

Options for Home HIV/STI Testing

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Disclosures



- I attended Gilead's 2018 U.S. Latinx/Hispanic PrEP Advisory Program.
- Only FTC/TDF and now FTC/TAF are approved by the FDA and only for use as daily PrEP in some but not all populations.

Case

A 23 year old male PrEP patient calls your clinic in mid-April 2020 because he took a home HIV test and it was reactive.

In last year:

- condomless receptive sex with ~30 partners, last ~2 weeks ago
- episode of secondary syphilis 6 months ago, tx'd with IM PCN
- occasional alcohol but no injection drug use or other substances

- Has been on daily PrEP for three years
- Has had regularly quarterly visits and labs, last seen 1 mo ago
- Reports close to 100% adherence, last missed dose NYE 2019
- No other PMH or medications

Which of the following is your interpretation and next step?

- A. Tell him it was a false-positive test and recommend he come in for his regular appointment in two months.
- B. Tell him to stop his PrEP and recommend that he buy another self-test kit for confirmation.
- C. Reassure him that it was likely a false-positive test and recommend that he come to the clinic for laboratory-based HIV testing.
- D. Prescribe a third drug as HIV antiretroviral therapy and plan to have him return to clinic in July, when the COVID pandemic is over.

“Dear Colleague” Guidance PrEP During COVID-19 (5/15/2020)

2. “Quarterly testing should be continued for patient safety... Lab-only visits... are preferred. When these are not available or feasible, CDC recommends considering two additional options.”

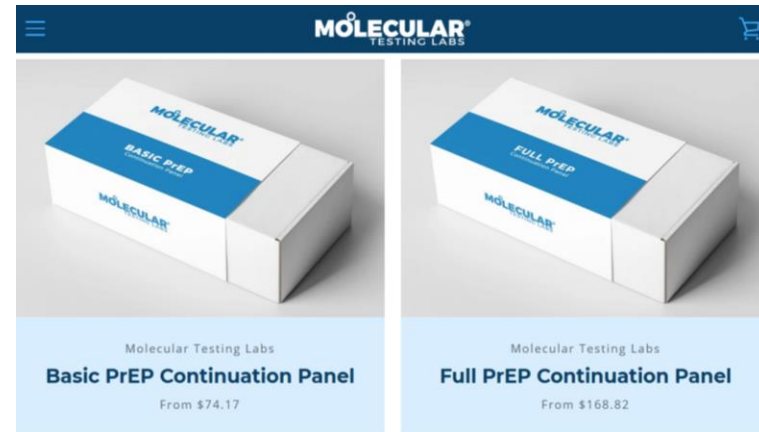
- A home specimen collection kit ... which is covered by most insurance plans and can be ordered by clinicians. Some laboratories (such as Molecular Testing Labs) have validated protocols...
- An oral swab-based test. Although this type of self-test is usually not recommended for PrEP patients due to its lower sensitivity in detecting recent infection, clinicians should consider use of these tests when other options are not available.

Options for Home HIV/STI Testing

Outline

- Home testing availability and characteristics
- Adequacy of self-collected specimens for HIV/STI testing
- The challenges of syphilis...

Home self-tests and collection kits in U.S.



Uber Box – 8 Panel Home STD Test Pack

\$269.00

- ◆ Our comprehensive 8-panel STD test kit includes tests for HIV (I & II), Hepatitis C, Herpes Simplex Type II, Syphilis, Chlamydia, Gonorrhea, and Trichomoniasis.
- ◆ Mail-in kits for home use
- ◆ Test in just 5 minutes
- ◆ Lab results in 2-5 days
- ◆ 100% pain free
- ◆ Free physician consultation
- ◆ Enjoy free & discreet shipping

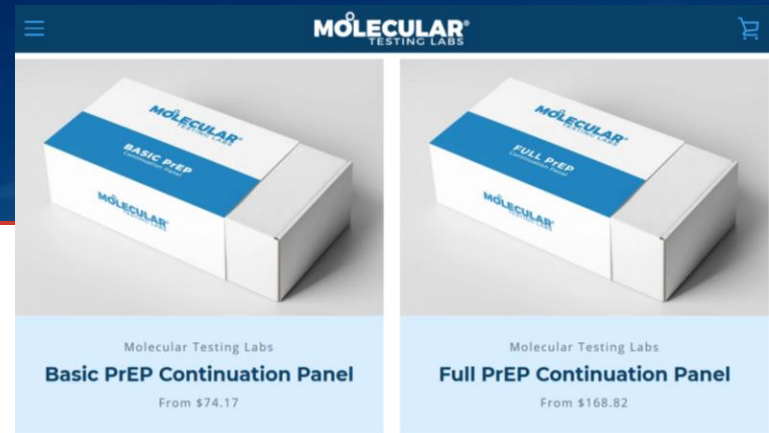


(May not be available in all states)



