

Considerations for Implementing HIV/STI Testing Outside the Clinic Setting

Chase Cannon, MD, MPH

Division of AID, Univ. of Washington

Last Updated: 2 Jun 2022

Disclosures

None

Disclaimer

Funding for this presentation was made possible by U1OHA29296 from the Human Resources and Services Administration HIV/AIDS Bureau. The views expressed do not necessarily reflect the official policies of the Department of Health and Human Services nor does mention of trade names, commercial practices, or organizations imply endorsement by the U.S. Government. *Any trade/brand names for products mentioned during this presentation are for training and identification purposes only.*

Overview

- HIV/STI service delivery models
- Options for expanding access
- Available home/POC testing
- Benefits and limitations of testing options
- Local experience with developing remote care model
- Challenges and questions

Where is care delivered?



Need to expand service access and delivery

- National HIV incidence on decline, but PrEP coverage remains suboptimal (23% in 2019)
- STI incidence very much on the rise, especially syphilis and CS
- Limited numbers of dedicated SHC and budgets, staff redeployments and HCW burnout
- COVID: operational capacity limitations, move toward expanding remote care/telehealth capacity

Home-based services (HBS)

- **“Package deal”**
 - Telehealth
 - Provider-ordered testing or sampling
 - Treatment: home, pharmacy, public SHC or other facility
- Highly acceptable and feasible in many locations
- Mostly evidence from pilot studies and research settings



Existing HBS models

- 55 men on PrEP from SF, St. Louis, Boston
- Kits: 3-site GC/CT NAAT; FSWB for RPR @ fixed 1:4 titer, creatinine, 2nd gen HIV
- 93% completion, >85% would prefer HBS
- Telemedicine model using pharmacists
- Labs from public health clinic or another site, 95% completion
 - Self-collected extragenital screening limited
- PrEP mailed to home



Testing vs sampling

“Home testing”

- Self-collect sample
- Perform test at point of care and receive results at home

VS

“Home sampling”

- Self-collect sample
- Send sample via mail to laboratory for analysis
- Receive results later



Home/POC options: HIV testing

Test Category ^a	HIV Screening Tests	Run Time	Instrument	Report Ag and Ab separately	Detects IgG	Detects IgM	Uses whole blood (WB) specimens	Uses oral fluid (OF) specimens
Ag/Ab rapid test	Determine HIV-1/2 Ag/Ab Combo	20 mins	single-use	✓	✓	✓	✓	
Ab rapid test	DPP HIV-1/2 Assay	10 mins WB/ 25 mins OF	single-use		✓		✓	✓
	HIV 1/2 STAT-PAK	15 mins	single-use		✓		✓	
	INSTI HIV-1/HIV-2 Antibody Test	<2 mins	single-use		✓	✓	✓	
	OraQuick ADVANCE Rapid HIV-1/2 Antibody Test	20 mins	single-use		✓	✓	✓	✓
	Reveal G4 Rapid HIV-1 Antibody Test	<2 mins	single-use		✓		✓	
	SURE CHECK HIV 1/2 Assay	15 mins	single-use		✓		✓	
	Uni-Gold Recombigen HIV-1/2	10 mins	single-use		✓	✓	✓	

Home/POC options: HIV testing

Test Category ^a	HIV Screening Tests	Run Time	Instrument	Report Ag and Ab separately	Detects IgG	Detects IgM	Uses whole blood (WB) specimens	Uses oral fluid (OF) specimens
Ag/Ab rapid test	Determine HIV-1/2 Ag/Ab Combo	20 mins	single-use	✓	✓	✓	✓	
Ab rapid test	DPP HIV-1/2 Assay	10 mins WB/ 25 mins OF	single-use		✓		✓	✓
	HIV 1/2 STAT-PAK	15 mins	single-use		✓		✓	
	INSTI HIV-1/HIV-2 Antibody Test	<2 mins	single-use		✓	✓	✓	
	OraQuick ADVANCE Rapid HIV-1/2 Antibody Test	20 mins	single-use		✓	✓	✓	✓
	Reveal G4 Rapid HIV-1 Antibody Test	<2 mins	single-use		✓		✓	
	SURE CHECK HIV 1/2 Assay	15 mins	single-use		✓		✓	
	Uni-Gold Recombigen HIV-1/2	10 mins	single-use		✓	✓	✓	

Home/POC options: syphilis



USA: Syphilis Health Check™

- FSBS, 2 steps, 10 min
- FDA-cleared, CLIA-waived
- Good performance, depends on population



(Mostly) international: dual HIV/syphilis RDTs (mostly for PMTCT), *TT/NTT or either alone*

Home/POC options: GC/CT



2019



2019-20, 2022

Direct to consumer (DTC) care

- Internet-based
- Non-clinic affiliated, often proprietary
- Send kits or authorize lab orders to be fulfilled locally
- +/- medical consult
- Cost: \$24 - \$522 out of pocket, some take insurance



home sti testing



Google

home sti testing

everlywell

QuestDirect™



HealthLabs.com
Fast, Private & Affordable Lab Testing



Complete

\$180

Your complete screening solution for the most common STDs. 7 STDs tested including Herpes 2 and Hepatitis C.

