

Self-Testing Strategies for HIV Testing and PrEP Access Webinar Series

Providing At-Home Testing Through the BHOC Partnership (Re-
Introduction)

October 15, 2020 | 2:00 PM – 3:30 PM

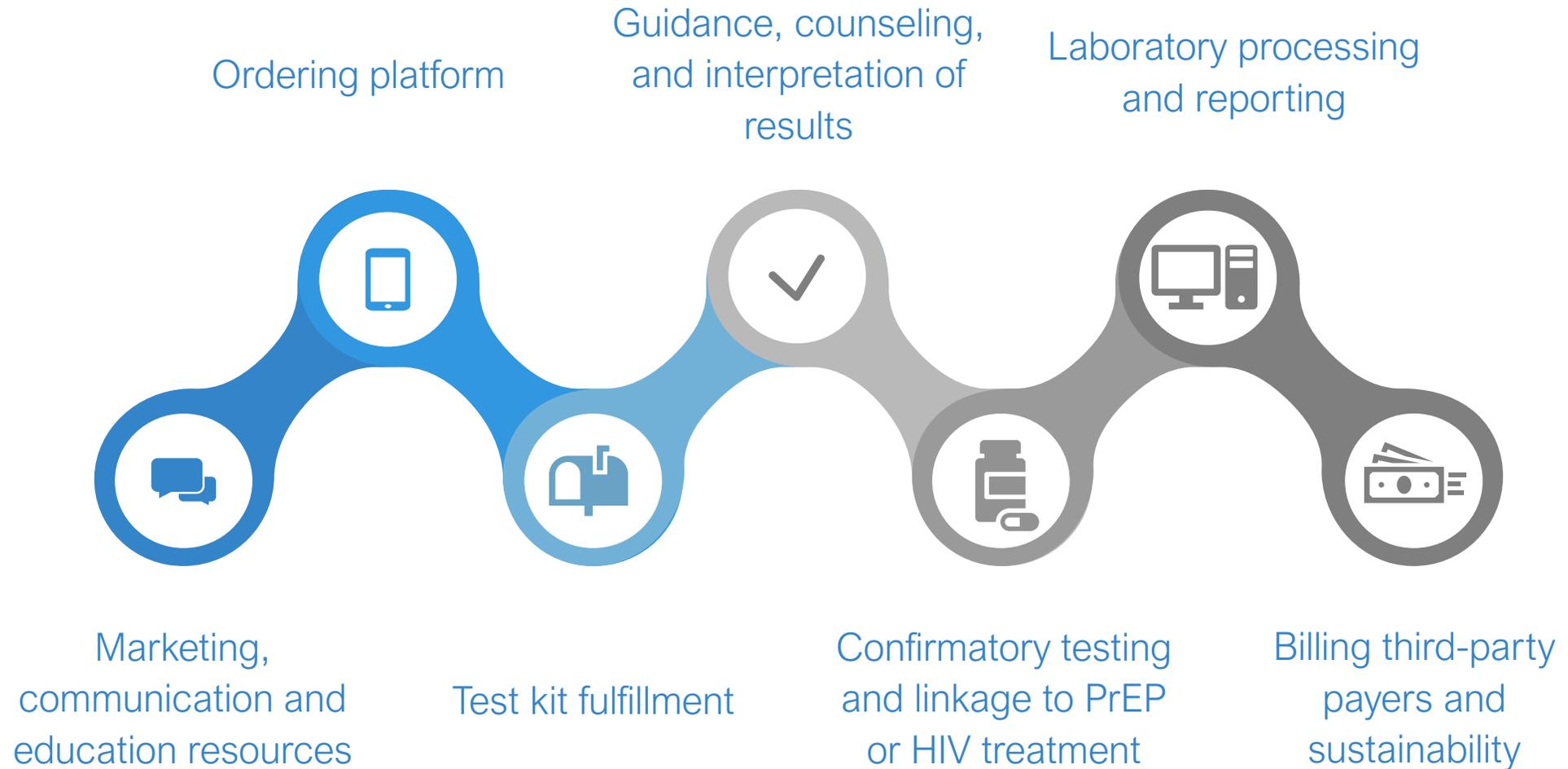


Agenda

- ✓ Overview of self-testing initiatives – NASTAD/NCSD/NACCHO
- ✓ Overview and expansion of Building Healthy Online Communities— BHOC
- ✓ Wrap-up



Self-Testing Elements



Self-Testing Pathways

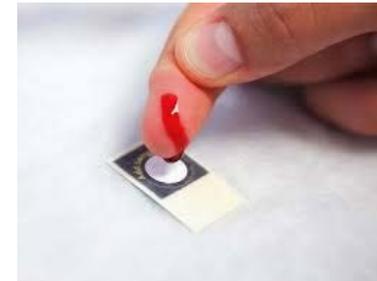
Rapid Test

- Test: HIV
- Ordering: online, pharmacies, etc.
- Sample collection: client self-collects oral fluid
- Results: rapid, no laboratory processing, client interprets the results
- No billing involved



Self-Collected and Processed at a Laboratory

- Tests available: HIV, HBV, HCV, creatinine, Syphilis antibody, gonorrhea, and Chlamydia
- Ordering: online, pharmacies, etc.
- Sample collection: client self-collects dried blood spots, swabs, and urine samples
- Results: specimen is sent to a laboratory for processing and accessed through a portal; public health reporting



Technologies

Rapid Test

- FDA-approved test—3rd generation antibody

Self-Collected and Processed at a Laboratory

- Dried blood spot samples used in a lab that uses a 4th gen RNA amplification PCN test—validation considerations, range of tests and sample types

NASTAD's Self-Testing Request for Information

The RFI

- NASTAD surveyed its members to learn more about how health departments are providing access to at-home HIV, HCV, STI, and PrEP self-testing services.
- Of the 38 respondents, 21 jurisdictions currently offer HIV self-testing services. Almost all offer rapid at-home testing kits.

Findings

- Almost three fourths of health departments plan to expand self-testing services by the end of the year, including jurisdictions already offering self-testing.

