

Home-Based Testing for STIs



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What are the basics of at-home testing for STIs?



At-Home STI Testing

- **At-home STI/HIV test kits are either point of care tests, with an immediate result (some HIV tests), or self-sampling with specimens mailed to a commercial lab**
 - Typically are sold directly to consumers or through on-line telehealth companies
 - Some health departments and NGOs also offer free home-testing programs (more on that later!)
- **The types of tests often include HIV/syphilis (dried blood spot), and GC/CT/trichomoniasis with urine based testing**
- **Some companies also offer throat/rectal swabs for GC/CT, as well as dried blood spot tests for hepatitis C, HSV1/2**

<https://www.kff.org/womens-health-policy/issue-brief/telemedicine-in-sexual-and-reproductive-health/>

Sample list of providers/sites

Alpha Medical

Binx Health

TBD Health

Lemonaid

Let's Get Checked

myLAB box

Nurx

Everlywell

CheckMate

PersonaLabs

STD check

PlushCare

Virtuwell

Roman

Quest Diagnostics

with PWN

- Kit may be mailed to home, or patient orders/pays and gets drawn at a local commercial laboratory



Sample Workflow (courtesy Molecular Testing Labs)

Order Created

- Licensed provider in patient's state approves patient for self-collection and orders necessary assays.

Kit Sent

- Collection Convenience Kit is delivered (via USPS) to the patient's preferred address in 1-5 days.

Sample Collected

- Patient collects required samples, and ships back to the lab with pre-addressed return label.

Sample Analyzed

- Lab analyzes samples and notifies the provider of results. Most results available within three days.

Results Reported

- Ordering provider releases results to the patient and provides linkage to care resources.

Over the counter STI/HIV testing @ CVS

- Dried blood spots for HSV-2, syphilis, hepatitis C, HIV
- Urine for GC/CT, trichomonas (No rectal/pharyngeal testing)
- Tests mailed to laboratory (MTL)
- \$99.99 (or \$79.99 with paid membership)



Regulatory issues

- There is an FDA approved home HIV test, but STI tests not approved for home collection.
- A laboratory could validate home collection of an FDA approved test or offer their own Laboratory Developed Tests (LDT)
- LDTs are often compared against an FDA approved test (or other gold/reference standard), and that data is shown to laboratory inspectors
- However, test performance data for many LDTs are proprietary and not published.



Regulatory issues

- LDTs do not require FDA approval, but are regulated by a complex set of guidelines associated with their design and approval.
- FDA has regulatory authority over LDTs in the U.S., other state and Federal agencies provide day-to-day oversight –Clinical Laboratory Improvement Amendments and College of American Pathologists
- CLIA-certified labs used for home-based testing must report all reactive results to local health departments
- Negative results reported to patient only, not health department

Clinical issues

- Dried blood spot testing for HIV and hepatitis C has been used for many years and is comparable to laboratory based testing
- Dried blood spot testing for syphilis is less clear. Other issues:
 - All people with syphilis need two types of tests (e.g., RPR plus a treponemal test)
 - Dried blood spot tests are treponemal tests only, so cannot be used alone to confirm diagnosis or monitor response to treatment. Generally positive for life, so those with a prior history of syphilis should not use this test
 - Validated against other treponemal EIAs (generally sensitive, but some can have specificity issues)

**Do insurance
companies pay for
at-home sampling
or at-home
screening test kits ?**



Insurance Coverage of Home STD Tests

- **If the patient self-samples, returns it to the clinic or lab, then has the same test performed per clinic routine, it should be covered**
- **A point-of care test purchased in a pharmacy, (e.g., oral HIV test; or CVS HIV/STD kit) not covered, although may be able to use HSA**
- **On-line STD home-testing products**
 - Test kits start at ~\$100; higher with multiple organisms (up to \$379)
 - Interpretation of result and clinician advice included with kit
 - Usually not covered by HMO, Title X, or state FP programs