LEARN MORE

ADD TO CART





ALL ABOUT STI TESTING WITH NURX

How do home STI tests work? How often should you get tested? Which kit is right for you? Find answers to these questions and more in this short video guide to our STI Home Test Kits.



How do they measure up?

Delivery model	Pros	Cons
Traditional SHC	<ul style="list-style-type: none"> • Tried and true • Locations across the US metro areas • Care at low or no cost 	<ul style="list-style-type: none"> • Limited rural coverage • Not always discreet • Limited budget, staffing
Primary/urgent care	<ul style="list-style-type: none"> • Large national networks • Diagnose most STIs • More comfort/familiarity 	<ul style="list-style-type: none"> • Health equity: limited access, lack of insurance • Providers may be unfamiliar with epi data & best practices
DTC (commercial)	<ul style="list-style-type: none"> • Increases access • Discreet or anonymous • Convenient – “Burger King” • Results delivered directly • \$\$: out of pocket or insurance 	<ul style="list-style-type: none"> • Testing may be inappropriate • Privacy concerns • Need internet and address • Limited counseling, link to care • Dx inconsistently reported • \$\$

Not all that glitters...

Sexually Transmitted Infection Testing Using Online Companies: Benefits, Drawbacks, and Call for Official Guidance

Chase A. Cannon, MD, MPH, Alyssa K. Piraino, BA,†
Matthew R. Golden, MD, MPH,*† and Lindley A. Barbee, MD, MPH*†*

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

Cara Exten, PhD, MPH, Casey N. Pinto, PhD, MPH, CRNP,†
Anne M. Gaynor, PhD,‡ Beth Meyerson, MDiv, PhD,§
Stacey B. Griner, PhD, MPH, CPH,¶
and Barbara Van Der Pol, PhD, MPH,||**
on behalf of the Board of Directors of the American Sexually Transmitted
Diseases Association*

Menu of home-based HIV/STI and PrEP monitoring test options

Test	Acceptability	Test options	Sample type	Availability	FDA approval @ home
HIV ab	Yes	OraQuick, INSTI	FS, oral swab	Home or POC, in clinics	OraQuick only
HIV ag/ab	Yes	3 rd party, LDT	FS, venipuncture	Determine (POC), lab based	Not quite... Determine is (CLIA-waived)
HIV VL	?	Hologic Aptima	Venipuncture (plasma)	Lab based (high complexity)	No
Syphilis (NTT)	Yes	RPR card, automated, 3 rd party	Venipuncture (serum)	Card (POC), lab based	No
Syphilis (TT)	Yes	DPP HIV-syphilis, Health Check, 3 rd party, LDT	FS, venipuncture	DPP & Health Check (POC), lab based	Not quite... DPP/SHC are CLIA-waived
GC/CT	Yes	NAAT, GC cx, 3 rd party	Multi-swab	POC, lab based	No
Creat	Yes, more limited	iSTAT, etc; 3 rd party, LDT	FS, venipuncture	POC, lab based	Not quite... Few waived

The best of all worlds?

	<i>Maximize pros</i>	<i>Limit cons</i>
Optimized delivery model	<ul style="list-style-type: none">• Care at low or no cost• Discreet, private• Confidential• Convenient• Results delivered directly• <i>Extragenital GC/CT NAATs</i>• <i>Telehealth option</i>	<ul style="list-style-type: none">• Potential for rural reach• Staffing constraints• Addresses health equity• Appropriate tests• Established follow up• Dx are reported to public health• <i>4th gen HIV ag/ab and syph testing including quant RPR</i>• <i>Avoid fingersticks</i>• <i>Minimize 3rd party lab involvement</i>

Our local option: HOT4PrEP RCT

- Home-based PrEP monitoring through PHSKC SHC
- Pilot data: highly acceptable to pts, good accuracy with clinical gold standard (venipuncture), volume may present challenge
- Self-collection of capillary blood specimens using Tasso+ device: 600-700 μ L for HIV ag/ab, qual & quant RPR, serum creatinine + extragenital GC/CT swabs
- Combination HIV/STD program implementation + research



Implementation challenges and questions

- When will FDA officially approve home-collected specimens?
- High start-up and implementation costs for individual clinics
- Lab and administrative buy-in – ex. validating Aptima swab self-collection
- If partnering with 3rd party lab: ensuring appropriate tests are run, TAT is reasonable for clinical care, timely reporting
- Reimbursement: clinic subsidies, private insurance, Medicaid?
- 2021 CDC PrEP guidelines: How to manage HIV-1 RNA testing?

Comments?

Chase Cannon
ccannon5@uw.edu

Acknowledgment

The Mountain West AIDS Education and Training (MWAETC) program is supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) as part of an award totaling \$2,908,478 with 0% financed with non-governmental sources.

The content in this presentation are those of the author(s) and do not necessarily represent the official views of, nor an endorsement by, HRSA, HHS, or the U.S. Government.