Top Five Potential Challenges

- Cost of the commercial self-testing services
- Integration of current care models and self-testing services
- Shipping costs and logistics
- Reporting and secured communication with providers and clients
- Laboratory validation of self-collection methods

NASTAD Self-Testing RFI Themes: <https://www.nastad.org/resource/self-testing-rfi-themes>

The Landscape of HIV/STI Self-Testing through Local Health Departments: Successes, Challenges and Considerations

Julia Zigman (she/her) - Program Analyst, HIV/STI/Viral Hepatitis

Latisia Grant (she/her) - Senior Program Analyst, HIV/STI/Viral Hepatitis

What NACCHO Does for Local Public Health



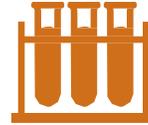
Challenges faced by existing & developing self- testing programs



Reliability and validation challenges



Lack of funding prevents expansion



Limited range of tests available as self-tests



Surveillance and follow-up



Low buy-in



Staff time



Dissemination mechanisms



COVID-19

Facilitators



- Dedicated funding



- Established laboratory systems & relationships (for STI testing)



- Buy-in across local (and state) health department



- “Tech-savvy” outreach staff



- Organizational relationships and community rapport/trust

Charlottesville, VA

- Thomas Jefferson Health District uses social media to expand self-testing in rural and urban communities
- Mail-based or pick-up at health department
- Outreach: dating apps, social media
- Clients complete phone survey with certified tester
 - HIV/STI/Harm Reduction staff cross-trained to support testing + linkage
- Tests arrive in plain brown box with linkage to care resources and safer sex items
- Active referral to PrEP and expedited STD testing



Don't let staying at home prevent you from knowing your HIV status!

In today's #COVIDConvo, Shannon answers some of your questions about in-home HIV test kits that can be mailed directly to you.

Have more question? Give us a call at 434.989.3292!

👍 6 💬 Comment ➔ 8

Baltimore, MD

- Baltimore collaborates with a Johns Hopkins University initiative to offer self-testing for HIV and STIs
 - Partnered with I Want the Kit (IWTK) to make HIV self-testing available in Baltimore
 - Order personalized test kits online: extragenital GC/CT and rapid HIV oral swab
 - Link self-testing programs to existing programs and information, ex. DIS, condom distribution, and PrEP
 - BCHD uses IWTK for extragenital STI testing for telePrEP monitoring
 - Share pictures of test kit's contents online



IWTK

I WANT THE KIT

Denver, CO

- Denver Public Health uses **coupon codes** to implement self-testing for HIV with limited staff capacity
 - DPH purchases and distributes coupon codes from manufacturer
 - Clients can redeem free tests directly from manufacturer using code
 - Orasure handles kit logistics and shipping, allowing DPH staff to focus on outreach and other programs
 - Personalized inserts in test kits share linkage to care info
 - Separate TelePrEP program also uses self-testing

The OraQuick® In-Home HIV Test

Follow The Instructions In The Test Kit For Accurate Results.

If you have questions about the test or need help reading your result, call an OraQuick® representative at 844.669.2344 (toll-free, available 24/7), or watch the how-to video at OraQuick®.com.

If Your Test Result Is Negative:

- Antibodies to HIV were not detected in your oral fluid.
- If you think you may have been exposed to HIV in the past three months, we recommend getting retested three months after your last possible exposure to HIV.
- Regular testing is the best way to keep up to date on your status. Find testing locations at:
denverpublichealth.org/HIVtest

If Your Test Result Is Positive:

- Antibodies to HIV were detected in your oral fluid.
- Call Denver Public Health Linkage to Care to speak confidentially with a case coordinator at: **303.602.3652**. Linkage to Care will help you access confirmatory testing and guide you through the next steps. This is a free service. Insurance is not needed.
- If it is after hours, leave a message and a case coordinator will call you the next business day.
- You can also get confirmatory testing at a doctor's office, or the DPH STD Clinic.



Resources

Stay HIV-negative by doing the following:

- Use condoms and lube as often as possible.
- Take PrEP, a pill that prevents HIV. Contact Denver Public Health Linkage To Care for information on PrEP: **303.602.3652**. You do not need insurance to access PrEP.
- If you inject drugs, use your own equipment (needles and works).

Denver Public Health Outreach Testing

For locations and times call/text: 720.415.7075.

All testing is free.

No appointment needed.

Denver Public Health STD Clinic

605 Bannock St. Denver, CO 80204

denverpublichealth.org/HIVtest

303.602.3540

Monday-Friday 7:45am-5pm

24/7 Mental Health Crisis Line

Colorado Crisis Services

1-844-493-TALK (8255)

ColoradoCrisisServices.org



Other innovative ideas

Curbside STI testing

Testing hotline for education and data collection

Telephone-based follow up for smaller programs

Kit distribution at outreach events where on-site testing unavailable

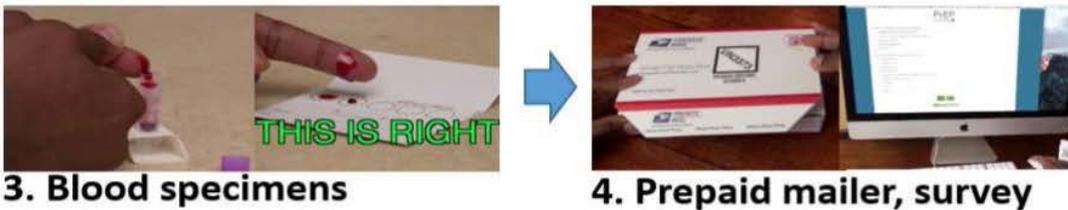
Optimize distribution criteria for mailing to shelters

Non – LHD programs: PrEP At Home

Providing tailored, appropriate care



Home care system for PrEP could reduce clinician visits from 4/year to 1/year



Participant Test Summary Form PrEP@ Home

Participant Information		● Optimal ● Elevated ● High	
Participant Name	Doe John E. Last First MI	Date Specimens Collected	6/13/2016
Participant Initials	D J E	Date Specimens Tested	6/17/2016
Section 1: HIV Testing		HIV Oraquick ● Interpretation: Non- Reactive HIV test	
Section 2: Symptomatic Screening for Acute HIV		Fever, Swollen Glands, Sore Throat, Muscle and Joints Aches and Pains, ● Interpretation: No Acute HIV symptoms	

5. Results report to clinician



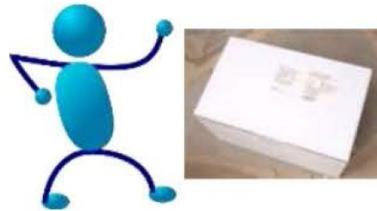
Siegler AJ, Mayer KH, Liu AY, Patel RR, Ahlschlager LM, Kraft CS, et al. Developing and assessing the feasibility of a home-based PrEP monitoring and support program. Clinical infectious diseases : an official publication of the Infectious Diseases Society of America. 2018;Jul 4.

