MOLECULAR® TESTING LABS

IAPAC Adherence 2022
Washington, DC

"Give me the Kit": Choice of Self-Collected Testing in TelePrEP

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DEDICATION

Dr. Dawn K. Smith

(MD, MS, MPH)

1949-2022

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HOW SPECIMEN SELF-COLLECTION WORKS

Lab Order Created

- Provider licensed in patient's state approves patient for self-collection and orders necessary assays.

Collection Kit Sent

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

Specimens Collected

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

Specimens Analyzed and Resulted

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

Provider Discloses, Treats, and Links

- Ordering provider releases results to patient, if needed providing counseling and linkage to treatment/care.

IMPROVING ACCESS

In order to allow more healthcare providers to take advantage of our validations for non-clinical self-collected specimens, standardized Collection Kits have been developed that include all the materials to successfully collect and return specimens.

These kits are simple, cost effective, and can be used in a variety of non-clinical settings, including the home.

REGULATORY CONSIDERATIONS VARY GLOBALLY

Regulatory requirements surrounding devices developed to support self-collected specimen collection (e.g., dried blood spot cards, microtainers) vary globally.

Summary Regulatory Requirements for Global Medical Device Registration in the Primary Target Markets

Primary Target Markets	United States (US)	European Union (EU) and EU Member States	Canada	Japan	China	Australia	Brazil
Governing Regulatory Authority	U.S. Food and Drug Administration (FDA)	European Commission and EU Member States	Health Canada (HC)	Pharmaceuticals and Medical Devices Agency (PMDA) and Ministry of Health, Labour, and Welfare (MHLW)	China Food and Drug Administration (CFDA)	Australian Therapeutic Goods Administration (TGA)	Agência Nacional de Vigilância Sanitária (ANVISA)
Governing Regulations	21 CFR Part 820	European Medical Device Regulations (MDR) and In-Vitro Diagnostic Regulations (IVDR)	Canadian Medical Device Regulations (CMDR SOR/98-282)	Pharmaceuticals and Medical Devices Act (PMD Act)	China Medical Device Regulations	Therapeutic Goods Medical Device Regulations of 2002	Resolution RDC 185/2001
Device Classification based on Risk Level	• Class I • Class II • Class III	• Non-Sterile, Class I, Non-Measuring • Sterile, Class I, Measuring • Class IIa • Class IIb • Class III	• Class I • Class II • Class III • Class IV	• General Class I • Specified Controlled Class II • Controlled Class III • Highly Controlled Class IV	• Class I • Class II • Class III	• Non-Sterile, Class I, Non-Measuring • Sterile, Class I, Measuring • Class IIa • Class IIb • Class III	• Class I (Cadastro) • Class II (Cadastro) • Class III (Registro) • Class IV (Registro)
Implementation of a Quality Management System (QMS)	FDA Quality System Regulation (QSR) – 21 CFR Part 820	ISO 13485 Certification	ISO 13485 Certification under the Canadian Medical Device Conformity Assessment System (CMDCAS)	Ordinance No. 169 Certification (based on ISO 13485)	ISO 13485 Certification	ISO 13485 Certification	Brazil Good Manufacturing Practices Quality System (BGMP) Certification for Class III and Class IV devices. BGMP is based on ISO

LOWERING BARRIERS TO TESTING

By lowering the barriers to testing, infections identified that might otherwise have gone undetected and untreated.

Shown are all self-collected specimen Kits from respective states.

As a CLIA-certified lab, all positive results reported to appropriate local health jurisdictions.

State	# of Assays	Detected Rate
New York	5,391	3.52%
Mississippi	5,864	3.10%
Georgia	56,748	2.93%
Texas	128,372	2.82%
Alabama	17,379	2.76%
Florida	115,874	2.74%
South Carolina	17,718	2.68%
Kansas	4,248	2.61%

All specimens, 9/2018 - 9/2021

RESULTS: TelePrEP and Self-Collect Testing, 2018-2021

With Emory & Oregon Health & Sciences University, the impact of self-collect testing on PrEP initiation and persistence was analyzed.

Since 2018, Molecular has supported >43,000 U.S. PrEP users with self-collect testing.