Increased access to home-based testing in CA

Los Angeles Times

Subscribe Now
\$1 for 4 months

CALIFORNIA
f
t
With sexually transmitted infections soaring in California, new law pushes at-home tests

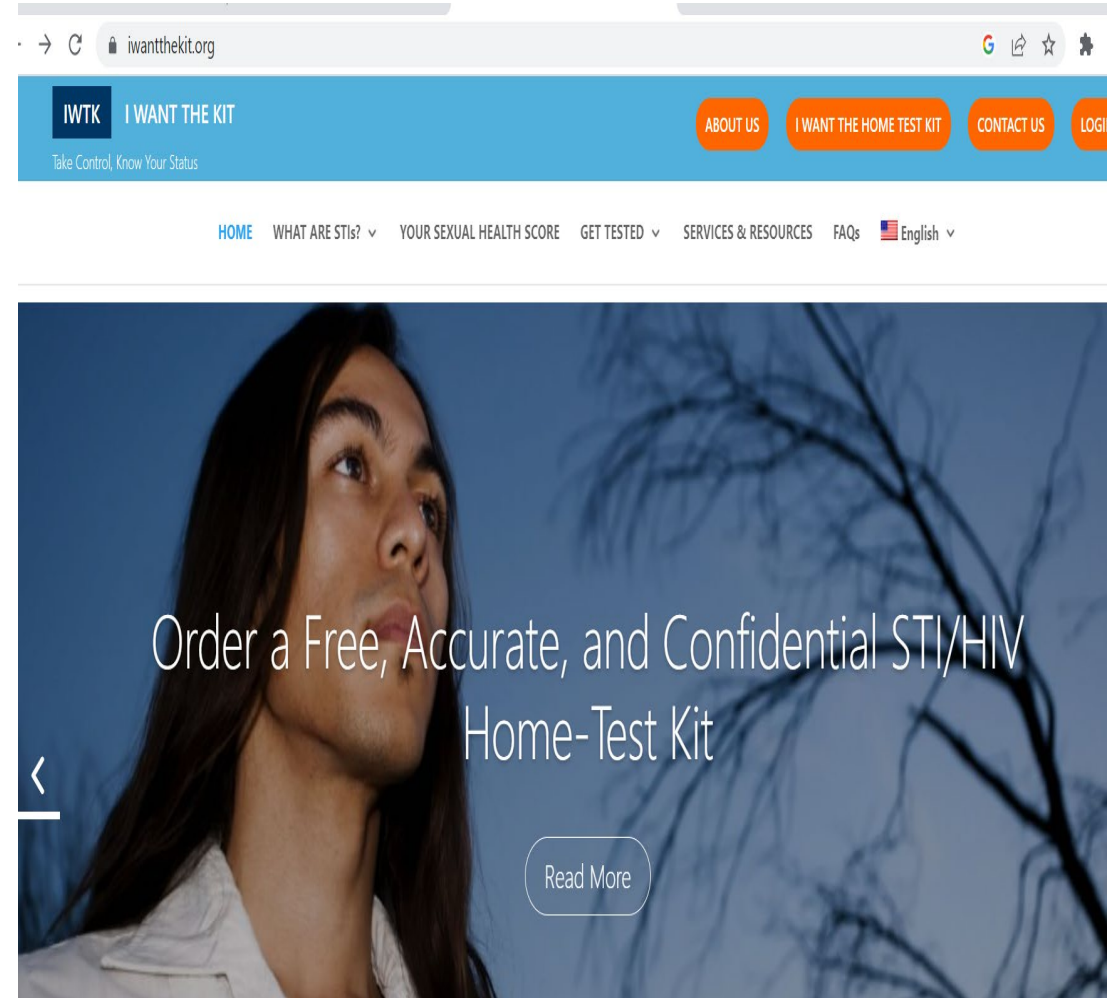
- **First law of its kind**
- California SB 306, went into effect Jan 2022
- Requires private insurers to cover the cost of at-home STI & HIV tests ordered by a healthcare provider
- Law also includes Medi-Cal (California Medicaid) and Family PACT California State family planning program)
- BUT: None of the currently FDA cleared NAAT tests are approved for home collection
- The timeline for implementation is unclear

What home-based testing is available at no charge to clients/patients?