Slides reproduced from Mayer, K. & Dormitzer J, “PrEP@home: Tele-PrEP in the time of COVID-19,” presented April 2020 for Northeastern AETC.

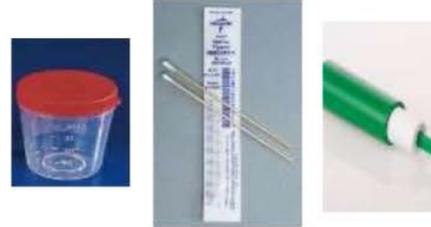
Low-touch PrEP home care: Reduce clinician visits from 4/year to 1/year



Standard PrEP
Initiation and follow up at 1 and 3 months



Subsequent follow-up visit, participant receives kit from central lab



Participant uses kit, returns mailer to lab



Lab receives kit. Results collated with behavioral survey.



Results sent to provider



EMORY UNIVERSITY
PrEP
AT HOME

Siegler AJ, Mayer KH, Liu AV, Patel RR, Ahlschlager LM, Kraft CS, et al. Developing and assessing the feasibility of a home based PrEP monitoring and support program. CID.

For Questions please contact:

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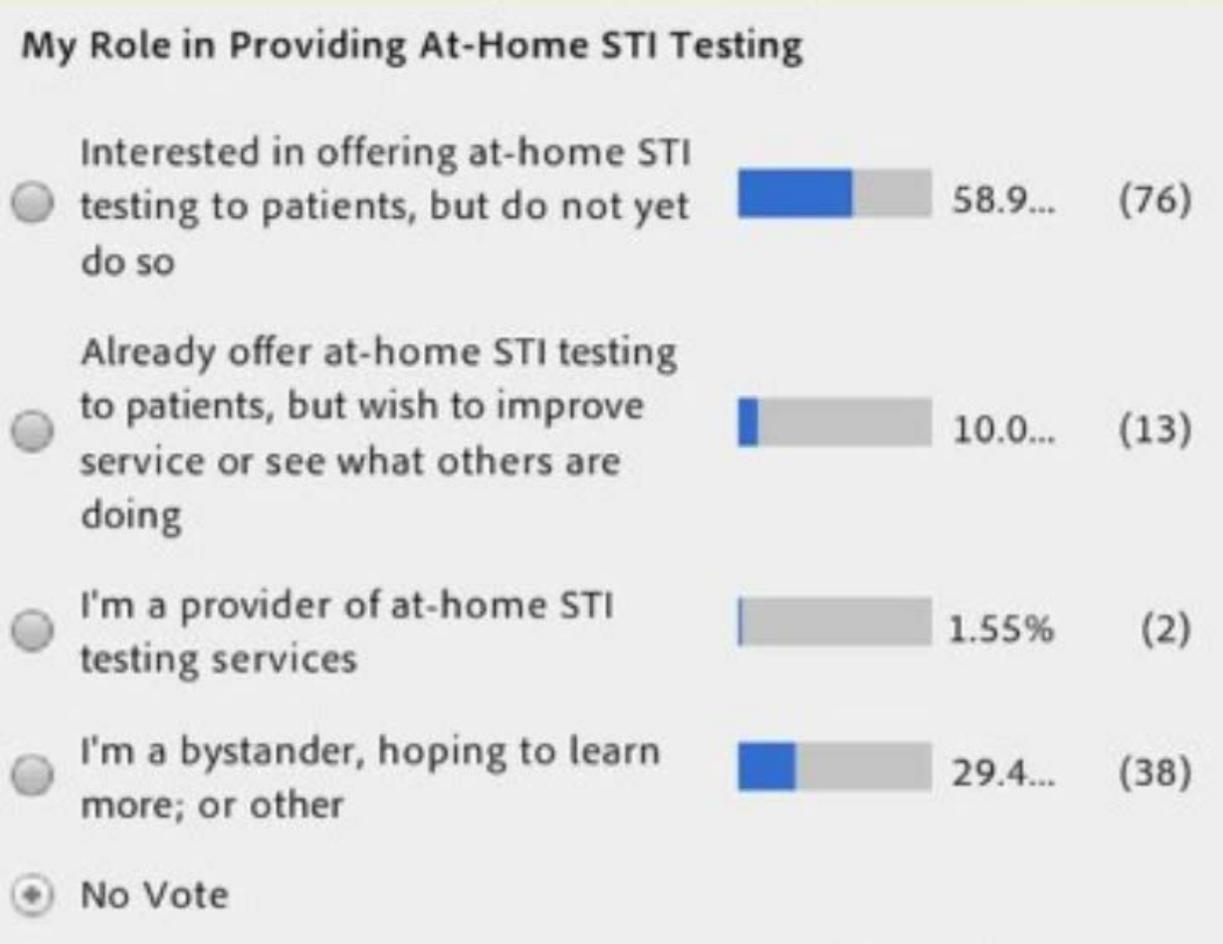
lgrant@naccho.org

Non-clinic-based
Self-collected STI Lab Testing:
Technical assistance
& New Initiatives

Christopher Hall, MD, MS
Jenny Mahn, MPA



NCSD Members in June 2020



NCSD Technical assistance plan

- Four-part Webinar series with Field reports
- Enduring materials - TA brief with FAQ
- Pointing to available resources (academic, public, and commercial)
- Collaborations

Pathways to realizing at-home STD testing

 1	 2	 3
Homegrown At-home STD Testing Solution	Third-party At-home Lab interface Solution	Third-party End-to-end Digital Provider + Lab Solution
Local PHL/lab, in-house providers, and self-fulfillment of kits ✓ JHU “IWantTheKit” ✓ LAC “IKNOW”	In-house providers, with 3 rd party lab kit fulfillment ✓ Colorado	Both provider and lab functions outsourced ✓ Use of PWNHealth, Binx, MLB, Nurx, etc.

