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Direct-to-Consumer STI Testing Services: A Position Statement from the American Sexually Transmitted Diseases Association

Cara Exten, PhD, MPH[1], Casey N. Pinto, PhD, MPH, CRNP[2], Anne M. Gaynor, PhD[3], Beth Meyerson, MDiv, PhD[4], Stacey Griner, PhD, MPH, CPH[5], Barbara Van Der Pol, PhD, MPH[6,7] on Behalf of the Board of Directors of the American Sexually Transmitted Diseases Association

[1]The Pennsylvania State University, College of Nursing, University Park, PA

[2]The Pennsylvania State University, College of Medicine, Department of Public Health Sciences, Hershey, PA

[3]Association of Public Health Laboratories, Silver Spring, MD

[4]University of Arizona, Southwest Institute for Research on Women, College of Social & Behavioral Sciences, Tucson, AZ

[5]University of North Texas Health Science Center, School of Public Health, Fort Worth, TX

[6]University of Alabama at Birmingham, School of Medicine, Birmingham, AL

[7]University of Alabama at Birmingham, School of Public Health, Birmingham, AL

Corresponding Author: Barbara Van Der Pol, PhD, MPH

703 19th St S, ZRB 238, Birmingham, AL 35294

+1.205.975.4268

e-mail: bvanderp@uab.edu

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Short Summary

On behalf of the American Sexually Transmitted Diseases Association (ASTDA), we discuss benefits and challenges of direct-to-consumer test services for sexually transmitted infections and offer recommendations for future directions.

Abstract

Direct-to-consumer test services have gained popularity for sexually transmitted infections (STIs) in recent years, with substantially increased use as a result of the SARS-CoV-2 (CoVID-19) global pandemic. This method of access has been variously known as ‘self-testing’, ‘home testing’, and ‘direct access testing’. While these online services may be offered through different mechanisms, here we focus on those that are consumer driven, require self-collected samples, and sample shipment to a centralized laboratory without involvement of healthcare providers and/or local health departments. We provide ASTDA’s position on utilization of these services and recommendations for both consumers and healthcare providers.

Keywords: sexually transmitted infections, consumer-driving testing, online test services, STI Diagnostics, direct access testing, self-testing, home testing, self-collection, direct to consumer, over the counter, self-sampling

Background

Direct-to-consumer (DTC) test services for sexually transmitted infections (STI) are available in many configurations. This position statement focuses on online test services with DTC purchasing options that involve self-collection of samples in a non-clinical setting and transport (through mail or direct drop off) of samples to a testing laboratory. These tests have been variously referred to as 'online testing', 'self-testing', 'home testing', and 'direct access testing'. Here we will use the phrase "direct-to-consumer" (DTC) testing. DTC products include access to testing kits directly through a retail outlet or through websites offering STI screening services. From online vendors, collection materials are shipped to consumers who then collect a sample to be sent to a laboratory for testing. Transport to the laboratory may be accomplished via drop-off at a laboratory or healthcare facility or, more commonly, via shipment or courier service directly to the testing laboratory. We understand that similar testing access is available through alternate mechanisms such as telehealth or via local health departments in some jurisdictions, but these are not the focus of this position statement since these are directed by a healthcare entity who has a working relationship with the laboratory and established mechanisms for handling results and providing care. Here we focus on the advantages and challenges, along with our recommendations relating to DTC STI testing.

Advantages of DTC Test Services

Modalities of DTC testing can potentially address documented barriers to STI testing including inconvenience, privacy concerns and the sense of stigma associated with seeking STI-specific care. Compared to face-to-face care, DTC testing services are perceived as offering more privacy, a primary concern among teens and young adults (1-3). They also address concerns of

embarrassment or discomfort around a discussion about sexual history and/or sexual health examination, both of which are cited as major barriers to care utilization (4). The fear of stigma, a well-documented concern around STI testing and management (3, 5), may be alleviated by the use of DTC test services. Further, the use of DTC test services could improve access to testing for persons that otherwise would not attend clinics that provide STI services due to limited access (4-7).