Molecular Testing Labs

- Basic PrEP panel
 - HIV, creatinine
- Full PrEP continuation panel
 - HIV, HCV, syphilis EIA, creatinine, 3 site GC/CT NAT
- Lab used by Nurx
- In-network for many but not all common insurance plans
- Syphilis EIA does not reflex into RPR titer
- Turn around time supposed to be 2 days from receipt of DBS at lab, but total duration (from order to shipping to receipt by patient to return back to lab to results) ~3 weeks



Home self-testing



Phase III Clinical Trial

Sensitivity

96 tested HIV+ by EIA

88 self-test +

91.7% (95% CI 84.2-96.3%)

Stated window period: 90 days

Specificity

4903 true negative

4902 self-test -

99.98% (95% CI 99.9-100%)

PrEP may lead to delayed seroconversion and false-negative tests, particularly with oral fluid tests

OraQuick In-Home HIV Test Package Insert: <https://www.fda.gov/vaccines-blood-biologics/approved-blood-products/oraquick-home-hiv-test>

Curlin et al CID 2017; 64(12): 1663-69; Donnell et al AIDS 2017; 31(14): 2007-16



Adequacy of self- v clinician-collected sampling

Systematic review and meta-analysis

Chlamydia	Sample size	Sens (95% CI)	Spec (95% CI)
Urine/urethra (men)	2133	0.88 (0.83-0.93)	0.99 (0.94-0.99)
Urine/cervix (women)	6182	0.87 (0.81-0.91)	0.99 (0.98-1.0)
Vaginal/cervix (women)	1806	0.92 (0.87-0.95)	0.98 (0.97-0.99)
Rectal (men)	(2312)	0.88 (0.81-0.92)	0.99 (0.98-0.99)
Rectal (women)	(2312)	0.88 (0.79-0.94)	0.99 (0.98-0.99)
Pharyngeal (MSM)	473	0.83 (0.36-1.0)	1.0 (0.98-1.0)

Adequacy of self- v clinician-collected sampling

Systematic review and meta-analysis

Gonorrhoea	Sample size	Sens (95% CI)	Spec (95% CI)
Urine/urethra (men)	1012	0.92 (0.83-0.97)	0.99 (0.98-1.0)
Urine/cervix (women)	2066	0.79 (0.70-0.88)	0.99 (0.99-1.0)
Vaginal/cervix (women)	309	0.98 (0.88-1.0)	0.97 (0.94-0.99)
Rectal (men)	929	0.88 (0.78-0.95)	0.98 (0.97-0.99)
Rectal (women)	697	0.85 (0.55-0.98)	1.0 (0.99-1.0)
Pharyngeal (MSM)	473	0.91 (0.75-.98)	0.97 (0.95-0.98)

Is self-collection adequate?

Dried blood spots

A few examples

- eSTAMP: 27% (6/22) of DBS cards were of “bad” quality
- Hirshfield : 554 MSM enrolled in DBS feasibility study of home HIV VL monitoring
 - 439 attempted to collect blood
 - 418 mailed a DBS specimen
 - 337 (337/439 = 77%) had an adequate DBS
- Kromdijk: Netherlands feasibility study of home TDM
 - 50 subjects collected 200 DBS
 - 87.5% suitable for analysis
 - 68% of participants reported success with first DBS attempt

eSTAMP: MacGowan et al; AIDS Behav, 2018 Jan 22(1): 117-26.

Hirshfield et al; JMIR Public Health Surveillance 2018 Nov 1; 4(4) e10847

Kromdijk et al; Antivir Ther 2013; 18(6) 821-5



Options for home testing for syphilis

- DBS
 - TPPA sensitivity 95.5%, specificity 99%
(Smit et al, BMC Infec Dis 2013 Feb 26)
 - T pallidum Ig Biokit sensitivity 93%, specificity 99%
(van Loo et al, PLoS One, 2017 oct 20; 12: e0186722)
 - Industry is working on non-treponemal tests for DBS