Webinars: “At-home” STD testing

- Why non-clinic-based self collected (NCBSC) testing?
 - Ultimately patient-centered (and accepted by patients)
 - Responsive to decreased availability of brick-and-mortar testing in the COVID-19 era
 - Minimizes PPE requirements of specimen collection
- Regulatory permissiveness (LDT validation by CLIA labs)
- STD test options: 3-site extragenital testing for GC/CT, syphilis testing (both non-treponemal and treponemal), +/- other testing (HPV, HCV, PrEP)
- Payment concerns: for patient, for clinic
 - NCBSC testing adds the expense / time of R/T shipping & kitting
 - CMS-governed payment rates do not reflect true costs of NCBSC
 - Billing for ancillary provider services lagging
- Geographical limitations: reach of some services restricted for some labs & some digital health providers; availability variable

Technical assistance brief + FAQ

National Coalition of STD Directors

At-home Self-collection Lab Testing for Sexually Transmitted Infections

Technical Assistance Brief

Updated May 20, 2020

I. Background: Home-based STI Testing with Digital Health Support

Since the advent of COVID-19 in the U.S. in January 2020, STD facilities and program/clinic staff have been frequently repurposed and redeployed substantially in an effort to scale up SARS-CoV-2 testing, contact tracing, and build infrastructure and response to this expanding epidemic. Digital health platforms can work hand-in-hand with their traditional clinician counterparts, achieving better health outcomes by breaking down access barriers to healthcare. Home-based sample collection followed by lab-based testing can facilitate patient care without the patient having to leave home.

Telehealth is a tool for delivering medical services rather than a distinct medical service itself. Digital

Technical assistance brief + FAQ

III. STI Home Testing Landscape

Presently in the U.S., a very few high complexity laboratories have emerged to provide lab-based testing on self-collected samples collected in the home, using 510(k) cleared / PMA cleared assays.

The largest commercial labs (LabCorp and Quest) have involvement in this arena limited by heavy investment in brick-and-mortar draw stations and related infrastructure. Pixel by LabCorp offers home collection of a urine sample to test for three common STIs, including Chlamydia, gonorrhea, and trichomonas. QuestDirect offers home collection for testing for chlamydia and gonorrhea, trichomonas, hepatitis B and C, syphilis and HIV. Both services integrate a remote clinician evaluation and order to initiate fulfillment of respective test kits.

Online Contraception and STI Service Platforms KFF

Services by Platform
[Click on a box to see more information about the platform.](#)

	Pill	Patch	Ring	EC	STI Testing
AfterPill	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Alpha Medical	<input checked="" type="checkbox"/>				
Binx Health	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

Filter Results

State

Accepts Insurance

Technical assistance brief + FAQ

Figure 1: Comparing at-home STD integration options

	(1) In-house/ "Homegrown" Program	(2) Integration with a Lab Service	(3) Integration with a Digital Healthcare Provider	(4) Hybrid / other Solutions
<i>Examples</i>	<ul style="list-style-type: none"> • JHH "I Want the Kit" (IWTK) • Howard Brown Health 	<i>Program develops platform (API, other) to access at-home testing lab kits</i>	<i>Program integrates with digital healthcare provider to offer end-to-end care and testing solution to its patients</i> <ul style="list-style-type: none"> • Colorado Dept of Public Health & Environment 	<ul style="list-style-type: none"> • Building Healthy Online Communities (BHOC): TakeMeHome service
Potential Benefits	<ul style="list-style-type: none"> • Seamless patient experience and management • No loss of surveillance or disease investigation integration with care 	<ul style="list-style-type: none"> • In some settings, as straightforward as building a new lab integration (to supplement existing lab order options) • Outsources kitting, fulfillment, and specimen handling 	<ul style="list-style-type: none"> • Outsourced lab/specimen logistics, clinician ordering, and patient support • Least internal resources required for at-home test integration 	

Technical assistance brief + FAQ

VI. Frequently-asked Questions (FAQ)

Regulatory questions

Q: For an at-home self-collect test to be “validated,” does the self/sample collection have to be validated specifically?

A: FDA-cleared tests are intended to be ordered by a clinician, with samples obtained for patients in a clinical setting or draw station. When tests are used outside the clinical setting, a validation study must be performed to make sure that accuracy is maintained, and that new aspects of the testing methodology (such as shipping of samples, stability of specimens in transport devices) do not affect the integrity of the test. Self-collection also relies on individuals’ understanding of collection instructions, and human behavior that contributes to accurate collection of a sample, especially when collected by oneself, which may be inherently challenging and may contribute to inadequate collection. Therefore, a laboratory-developed test (LDT) must be validated such that every methodologic step of its use (i.e., self-collection, collection in a non-clinical setting, etc.) that differs from the 510(k) cleared or PMA cleared version of the same test must be validated.

Laboratory questions

Q: How accurate are at-home tests?

A: Sensitivity and specificity and other test performance characteristics are generated and documented in the validation study of the laboratory-developed test. At minimum, basic accuracy information should

Technical assistance brief: Future

VIII. The National Coalition of STD Directors is working to address these gaps in integration of home-based STI testing into state STD programs and affiliated clinics:

- 1) Provide STD clinics and programs **guidance on the availability of self-collect, home-based STI testing** (as well as other modes of home-based testing including FDA-approved home HIV testing, for instance).
- 2) Refer to **public-private opportunities** to link interested local and state programs (and clinics) with available digital/lab services, by matching program needs with service provider features.
- 3) Provide STD clinics and programs **technical assistance to integrate their traditional care models with existing digital and/or lab services** in this space.
- 4) Identify **Resources** to make home-based STI services and labs **cost-effective** for deployment by STD clinics and programs serving patients of limited means, some of whom may be uninsured or underinsured.

