

Texas Department of State Health Services
TB/HIV/STD Section
Interim Guidance on Home Self-Collection and Testing Kits

Purpose

This document is to provide interim guidance on the creation of policies for the use of Food and Drug Administration (FDA) approved home testing kits for Human Immunodeficiency Virus (HIV), and Laboratory Developed Tests (LDTs) for self-collection kits for HIV, sexually transmitted diseases (STDs), hepatitis C (HCV) and tests required for pre-exposure prophylaxis (PrEP) prescriptions. This interim guidance is intended for use by programs funded or otherwise supported by the Department of State Health Services (DSHS) TB/HIV/STD Sectionⁱ.

Definitions

Home testing kits – FDA approved tests which allow an individual to complete the entire testing process in their home (or other private location) including the interpretation of the preliminary test result.

Home self-collection kits – LDTs (under a medical order by a licensed provider) which allow an individual to collect specimens in their home (or other private location) to be submitted to a laboratory that processes the test and reports the test result to the provider who ordered the test.

Laboratory developed tests (LDTs) – For the purposes of this document, manufacturer’s tests which have been validated by a laboratory for off-label alternative collection methodologies. This applies to tests that were not FDA cleared for this use (e.g. self-collection in the home setting). LDTs are subject to review of validation methods and outcomes by their prevailing CLIA authority.

Background

Individuals may be reluctant to visit a health care provider or other agency to be tested for HIV, STDs, and HCV. Texas has a significant number of persons living with HIV who have not received an HIV diagnosis and are therefore living without the life-extending benefits of treatment. Additionally, STDs continue to increase in Texas and the need for continued diagnosis and treatment is imperative to reduce acquisition. Hepatitis C is greatly underdiagnosed although we have a cure. It is estimated that up to three in four people infected with hepatitis C are not aware of their infectionⁱⁱ.

Through the dissemination of this interim guidance, DSHS aims to increase access to HIV, STD, and HCV testing and linkages to medical treatment and other prevention services, including the tests required for PrEP prescriptions.

Please note that this interim guidance does not endorse a specific test technology, manufacturer, or laboratory. Agencies should not open the kits prior to distribution. The FDA approved home testing kits include required instructions on how to perform and interpret the results of the test. The self-collection kits include

specimen collection and submission instructions, which have been developed by laboratories and vendors who distribute LDT kits. Agencies may not replace, alter, or remove the instructions and inserts. Agencies may add locally relevant materials including local phone numbers and contact information for support and referrals.

Guidelines for the Development of Agency Specific Policies

Programs funded or supported by DSHS may use home testing kits or self-collection kits for distribution to eligible individualsⁱⁱⁱ. Programs implementing this activity must develop and maintain a DSHS-approved policy. Use the attached “Readiness for Home Testing/Self-Collection Table” to address the following required items:

- Identify the populations who are eligible to receive test kits;
- Identify which home testing and/or self-collection kit(s) are appropriate for the populations being served and why;
- Identify the funding source that will be used for the purchase of tests, staff time, postage, and other associated costs;
- Describe the processes in place to protect the security of program reporting data and the confidentiality of client information;
- State how the agency will obtain and document informed consent;
- Describe how kits will be shipped, stored, and maintained, including inventory and quality control measures;
- Describe how the distribution of test kits will be documented and tracked;
- Describe how demographic, priority population group, test result(s), and linkage data will be documented and tracked;
- Describe how the notification of test results, referrals for confirmatory testing as required, referral to and confirmation of medical care/treatment, partner services, and referrals for other essential prevention services will be made and tracked;
- Identify required staff training(s) specifically for home testing and self-collection kits and how staff will relay relevant information to persons requesting tests;
- Describe how test results will be accessed and reported to the local health authority; and
- If applicable, list incentives and describe how they will be used during the interaction with persons being tested.