DTC test services may also be advantageous to clinicians and clinical programs. The Centers for Disease Control and Prevention (CDC) (8) and the United States Preventive Services Task Force (USPSTF) (9) recommend annual STI screening for sexually active women under the age of 25 and more frequent screening for persons on pre-exposure prophylaxis (PrEP) (10). DTC test services may reduce the burden on healthcare providers, who cite insufficient time and staff as barriers to performing routine STI screening, particularly among asymptomatic persons (11, 12). The COVID-19 pandemic represents a situation in which face-to-face services were severely limited and many clinics have relied on online mechanisms for providing STI testing remotely. This may result in an increased demand for access to testing services through commercial entities due to increased comfort with the process.

Importantly, DTC STI test services have the potential to provide substantial support to the overall public health effort to control STIs. Identifying STIs, particularly asymptomatic cases, is a critical component of reducing transmission (13), thus any program that increases rates of testing may enhance overall control efforts. Several studies have suggested that self-sampling may increase uptake of chlamydia and gonorrhea testing (6, 14, 15) and it stands to reason that

consumers may also embrace DTC testing. It is conceivable that this strategy could improve the quality of partner management services by directing contacts to utilize DTC services. This could facilitate access to more convenient and private testing, while also reducing the burden on public health agencies who currently manage partners in clinical settings.

Challenges of DTC

While the potential for expanding the reach of STI screening by utilization of DTC services is great, there are challenges that need to be addressed in order to ensure the quality of testing, equity of access, communication of results, consumer and partner management, and comprehensive surveillance reporting. Data suggest that there is room for improvement in the process of managing persons with positive results identified via DTC testing (22) Cannon 2021, this issue).

Accessibility may improve due to DTC; however adolescents and young adults living with others cite privacy concerns related to mailed collection kits (16-18). Additionally, while DTC STI test services may increase access for some populations, other populations, for example persons experiencing housing insecurity, may not be able overcome potentially high costs and requirements for a mailing address and internet access (19). Even for those living in stable housing, about 8% of Americans lack internet access at home (20). This is particularly concerning given that these same populations are disproportionately impacted by STIs (8). Finally, the cost of DTC online testing services varies widely which also impacts accessibility. Chlamydia and gonorrhea testing prices range from $49 to $189 or higher. Bundled testing that includes other STIs can cost >$400 which may be prohibitive to the persons most in need of

increased access to care, including those who already cite cost as a barrier to STI testing (2, 21). Further, DTC services may not be reimbursable under some insurance plans since the testing is not ordered by a healthcare provider.

A second challenge associated with DTC STI testing is ensuring that appropriate testing is being ordered and performed. DTC online testing sites offer an array of testing options and may use algorithms or artificial intelligence, rather than healthcare providers, to assist the consumer with selecting the most appropriate test or test bundle. However, recommendations from the DTC service to the consumer frequently lack the clarity and details needed for an informed decision about which test/s is/are most appropriate and the follow-up that may be required (22) (Cannon 2021, this issue). Bundled testing, often includes unnecessary tests or tests that are only in recommended in very specific circumstances. For example, bundles may include molecular testing for *Ureaplasma spp.* or *Mycoplasma hominis* for which there are no screening or treatment recommendations, or *Mycoplasma genitalium* for which testing is only recommended in men with persistent urethritis or women with cervicitis or pelvic inflammatory disease (23). These bundles often include options for herpes simplex virus (HSV) molecular testing and/or testing for *T. pallidum* from urine or unobserved self-collected vaginal swabs even though such testing should only be performed from specimens obtained directly from lesions (13, 24). Finally, consumer knowledge of necessary tests may be limited which could result in over-testing out of an abundance of caution or under-testing due to a lack of understanding of their risk for certain infections.