NCSD: Where from here?

- Make available archived webinars and enduring TA materials
<https://www.ncsddc.org/resource/at-home-testing-webinar-series/>
- Work with national partners (NASTAD, APHL, NACCHO, others) to address priorities via collaborative / efficient approaches
- Pivot to incorporating NCBSC testing into NCSD's existing committee structures to determine best next steps...to further address further consider policy and advocacy priorities
 - Clinic+ Clinical Advisory Council
 - Industry Advisory Council

⇒ Promoting Services available to our Members

NCSD: Recommended platform solutions

Recommended Platforms	Programs using a PHL	Programs <i>without</i> a local lab
Ex: BHOC's TakeMeHome	IKNOW DontThinkKnow LAC; DenverHealth	MSHL MySexualHealthLabs (in development)
✓ HIV testing ✓ Addition of STD testing	✓ GC/CT by vaginal swab	✓ Comprehensive STD and PrEP maintenance labs



TakeMeHome

How to bring home testing
to your community



About BHOC

Building Healthy Online Communities (BHOC) is a consortium of public health leaders and gay dating website and app owners who are working together to support HIV and STI prevention online.

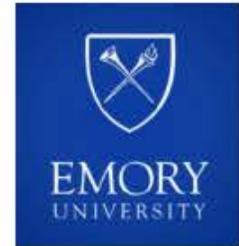
BHOC has worked with Grindr, Adam4Adam, GROWLr, and Daddyhunt to update their profile options to increase sexual health information exchanged by users. In partnership with BHOC, HIV testing reminders were implemented on A4A and Grindr.

Multiple PSAs and a web series exploring the sexual health of MSM were developed with Daddyhunt, and have **received over 14 million views**.

Grindr's Sexual Health FAQs, viewed by **15.5 million unique users** since November 2016, was developed with BHOC's input.

TellYourPartner.org, a partner notification service developed and disseminated by BHOC, launched in March 2019.

Public Health Partners



Website and App Partners



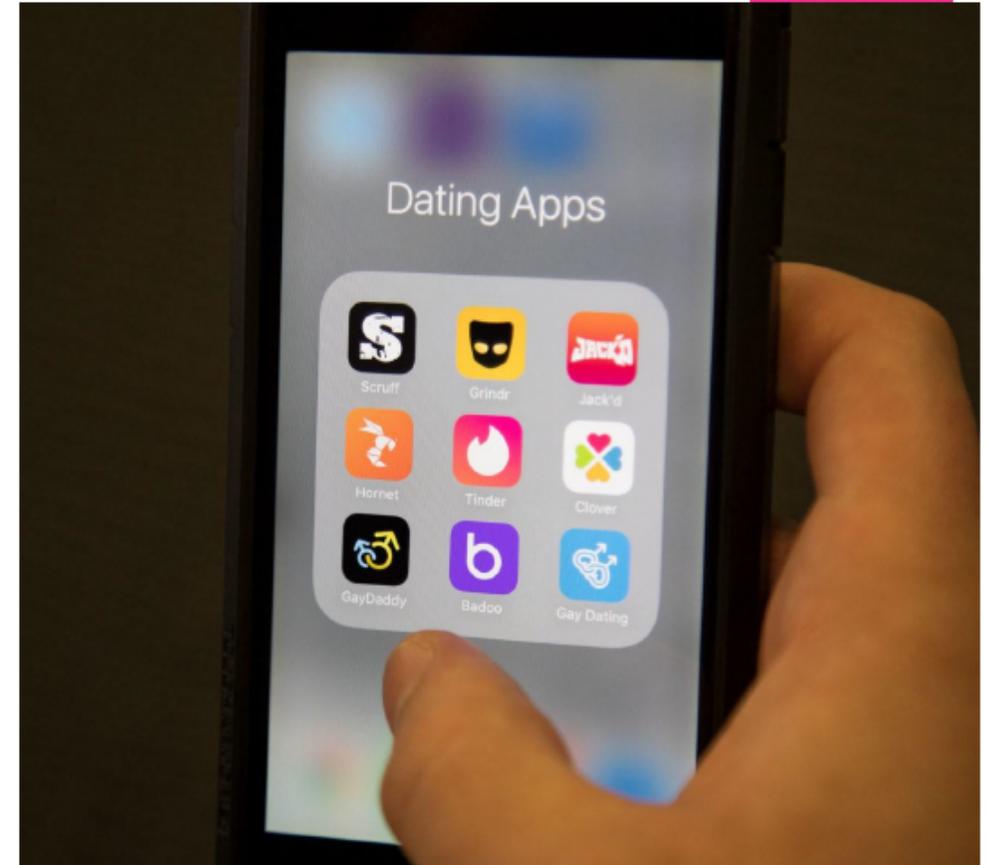
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MANHUNT



Why focus on apps?