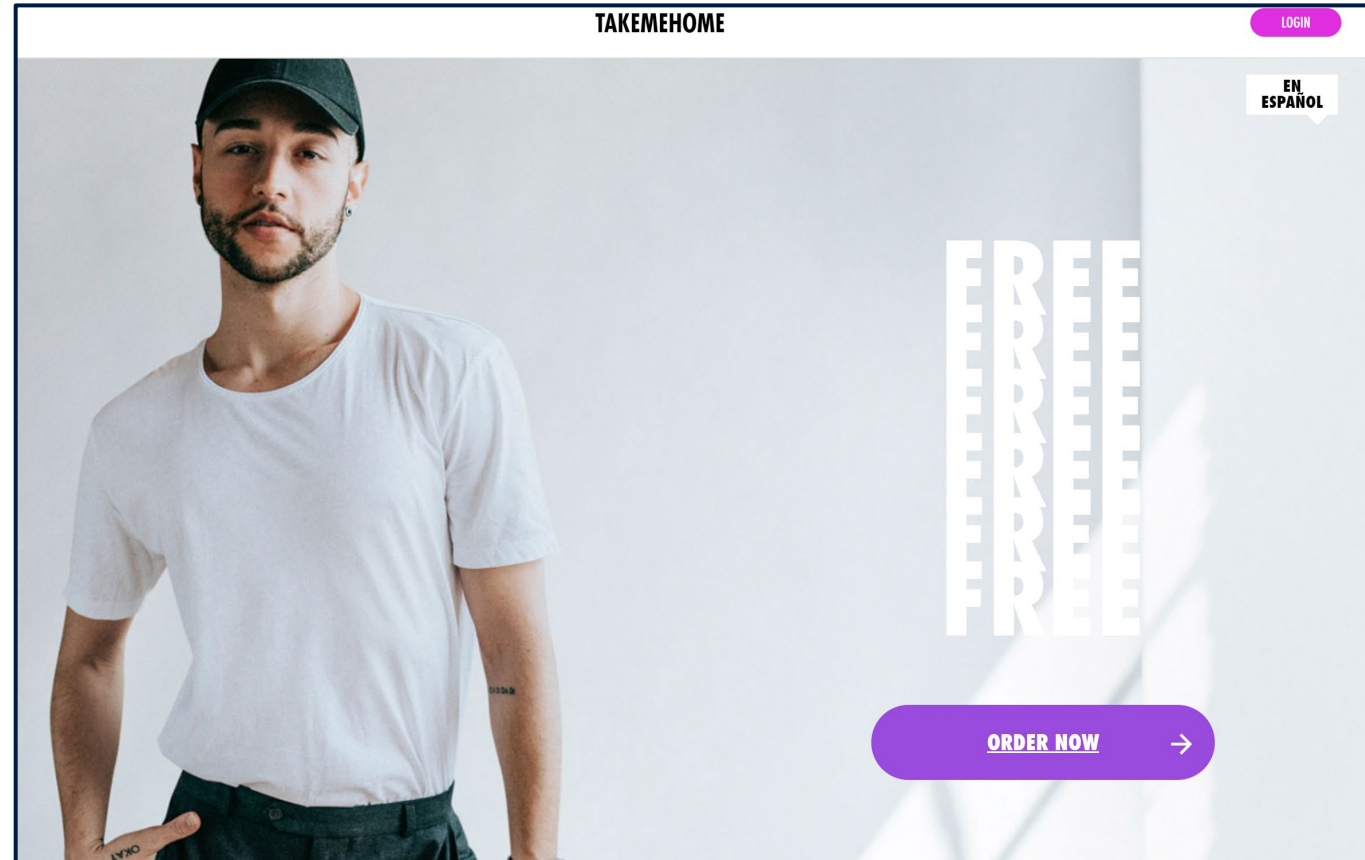
I Want the Kit (iwantthekit.org)