- *Of these, 1.2% were found HIV-positive (typically at initiation)*
- *Note: significantly higher positivity in the South (1.5%) and in rural (non-core) zip codes (1.3%; both results p<0.05 by chi-square test).*

In 2021*, Molecular's self-collect supported approx. 13% of U.S. PrEP users at some point

- *Among persons <35 years, approx. 20% were supported*
- *Among persons <25 years, approx. 30% were supported*

Diagnosing Sentinel STIs in PrEP Users

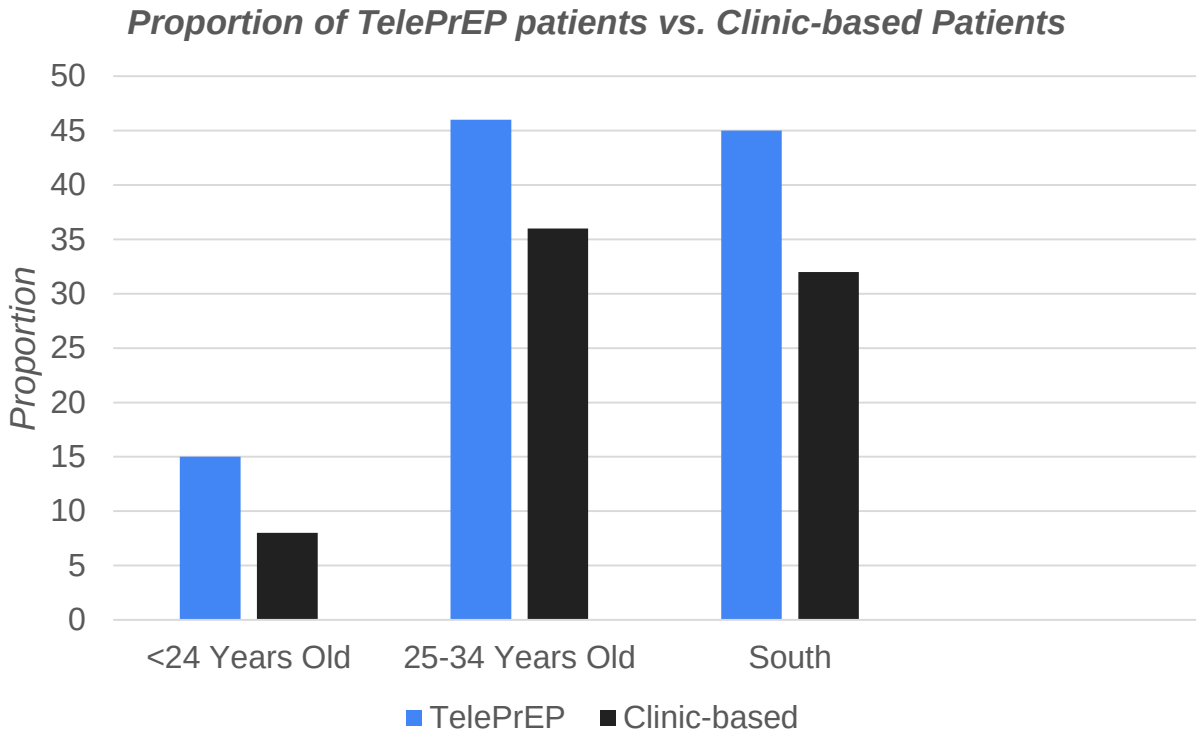
- Among the ~43K U.S. PrEP users tested by Molecular's healthcare partners, **30.1%** had positive rectal gonorrhea or chlamydia tests, and **8.3%** had reactive syphilis tests

** 2021 proportions are based on 2020 AIDSVu denominator data*

RESULTS: TelePrEP and Self-Collect Testing, 2018-2021

In 2021, the percentage of PrEP users supported by telePrEP was substantially higher than the percentage of clinic-based PrEP users in the following groups