READINESS FOR HOME TESTING/SELF-COLLECTION TABLE: Items for Consideration Prior to Distribution of Home Testing and Self-Collection Kits

Instructions: If you are interested in providing home self-collection kits, **read the attached** Technical Assistance Brief (5/20/2020) from the National Coalition of STD Directors (NCSD) entitled At-home Self-Collection Lab Testing for Sexually Transmitted Infections. Please communicate with your DSHS consultant regarding your plans to facilitate home testing and home self-collection. The DSHS staff are available to assist you with your planning. Complete the following table as thoroughly as possible. Use this document to inform the creation of an agency-specific policy. Once both are completed, submit this Readiness Table AND your proposed agency-specific policy to your designated DSHS consultant(s) for approval. DO NOT begin activities until your policy has been approved by DSHS.

| Questions for Consideration | Agency Answer |
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| What funds will your agency use to purchase test kits and staffing to support the serves? | |
| Which tests will you offer (e.g. HIV home testing, home self-collected HIV, GC/CT urogenital and extragenital, creatinine, HBV/HCV, or syphilis specimen)? Please specify the manufacturer of the home test kits and home collection kits. How will your agency select tests and tailor for individuals with specific risk factors or testing needs? | |
| If you will offer home self-collection kits, which laboratory or vendor will you partner with to process home self-collection kits? If you will partner with a vendor, which test processing laboratory will be used? | |

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| <p>If you will partner with a laboratory or vendor, have you discussed and confirmed that the laboratory will accept home self-collection specimens (i.e. has performed the required validations to meet CLIA requirements for LDTs [see NCSD TA Note for additional information and options])?</p> <p>NOTE: If an out-sourced vendor is to be used, be sure that the negotiated agreement includes the return of any relevant data including (but not limited to) demographics, test results, or other data related to test usage (e.g. dates of test distributions, number of tests returned, types of kits ordered).</p> | |
| <p>What measures will be in place to protect the security of program reporting data and the confidentiality of client information as per DSHS policies^{iv}?</p> | |
| <p>What is the process for individuals to request a test?</p> | |
| <p>Describe your test kit eligibility criteria (e.g., geographic area, priority population, demographics, HIV/STI history or contacts, assessing for PrEP services?)</p> <p>How do you plan to screen for eligibility?</p> <p>What age requirement(s) will be in place (different tests have different requirements related to age)?</p> <p>How often can individuals be given the test kit(s)?</p> | |

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| <p>How will the agency ensure that only appropriate tests are provided to people based on medical history and/or assessment (e.g. GC/CT extragenital sites, individuals with a prior HIV diagnosis should not receive an HIV test, persons with a history of syphilis should not receive a syphilis treponemal test)?</p> | |
| <p>How will the new services be marketed and tailored specifically to the eligible populations described above?</p> | |
| <p>Will tests be mailed or picked up? If they are mailed, what funds will be used to cover shipping costs? Who will cover shipping costs for self-collection kits that are returned by the individual to the laboratory? What steps are in place to ensure confidentiality is protected during the mailing process?</p> | |
| <p>How will the agency obtain and document informed consent (e.g. to receive test kits, to be contacted by a staff member of your agency, for counseling, and medical services as applicable to the encounter)?</p> | |
| <p>How will relevant data (e.g. demographic information, priority population group, test result(s), result notification, referrals for confirmatory testing, referral to and confirmation of medical care/treatment, and</p> | |

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| <p>referrals for other prevention services) be documented and tracked?</p> <p>What system(s) will be used? Be specific about how data will be entered and by whom.</p> <p>NOTE: All data collected must reported to and follow DSHS reporting requirements.</p> | |
| <p>What quality control measures will be used to maintain kits if they are being stored in your facility (e.g. rotating the stock of kits so none expire, double-checking that kits are sent out are not expired, storing kits according to manufacturer's requirements)?</p> | |
| <p>How will the agency minimize the impact of temperature extremes when mailing to ensure the kits are not damaged and results remain valid?</p> <p>How will the agency mitigate the risk of self collection kits being damaged or compromised when mailed to the lab?</p> | |
| <p>What training will be required for staff (e.g. performance of the test, explaining testing and/or collection processes to persons requesting tests, reading/interpretation of results, documentation of activities)?</p> <p>How will staff be trained on the limitations of each test and how will that information be provided to persons requesting tests (e.g. oral fluid in identifying early HIV infections, timeframes for detection of HIV/STDs/HCV)?</p> | |

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| <p>What information will be provided to clients on how to prevent the transmission of HIV/STDs/HCV including information on local prevention resources, including PrEP?</p> <p>Who will conduct this training and what expertise do they have?</p> | |
| <p>Will staff members schedule time with those who have received a home testing kit and conduct the test together or will individuals conduct the test on their own?</p> <p>Will individuals receiving a home self-collection kit be instructed by a staff member on how to collect the specimens at home or will they rely on written instructions included with the kit?</p> | |
| <p>If individuals will have a scheduled time with a staff member, what HIPAA compliant platform will be used to communicate with the person (e.g. video chat, phone, other telemedicine software or platform)?</p> <p>Does the agency have the necessary HIPPA compliant platforms to communicate with individuals via video chat (if this option will be used) for the provision of test results or telemedicine services?</p> <p>What considerations will be made for persons with hearing impairments.</p> | |
| <p>Are written instructions provided in both English and Spanish?</p> | |