- Program of Johns Hopkins University, testing done at JHU
- Free 3 site testing for GC/CT, HIV (includes Trich for residents of Baltimore)
- Available to residents of Maryland, Arizona, Alaska, Oklahoma



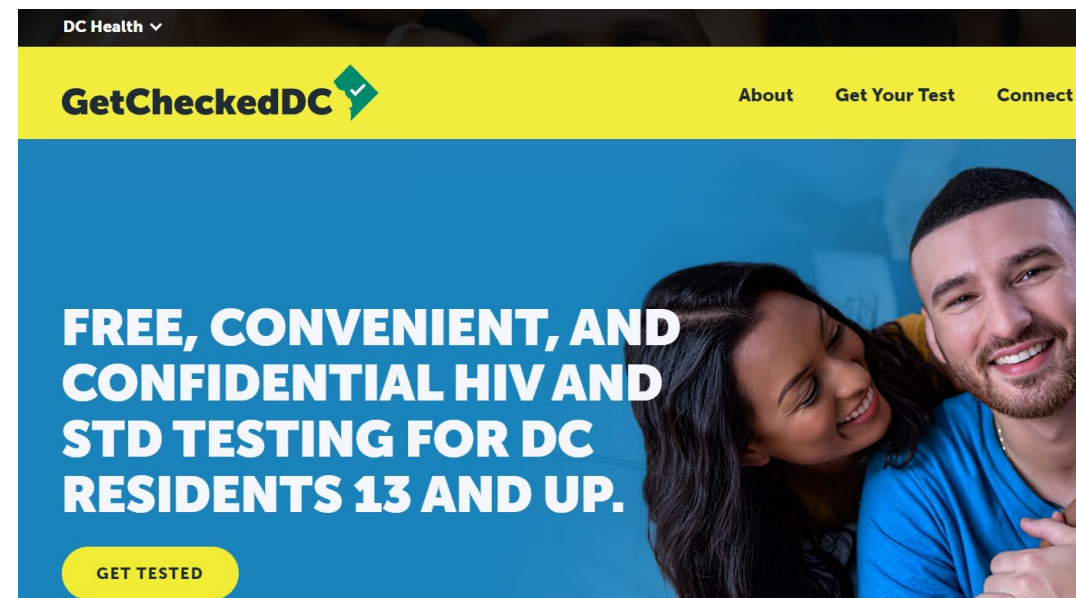
Takemehome.org

- Free sexual health home testing program, launched February 2021 by Building Healthy Online Communities
- **FREE** HIV tests and STI tests that clients can take in the privacy of their home. (GC/CT at 3 sites, syphilis, HIV, +/- HCV)
- Participating states: CA: Fresno, Riverside Sacramento, San Bernadino, SF, OR (entire state), IN (Marion County)



GetCheckedDC.org

The DC DOH published on their home-collection program experience, citing that *10.4% of patients had never been tested for STIs.*



RESEARCH ARTICLE

A Pilot of Mail-Out HIV and Sexually Transmitted Infection Testing in Washington, District of Columbia During the COVID-19 Pandemic

George M. Fistonich, MPH, Kenya M. Troutman, MPH, Adam J. Visconti, MD, MPH


Introduction: In 2019, the District of Columbia recorded a 20-year low rate in new HIV infections but also had near-record numbers of gonorrhea and chlamydia infections. District of Columbia Department of Health has supported numerous forms of community-based in-person screening but not direct at-home testing.

Methods: In summer 2020, the District of Columbia Department of Health launched GetCheckedDC.org for District of Columbia residents to order home-based oral HIV antibody test and urogenital, pharyngeal, and rectal chlamydia and gonorrhea tests. Initial and follow-up surveys were completed by individuals for both test modalities.

