/education/lapaudio/pdf/042110_Presentation.pdf

American Association for Clinical Chemistry

The American Association for Clinical Chemistry (AACC) is a global scientific and medical professional organization dedicated to clinical laboratory science and its application to healthcare. Our leadership in education, advocacy and collaboration helps lab professionals adapt to change and do what they do best: provide vital insight and guidance so patients get the care they need.

<https://www.aacc.org/health-and-science-policy/advocacy/position-statements/2017/oversight-of-laboratory-developed-tests>

American Journal of Clinical Pathology

Regulation of Laboratory-Developed Tests: A Clinical Laboratory Perspective

<https://academic.oup.com/ajcp/article/152/2/122/5523669>

Association of Public Health Laboratories

APHL works to build effective laboratory systems in the US and globally. The association represents state and local governmental health labs that monitor and detect public health threats.

<https://www.aphl.org/Pages/default.aspx>

(2) At-home Self-Collect Testing Partner Resources

Kaiser Family Foundation: “A Look at Online Platforms for Contraceptive and STI Services during the COVID-19 Pandemic.” The Kaiser Family Foundation reviewed digital health providers providing online STD care, some of which provide at-home testing. Kaiser Family Foundation, April 23, 2020.

<https://www.fda.gov/medical-devices/vitro-diagnostics/laboratory-developed-tests>

(3) At-home STD Testing – Patient Acceptability (in development)

Banerjee P, Madhwapathi V, Thorley N, Radcliffe K. A service evaluation comparing home-based testing to clinic-based testing for HIV, syphilis and hepatitis B in Birmingham and Solihull.

Int J STD AIDS. 2020 May 4;956462419900461. doi: 10.1177/0956462419900461. Epub ahead of print. PMID: 32366180.

Banerjee P, Thorley N, Radcliffe K. A service evaluation comparing home-based testing to clinic-based testing for Chlamydia and gonorrhoea in Birmingham and Solihull.

Int J STD AIDS. 2018 Sep;29(10):974-979. doi: 10.1177/0956462418767180. Epub 2018 Apr 24. PMID: 29690825.

Pearson WS, Kreisel K, Peterman TA, Zlotorzynska M, Dittus PJ, Habel MA, Papp JR. Improving STD service delivery: Would American patients and providers use self-tests for gonorrhea and chlamydia?

Prev Med. 2018 Oct;115:26-30. doi:10.1016/j.ypmed.2018.08.007. Epub 2018 Aug 7. PMID: 30096329.

Home-based versus clinic-based specimen collection in the management of Chlamydia trachomatis and Neisseria gonorrhoeae infections. Fajardo-Bernal L, Aponte-Gonzalez J, Vigil P, Angel-Müller E, Rincon C, Gaitán HG, Low N.

Cochrane Database Syst Rev. 2015 Sep 29;(9):CD011317. doi: 10.1002/14651858.CD011317.pub2.

McRee AL, Esber A, Reiter PL. Acceptability of home-based chlamydia and gonorrhea testing among a national sample of sexual minority young adults.

Perspect Sex Reprod Health. 2015 Mar;47(1):3-10. doi: 10.1363/47e2715. PMID: 25776809; PMCID: PMC5253707.

Rotblatt H, Montoya JA, Plant A, Guerry S, Kerndt PR. There's no place like home: first-year use of the "I Know" home testing program for chlamydia and gonorrhea.

Am J Public Health. 2013 Aug;103(8):1376-80. doi: 10.2105/AJPH.2012.301010. Epub 2013 Jan 17. PMID: 23327247; PMCID: PMC4007891.

VIII. The National Coalition of STD Directors is working to address these gaps in integration of home-based STI testing into state STD programs and affiliated clinics:

- 1) Provide STD clinics and programs **guidance on the availability of self-collect, home-based STI testing** (as well as other modes of home-based testing including FDA-approved home HIV testing, for instance).
- 2) Refer to **public-private opportunities** to link interested local and state programs (and clinics) with available digital/lab services, by matching program needs with service provider features.
- 3) Provide STD clinics and programs **technical assistance to integrate their traditional care models with existing digital and/or lab services** in this space.
- 4) Identify **Resources** to make home-based STI services and labs **cost-effective** for deployment by STD clinics and programs serving patients of limited means, some of whom may be uninsured or underinsured.