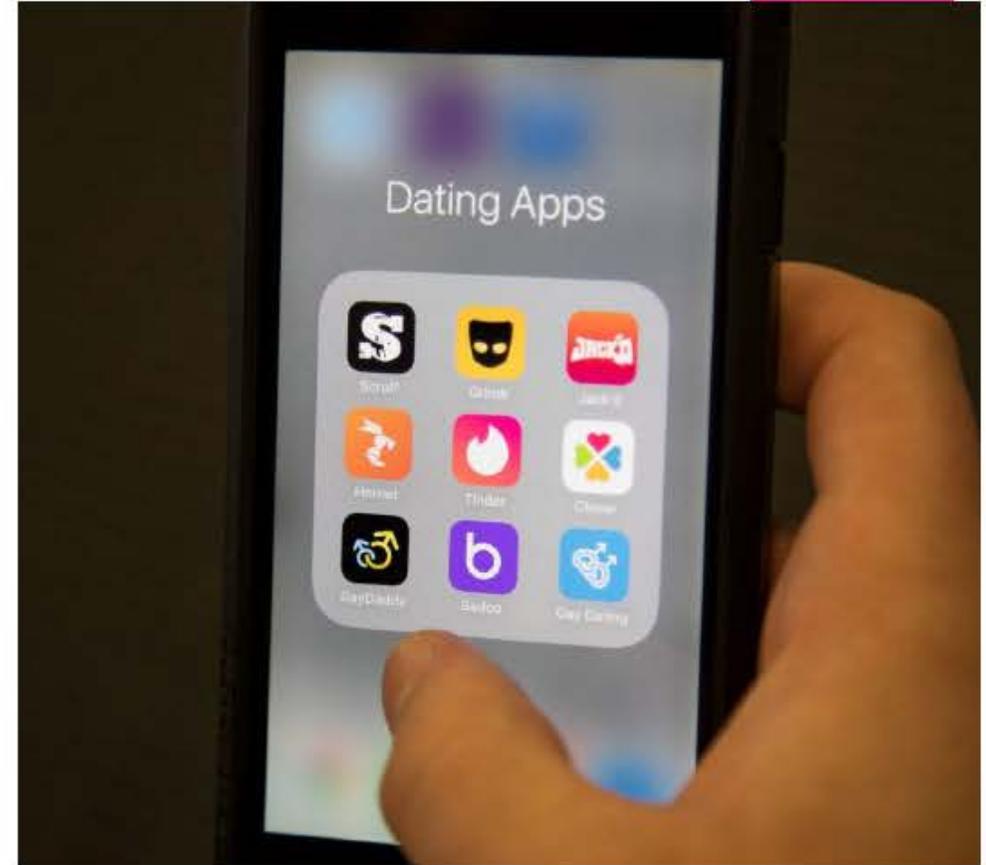
- Nearly **75% of MSM** reported using dating apps in the past year to meet a partner. (Emory University AMIS survey, 2019)
- Grindr users reported more: higher-risk sex acts, male partners, condomless sex in the past year, and higher rates of gonorrhea and chlamydia. (Hoenigl, 2019)
- App users more likely to have received a sexual health assessment (56% v. 40%) and to have received an STI test (57% v. 35%) (CDC/NCHS National Survey of Family Growth, 2011-2017)



Background

22% of MSM who use dating apps reported that they had NEVER tested for HIV.

77% of app users reported that they wanted to be able to order a home HIV test through a dating app.



Introduction

TakeMeHome is a national platform for ordering home test kits that helps public health departments ensure testing access for folks who might hesitate about walking into a clinic.

TakeMeHome is available to community members for free in participating health jurisdictions at [TakeMeHome.co](https://www.takemehome.co) and promoted through our dating app partners.

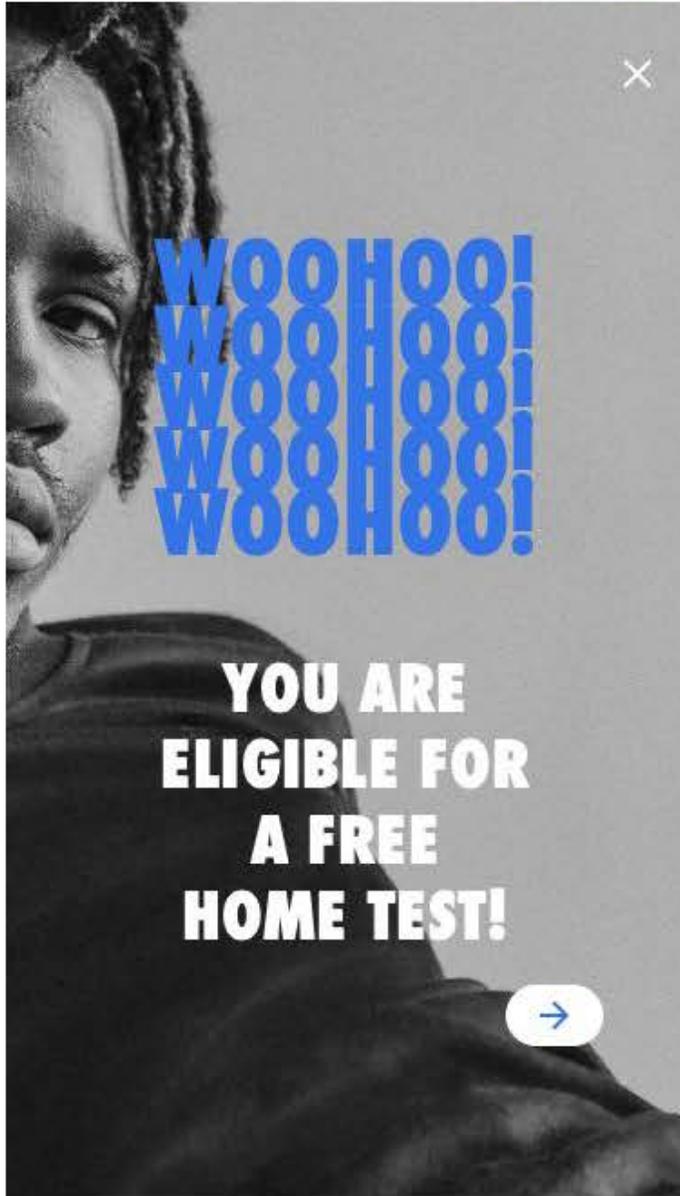


Partnership Model

To make mailed HIV testing most efficient for public health, BHOC created a partnership model:

1. Centralized system for HIV test kit ordering, distribution and results
2. Partnerships with public health agencies to fund HIV test kits and system infrastructure
3. Partnerships with apps, who engage with higher-risk persons, and can promote HIV testing to their users





2

PERSONAL INFO / MAILING ADDRESS

YOUR MAILING ADDRESS?

ADDRESS & STREET NAME

CITY, STATE AND ZIP CODE

PHONE NUMBER (OPTIONAL)



Watch: [How to order a test](#)



Frequently Asked Questions (FAQs)

Who is eligible to participate?

- Over age 18
- Have not had an HIV test in at least a year
- In a participating zip code

What happens when an individual tests positive?