Results: A retrospective analysis was conducted for the first 5 months of the program. During that period, 1,089 HIV and 1,262 gonorrhea and chlamydia tests (535 urogenital, 520 pharyngeal, 207 rectal) were ordered by 1,245 District of Columbia residents. The average age was 33.1 (median=31, range=14–78) years; 51.6% of requestors identified as Black; 39.3% identified as men who have sex with men; 16.2% reported no form of insurance; and 8.1% and 10.4% reported never being tested for HIV and sexually transmitted infections, respectively. More than half of people requesting tests reported convenience and COVID-19 as the reasons. In total, 39.5% of sexually transmitted infection tests were returned; 7.22% of people testing for sexually transmitted infections received a posi-

Alabama DPH-Binx

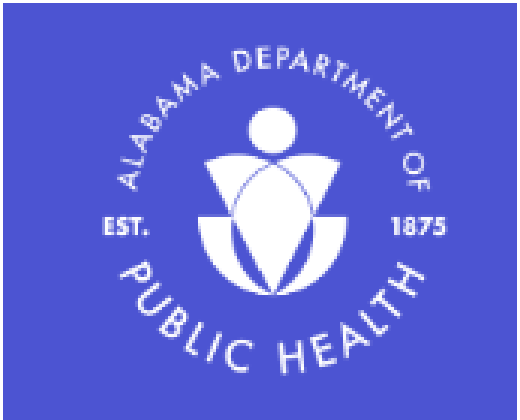
← → ↻ 🔒 adph.mybinxhealth.com/#howitworks

 How it Works Find My Test Activate Bo

Test easy, rest easy

Virtually all STIs are treatable and most are easily cured. The key is to get tested and know your status. The process is easier than you think and can be done entirely from home thanks to ADPH's partnership with binx health.