Options for home testing for syphilis

PrEP@Home

11. With a milking action, firmly squeeze your finger at the base and slide up until a large drop of blood forms.



12. Turn your hand over and wipe the blood drop on the inside of the tube.



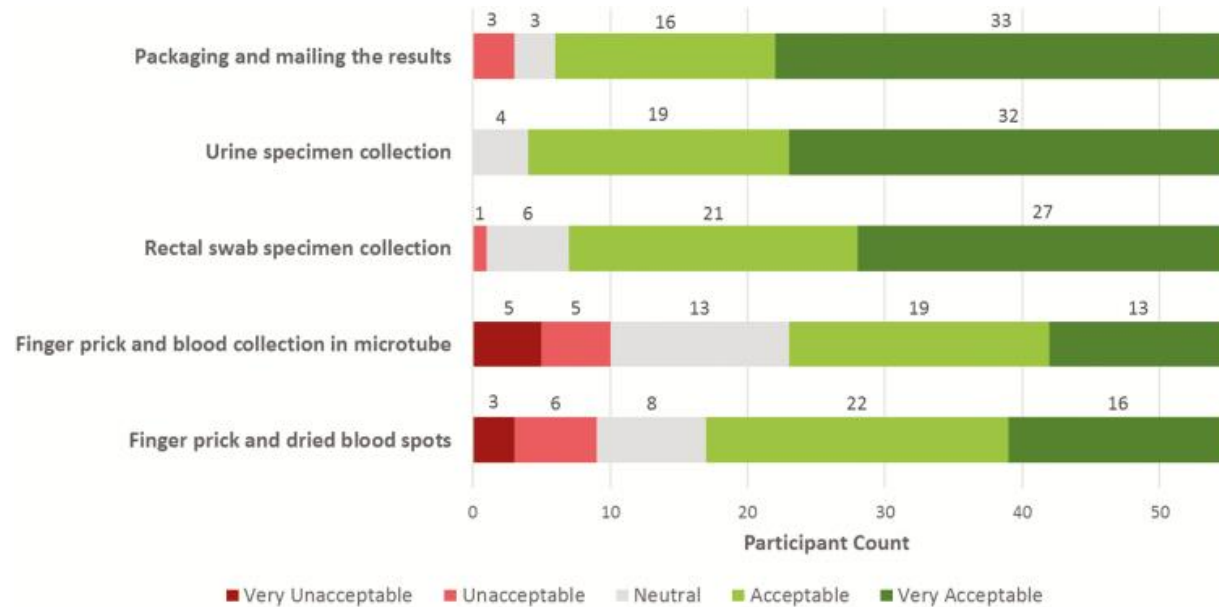
13. Usually the first few drops of blood will stick to the top and side of the tube. Keep going, and try getting bigger drops of blood. Your blood will eventually drop into the tube.



14. Fill tube to the black line. This may take 6-12 drops.

To increase blood flow:

1. Make a solid swipe with gauze pad to get blood flowing
2. If needed, use second safety lancet.



Options for home testing for syphilis NOT available for sale in the U.S.



Search STD information...



COMBO TESTS

CHLAMYDIA TEST

SYPHILIS TEST

GONORRHEA TEST

HERPES-2 TEST

HEPATITIS B TEST

HEPATITIS C TEST

HIV TEST

COVID-19 TEST



Syphilis Rapid Test Kit

The syphilis rapid test kit was designed to be as simple as possible to use. Simply follow the instructions: add one drop of blood and buffer to the test cassette.

The test kit will provide you with an accurate and reliable (sensitivity: 98.1% specificity: 98%) result within 15 minutes.

\$29.00

SKU#: syphilis-test

Buy 2 for \$24.50 each and save 16%

1

Add to Cart



**BETTER SAFE
THAN SORRY!**



- Accurate results
- Fast reliable results in 15 min
- Tested by certified laboratories
- ISO 13485 & GMP certifications
- WHO, USAID, FDA recognized
- Worldwide shipping
- Professional use only

Accuracy of home STI testing options

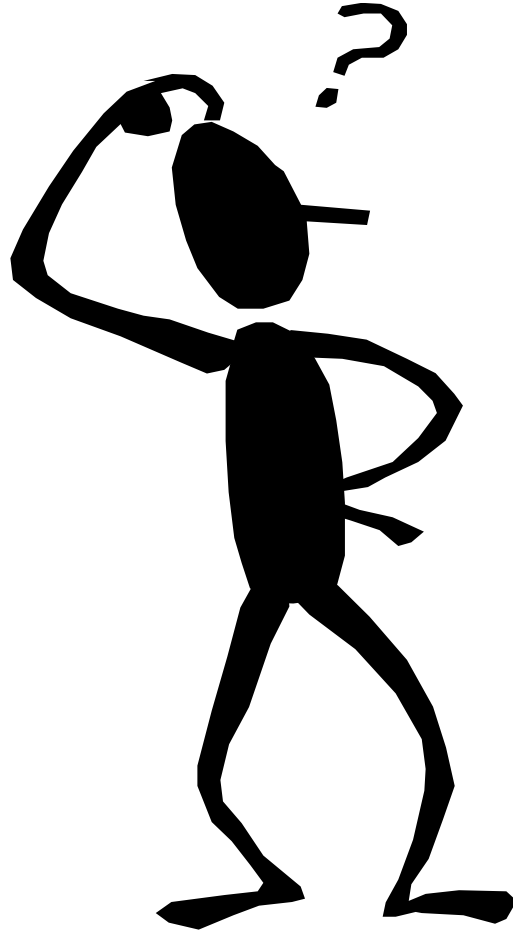
27 national/international internet sites offering STI kits/services

- Only 2 U.S. sites responded to surveys describing services
 - Turnaround time 1-7 days
 - Accredited by professional orgs & participate in lab proficiency prog
 - QA plans, biosafety plans, etc.

Kits acquired from 6 sites

- 2 mail-in kits returned results, all correct
- 2 self-tests gave false-negative results for vaginal swabs
- 2 mail-in kits sent to UK but results were never reported

Questions?



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