Individuals will be directed back to our site, where they will be encouraged to get confirmatory testing and given **local** resources to care, as well as OraSure resources. All participants will receive basic STI (sexually transmitted infection) testing, condoms, PrEP (pre-exposure prophylaxis), and U=U information.

How much does it cost, and what is included?

Costs are for the complete service, but when calculated on per-kit basis, it is \$46/kit. The service includes promotion, kit, shipping and handling, access to the ordering platform, and monthly data reports. Inventory is stored offsite, and health departments do not have to handle any logistics or hire any staff.

Frequently Asked Questions (FAQs)

What testing technology is being used?

TakeMeHome currently offers the OraQuick test, which is a 3rd generation rapid antibody test. HIV dried blood spot testing will become available soon, and uses 4th generation technology.

What do I need to do to get this service set up in my area?

- Identify your budget
- Work with NASTAD on contracting
- Gather local resources and zip codes

How do I promote self-testing?

BHOC has been able to work with our app partners to add in-app links and get free ads. However, we encourage you to promote as well. We will provide you with digital assets that you can use for additional free or paid promotion.

Feedback From Participants

- 97% would recommend to a friend
- 94% rated the experience 5/5

“I have never been tested. Being sexually active and with the current pandemic this means a lot to me. Thank you so much!”

- Latino male, 35 - Oregon

“What a great program. Smooth process without the anxiety of a doctors office.”

- Asian/White male, 50 - San Francisco

“This meant the world for me. I have been terrified about the prospect of contracting HIV for a long time but was unable to locate a health department near me, and I was scared to go to one to begin with. This was fast, anonymous, and helped me vanquish my fears. I will make safer decisions regarding sex from now on.”

- Latino/White male, 24 - Tennessee

Orders Since Launch and Participation

- Over 2,500 kits mailed
- Started with 4 health departments in late March, currently have 5 states and 19 counties participating