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| <p>Will bi-lingual staff be available to assist people who speak Spanish?</p> <p>How will people who speak other languages be assisted?</p> | |
| <p>Will individuals performing home testing without the assistance of a counselor be offered an incentive to call in to report their test results?</p> <p>Will individuals with a preliminary positive test result be offered an incentive to link to medical care/treatment?</p> <p>What incentives will be used and how will they be distributed?</p> | |
| <p>Does your agency have Standing Delegation Orders (if nurses and/or unlicensed staff provide HIV or HBV/HCV testing or STD testing/treatment as delegated by a physician) and other medical protocols (e.g. PrEP)?</p> | |
| <p>How will individuals with <i>positive home self-collection</i> results obtain their test result (e.g. an agency provider call, EHR portal, another medical provider or out-sourced vendor)?</p> <p>If individuals receive their test results from another medical provider or vendor how will your agency obtain those results?</p> <p>How will individuals be informed about how to obtain their results and will reminders be available for people to check their results?</p> | |

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| <p>How will confirmatory testing be performed with individuals who receive a <i>preliminary positive</i> test result from a <u>home testing kit</u>?</p> <p>For individuals who receive a preliminary positive result from a home testing kit, how will linkage to care/treatment be performed?</p> <p>How will referrals for other services be performed for persons testing preliminary positive with a home testing kit?</p> | |
| <p>How will individuals with a positive treponemal test receive an RPR test prior to initiation of treatment?</p> | |
| <p>How will referrals for PrEP be handled for persons testing <i>negative</i> on a <u>home testing kit</u>?</p> <p>How will referrals for other services be performed for persons testing negative from a home testing kit?</p> | |
| <p>For individuals who receive a <i>positive</i> result from a <u>home self-collection kit</u>, how will medications be provided (e.g. in-clinic, by mail, outside pharmacy)?</p> <p>Will Expedited Partner Therapy be an option for someone with a reactive GC or CT test result?</p> <p>Do outsourced providers have the appropriate licensure and prescriptive authority in Texas?</p> <p>What follow-up will occur for persons treated for STDs (e.g. RPR testing, schedule in-person visit if symptoms do not resolve).</p> | |

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| <p>What information will be included with the test kit when it is mailed?</p> <p>What local or national resources will be included?</p> <p>What information will be given about when to contact your agency with questions and when to contact a test kit company directly?</p> | |
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Considerations Moving Forward: It is recommended that your agency conduct on-going assessments regarding access, acceptance, and uptake of home testing and/or home self-collection kits. Please discuss this consideration with your designated DSHS consultant(s).

Note for Remote Staff: If home testing and/or home self-collection is to be implemented by staff working in remote locations, include information about how staff will ensure confidentiality is maintained while working from home. Be sure to address confidentiality of data (both physical and electronic) of the individual being tested when staff engage with them from their homes, including how information will be protected from members of the staff's household.

Endnotes:

ⁱ Testing that occurs in field settings and in clinic/office settings must continue to follow appropriate DSHS policies.

ⁱⁱ <https://www.cdc.gov/vitalsigns/hepatitisc/index.html>

ⁱⁱⁱ Partnering agencies may purchase test kits with their own funds or with DSHS funds (if they are available in current contracts). The purchase of test kits for dispersal by DSHS is dependent on the availability of funds.

^{iv} DSHS TB/HIV/STD Confidential Information Security policy, TB/HIV/STD Breach of Confidentiality Response Policy, and Breach Report Form/Breach Report Instruction (<https://www.dshs.texas.gov/hivstd/policy/security.shtm>)

Additional Resources:

CDC Resources

HIV Testing Information

<https://www.cdc.gov/hiv/testing/laboratorytests.html>

<https://www.cdc.gov/hiv/testing/self-testing.html>

Information about Testing for STDs Outside of Healthcare Settings/Clinics

<https://www.cdc.gov/std/prevention/disruptionGuidance.htm>

FDA Resource

Definition and Information About LDTs

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

NCSD Resource

Attachment: At-home Self-Collection Lab Testing for Sexually Transmitted Infections Technical Assistance Brief Updated May 20, 2020