An important and understudied issue related to DTC testing is a potential lack of diagnostic reliability and validity. Reliability of the results, such as receiving incorrect or inconclusive results (18, 25, 26) and concerns about collecting specimens appropriately (18, 26, 27) have often been reported with DTC services. Other potential service issues that have not been fully documented include whether testing materials/kits arrive to the correct location once purchased; the quality of the shipped samples (which may be affected by transport conditions); whether results are ever received and if received, the time from sample collection to reporting of test results. Currently, the testing quality and diagnostic reliability remains unclear and no commercially available assays have a FDA-approved/cleared claim for unobserved self-collected specimens in a non-clinical setting. The methodology utilized by the testing laboratory to determine the validity of their collection, transport, and testing processes is often not made public, and obtaining details about internal laboratory validation may be difficult for both consumers and providers. The sensitivity and specificity of the assay utilized is often not available on service websites, and when present, it may be difficult for consumers to interpret, particularly in the absence of understanding the entire validation approach. This creates uncertainty about performance characteristics for the assay utilized which hampers appropriate clinical management of the consumer.

Reporting and taking action on test results is imperative. Results must be reported to the consumer in clear language and must include information about the consumers' next steps. Nearly 36% of Americans suffer from low health literacy (28) and may be more likely to trust social media and blogposts for health information (29), which poses a challenge for delivering DTC test results. Results of testing for three common STIs, chlamydia, gonorrhea, and

trichomoniasis, are relatively simple to interpret with positive results requiring treatment and negative results requiring no further evaluation. However, results for other STIs necessitate interpretation that is often dependent on data from the clinical and medical history. For example, interpreting syphilis serologies requires knowledge of sexual history, previous exposures/diagnoses, information about the diagnostic test used, and/or confirmatory test results (13). In cases where confirmatory tests are not performed, test results may not be interpretable. For appropriate clinical management, especially in cases where the recommended treatment may involve injectable medications, direct interaction with a healthcare provider may be required.

Finally, communication of these reportable conditions by commercial testing services to public health providers and agencies may be problematic and can result in delayed time to treatment, and missed opportunities for partner services, surveillance, and prevention of community transmission (22). Linkage to care when using these services is difficult to ascertain and persons may not receive recommended treatment. Additionally, the process for healthcare providers to manage results from online test services remains unclear potentially resulting in redundant or unnecessary confirmatory testing. This redundant testing to confirm test results may increase cost and time to treatment thereby reducing the potential benefits from DTC testing. Finally, if reporting to public health agencies is delayed or not done, there may be gaps in partner services and treatment, impacting key recommendations for providing quality STI clinical services (30).

Recommendations

ASTDA supports leveraging appropriate tools to reduce the burden of STIs in all populations. Recommendations in **Figure 1** address five important areas to reduce the potential for harm and

improve outcomes for consumers, clinicians, and public health practitioners: Consumer protection and empowerment, test selection issues, laboratory-specific issues, clinical management concerns, and policy recommendations. These recommendations are directed to our STI policy, research, practice, laboratory, and clinical partners. We hope that consumers will request, and commercial services will engage in this process of increased transparency to ensure access to high quality and effective STI testing.

Consumer Protection and Empowerment Recommendations: These recommendations are focused on achieving information transparency and quality. Specific recommendations are to:

- Establish a national feedback system to publicly identify websites and service providers, their quality, and customer experience.
- DTC service providers should
    - Publish consumer-friendly, multilingual validation data and their interpretation, as well as detailed information about sample collection, testing processes, and potential for insurance reimbursement.
    - Publish and maintain up-to-date frequently asked questions (FAQs) on each test service website. FAQs should also be available to download. The key is to provide important information for healthcare providers and public health practitioners who make management decisions based on these test results. Information for these FAQs should be developed in collaboration with all stakeholders, and may include:

- expected time to results,
- evidence of involvement of a knowledgeable healthcare provider (MD/NP/PA/DO) in test selection and treatment options,
- the performance characteristics of each test and how these characteristics were determined,
- description of the mechanism for managing positive test results,
- linkage to STI healthcare specialists to answer consumer questions,
- insurance reimbursement and consumer financial liability,
- prevention services information and referrals.