Select My Test

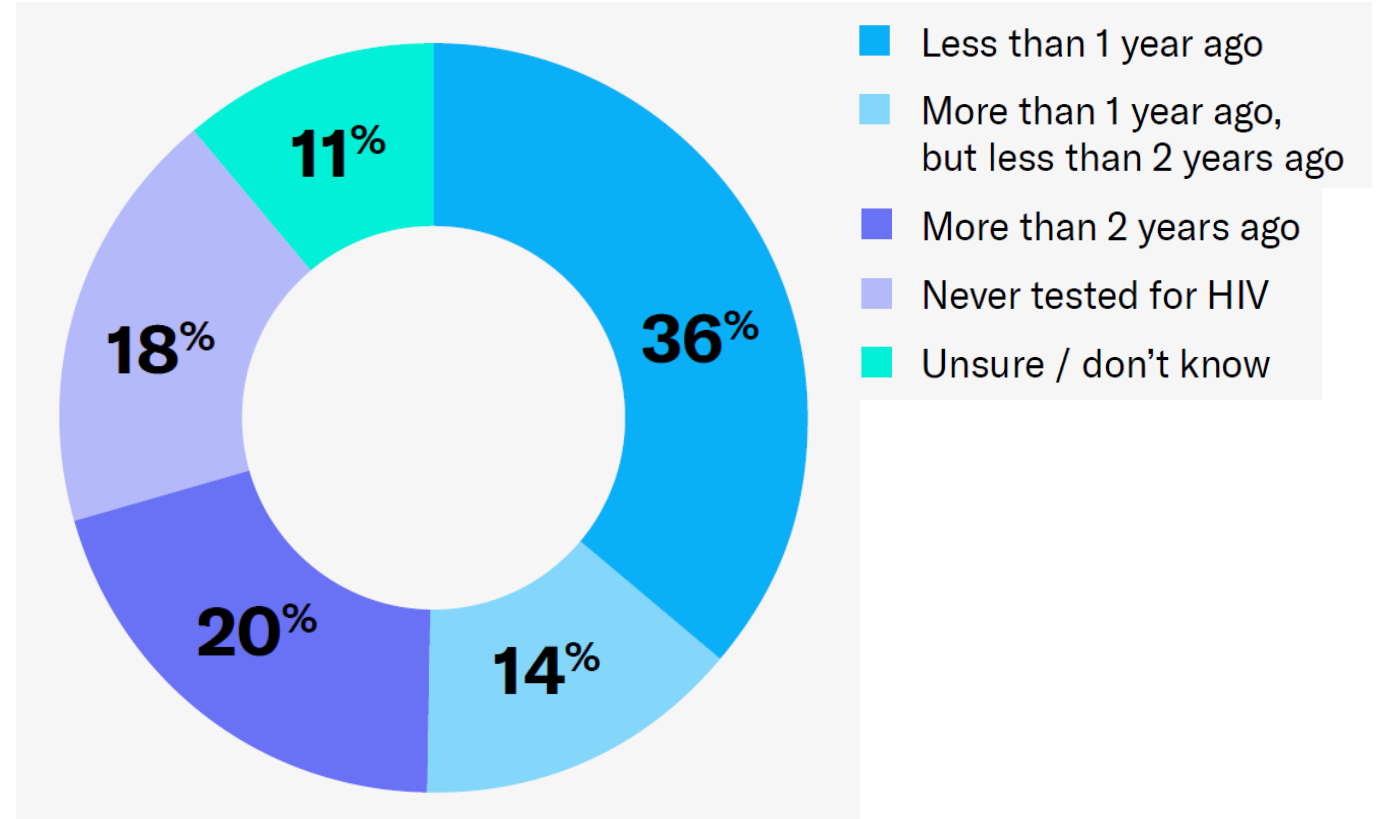


LOWERING BARRIERS TO TESTING

N=1866 kits requested between Apr-Dec 2021, 41% returned (92.5% w/in 30 days) 49% had never been HIV tested >2 yrs ago / never / uncertain

5.2% CT+, 3.2% NG+.

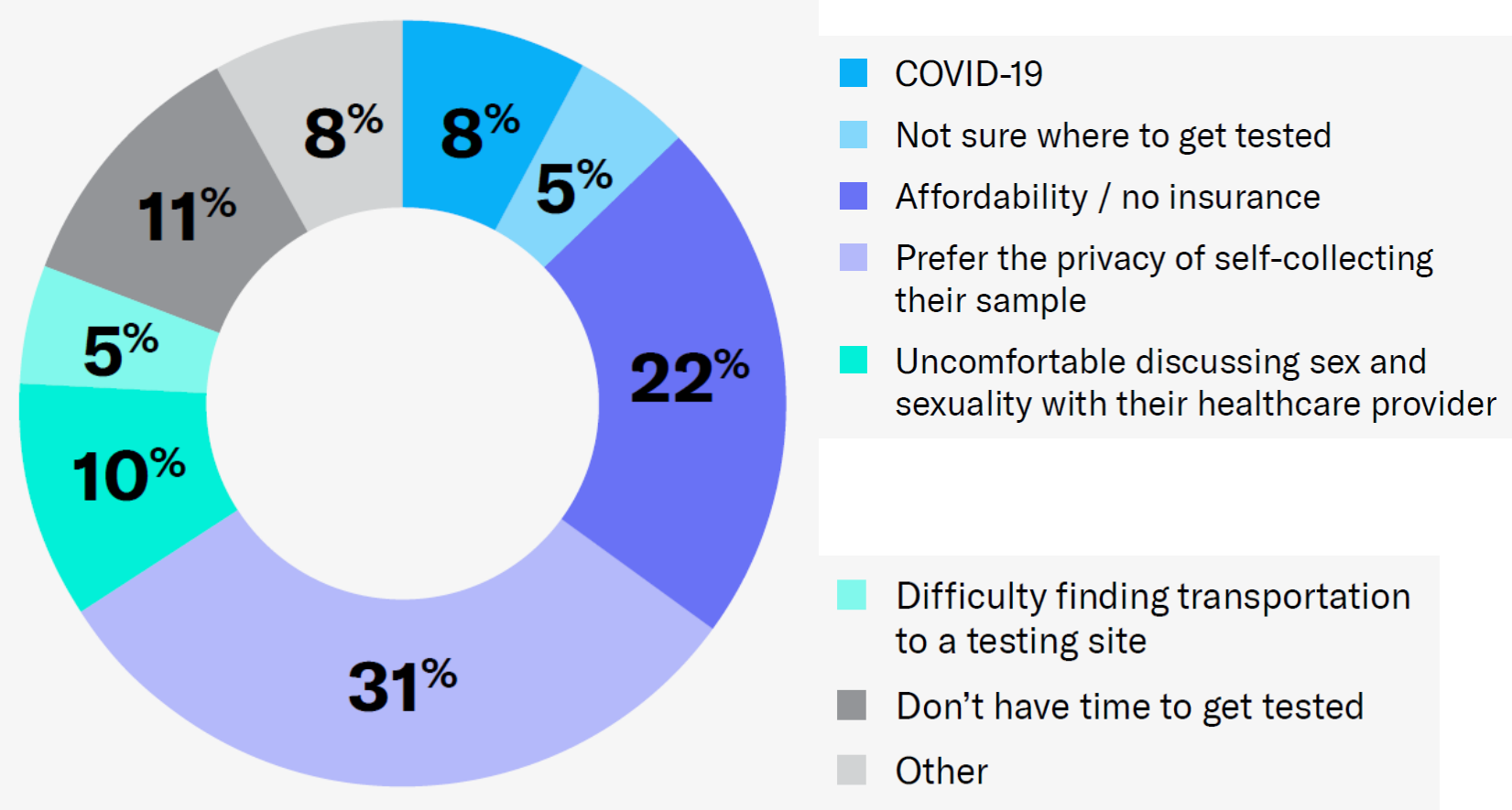
Alabama has 8th highest CT rate, 3rd highest NG rate, and 15th highest primary / secondary syphilis rate in U.S.