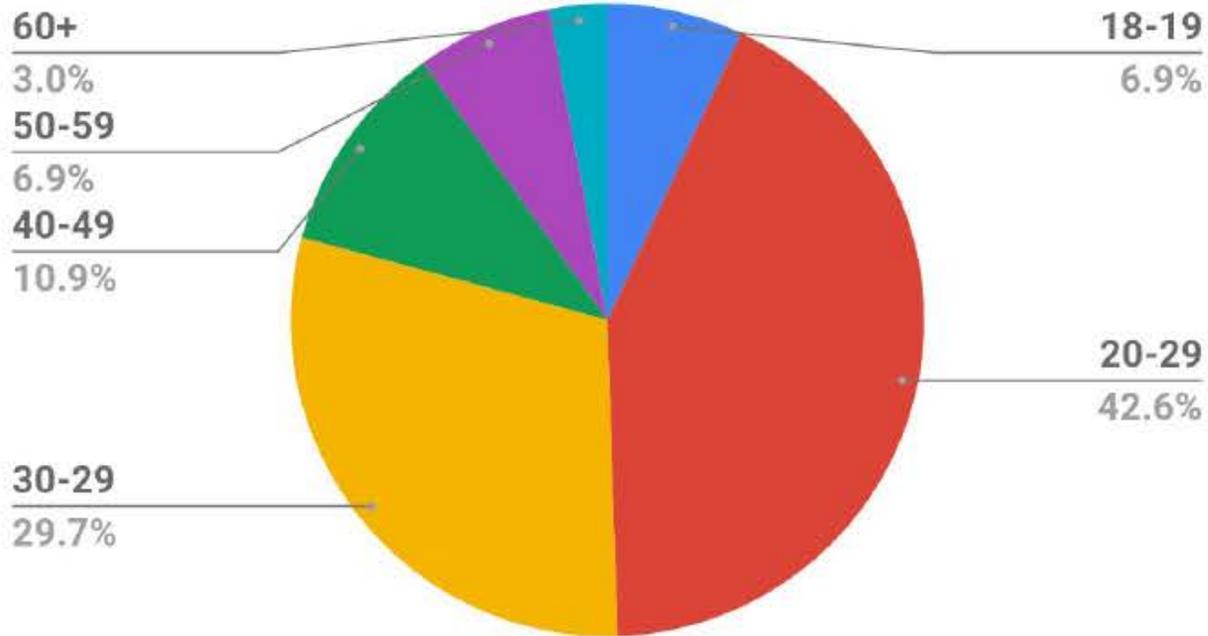


Participants

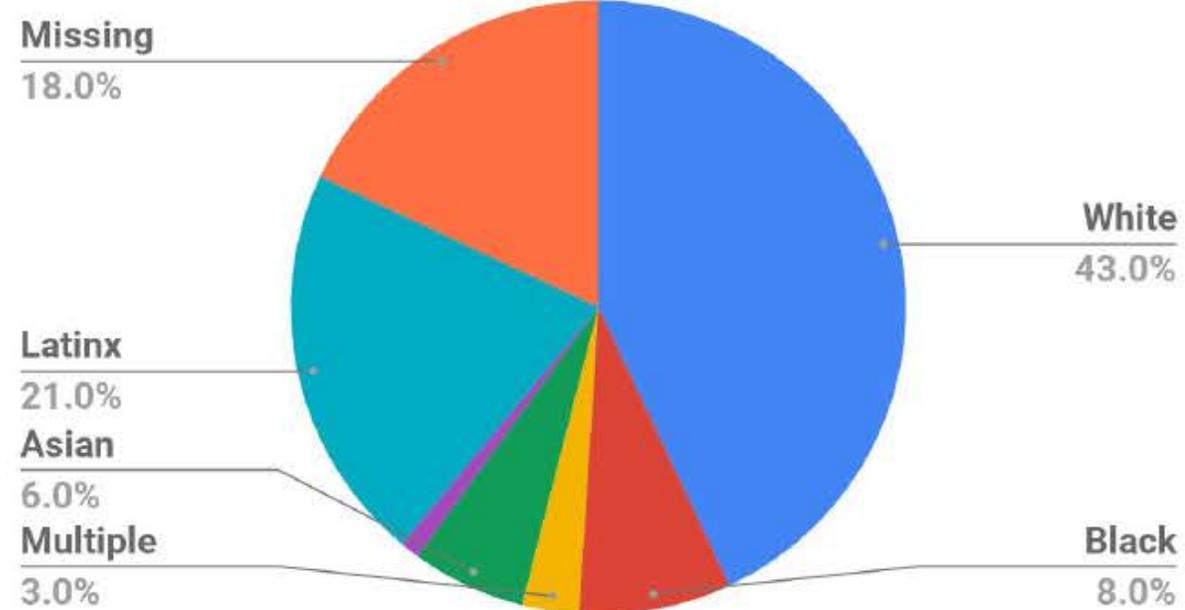


29% report never having taken an HIV test before

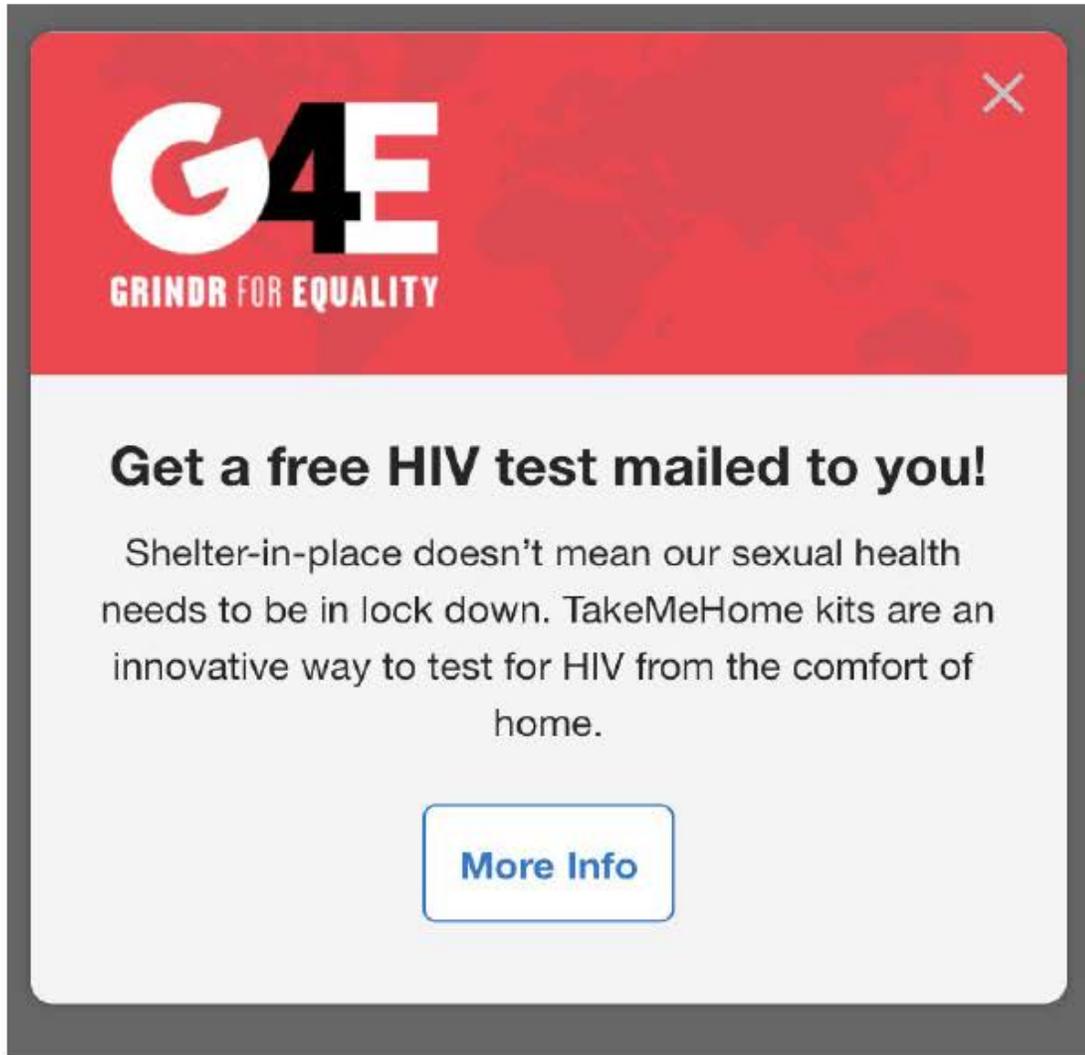
Age



Race/ethnicity



Promotional Materials



G4E
GRINDR FOR EQUALITY

Get a free HIV test mailed to you!

Shelter-in-place doesn't mean our sexual health needs to be in lock down. TakeMeHome kits are an innovative way to test for HIV from the comfort of home.

[More Info](#)



**FREE
HIV
TEST
KIT**

TAKEMEHOME.CO

Cost Savings

Based on a model developed by Harrell Chesson, we estimate that in sending out over 2500 HIV test kits, we have saved over \$200,000 in direct and indirect HIV care costs

(https://www.ncsddc.org/wp-content/uploads/2017/08/stic_figure_1.1b.manual.pdf)

What's Next: STI Testing & Admin Portal



New additions:

- STI testing — coming soon
- Client portal for access to results
- Immediate reporting of positive results to health departments
- Administrative portal will allow jurisdictions to download data directly and tailor eligibility criteria — early 2021
- Late 2020 goal for translation to Spanish

STI Self-collection Implementation

STI packages:

- HIV dried blood spot (DBS) only
- Gonorrhea and Chlamydia (3-site)
+ Syphilis + HIV DBS
 - + Hepatitis C, depending on risk eligibility
- PrEP panel
 - HIV DBS + creatinine



THANK YOU!

Sign up and learn more at
BHOCpartners.org/home-testing
jhecht@sfaf.org

BHOC

BUILDING HEALTHY ONLINE COMMUNITIES

Contact Information

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To Learn More or Request CDC CBA/TA services on this content area and other TA needs:

<https://www.cdc.gov/hiv/programresources/capacitybuilding/>