Test Selection Recommendations: DTC testing services and laboratory partners should only offer tests that are aligned with public health agencies (e.g. CDC, USPSTF) and professional societies' (e.g. the American College of Obstetrics & Gynecology, American Academy of Pediatrics, etc.) guidance. Recommendations are:

- Organisms for which we have no screening or diagnostic recommendations (e.g., *Ureaplasma spp.*, *Mycoplasma hominis*) should not be tested for via online services. They should not be offered as part of an STI screening panel for diagnostic/clinical management.
- Screening among asymptomatic populations should be limited to those infections for which there is demonstrated value to screening (e.g., asymptomatic screening for *M. genitalium* is not currently recommended).
- Population-specific warnings should be clearly communicated at the time a test is ordered (e.g., pregnant women should be encouraged to see an OB/GYN or their primary care provider for testing).

Laboratory recommendations: These recommendations focus on quality of laboratory testing that experts in the field must:

- Work with Centers for Medicare & Medicaid Services (CMS), the agency which oversees Clinical Laboratory Improvements Amendment (CLIA) regulations) to tighten regulatory requirements for DTC services that involve self-collection and transport of specimens.
- Work with College of American Pathologists (CAP), and other programs to strengthen the accreditation processes by requiring rigorous validation of assay reliability and quality of services.
    - Validation data should be available for review by any consumers: health care providers or persons using the DTC services.

Recommendations for Clinical Management: These recommendations are to help assist with decision-making when interpreting test utility and results as well as verifying functionality of local reporting processes.

- General recommendations for providers:
    - Become familiar with the available high-quality DTC services should patients request specific recommendations.
    - Suggest appropriate tests as recommended by public health or professional guidelines.
    - Advise in-person testing for patients with high-risk of potential negative outcomes (e.g. pregnant women) related to missed infections.
- Recommendations for providers related to interpretation of results:
    - Provide follow-up for interpretation of results (telehealth/in-person).

- Be cautious when interpreting results unless access to test performance data is available.
- Provide additional screening/testing when necessary (i.e., DTC chlamydia testing without gonorrhea testing) and provide appropriate risk reduction counseling such as HIV PrEP.
- Offer confirmatory testing where appropriate (e.g. for HIV and syphilis serology results) but do not let confirmatory testing be a barrier to treatment.
- Inquire about the use of DTC services during collection of routine medical history which may help illuminate patient medical concerns not otherwise expressed.
- Ascertain the treatment prescribed by the DTC to ensure appropriate therapy was provided for any identified pathogens.
- Verify reporting of notifiable infections identified by DTC testing. If reporting is not being done, work with local and state public health agencies to close the gap.

Policy Recommendations: Recommendations are made to help advance our policy and practice to utilize DTC testing to improve access to quality services that will assure health value. They are:

- Develop national guidance for validation and/or verification of self-obtained and shipped samples for STI testing. This guidance can be developed in partnership with the Association of Public Health Laboratories (APHL), ASTDA, and others.
- Design novel STI reporting processes to better support DTC testing services reporting.
- Work with the FDA and industry to try to develop a path toward achieving claims for self-obtained and shipped samples.

- Develop policies that provide public health underwriting of the cost of testing or increase the utilization of public health laboratories as a mechanism for reducing health inequities and improving access.

The Way Forward

STI professionals have a collective opportunity to expand the reach of STI control efforts by utilizing high quality DTC testing services. ASTDA supports this development and recommends actions to assure consumer protection and empowerment. This opportunity has the potential to improve not only the quality and impact of DTC STI testing services, but will also be relevant to over-the-counter STI tests when such tests become cleared for use by the FDA. Optimizing the process for DTC test services will prepare us for diagnostic testing modalities currently in use, in the pipeline, or yet to be envisioned. Doing so in a way that involves all stakeholders (e.g., consumers, public health practitioners, healthcare providers, laboratories, testing services providers and researchers) will serve to strengthen the future of STI testing services for all.

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Figure 1. The Pathway to Change summarizes the Recommendations for Direct to Consumer STI testing

Figure 1