BARRIERS TO TESTING

TOP 4

- *Desire for privacy*
- *Financial*
- *Lack of time,*
- *Discomfort discussing sex with clinicians*



Check Yourself

- Program that supports health departments to offer home-based testing to their constituents
- Sponsored by the National Coalition for STD Programs (NCSD)
- More from our next speaker!

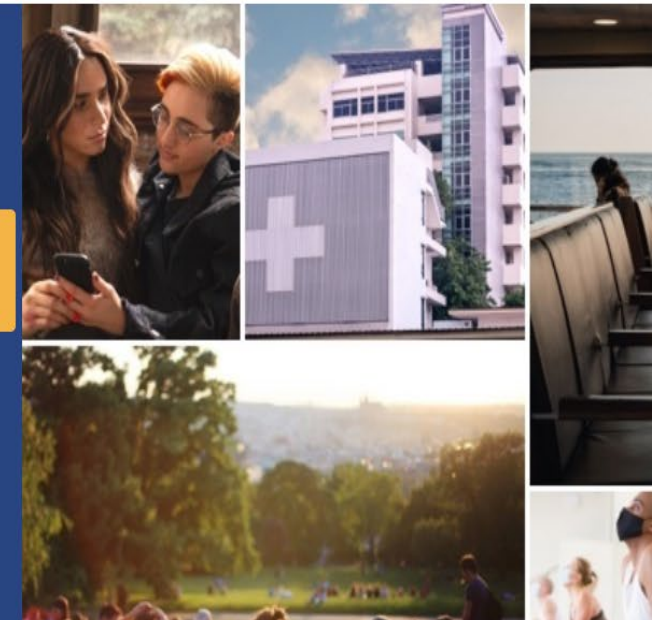


[WHY CHECK YOURSELF?](#)

[ABOUT](#)

**A NEW SEXUAL HEALTH
TOOL TO REACH THE
PEOPLE YOU SERVE**

Uniquely designed to expand capacity for self-collect STI



Acknowledgements

- Chris Hall MD, MPH (Molecular Testing Laboratories)



Thank you!

Questions?



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