(*AIDSVu data denominator)*

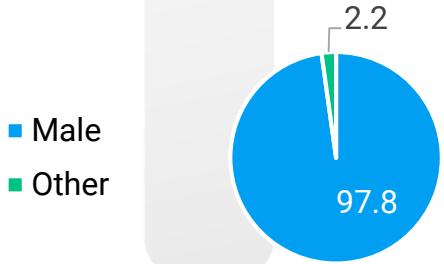


SUB-ANALYSIS: Q CARE PLUS TelePrEP Users

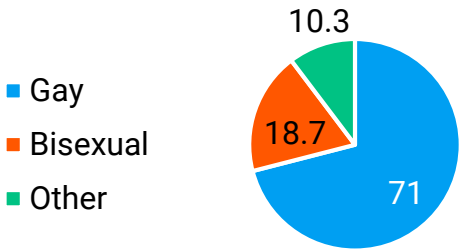
Further analysis conducted to understand the demographics and preferences of these patients utilizing HIV PrEP at one of Molecular's partners, ***Q Care Plus***.

In 2021, Q Care Plus served 5,090 unique PrEP patients who completed the enrollment process and an initial clinician visit.

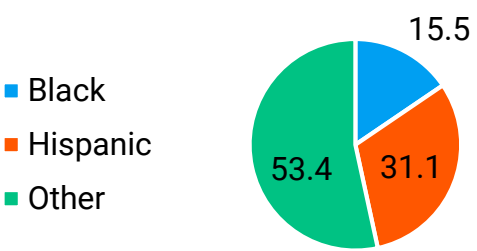
Sex



Sexual Orientation

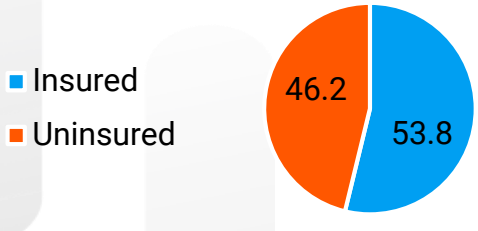


Ethnicity

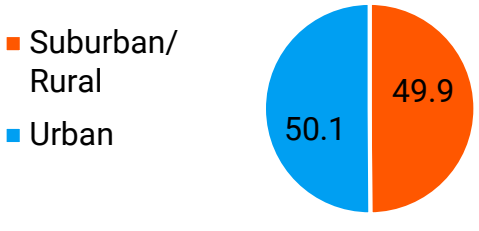


SUB-ANALYSIS: Q CARE PLUS TelePrEP Users

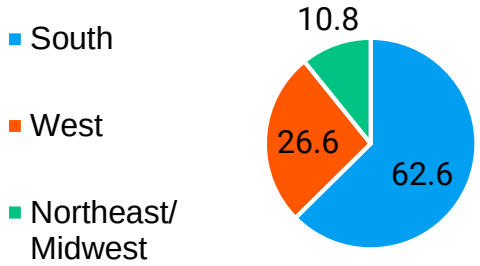
Insurance Status



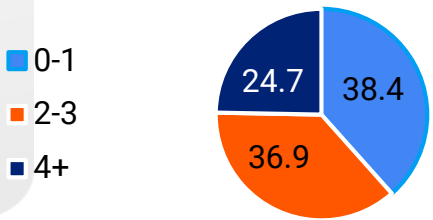
Urban/Rural



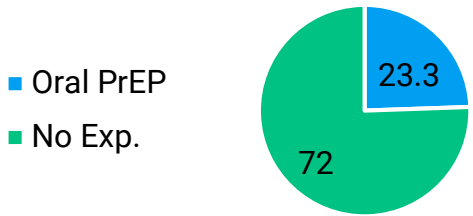
Region



Previous Partners*



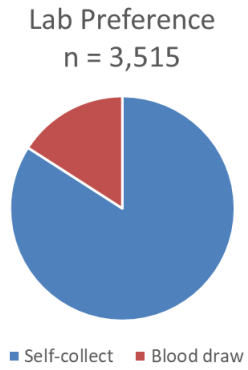
Previous PrEP Exp.



SUB-ANALYSIS: Self-Collect Testing Preference

Among 2021 QCP patients,
four-fifths elected a self-collect option

Of 2021 QCP patients initiating PrEP, 4,180 (82.1%) indicated a preferred specimen collection modality.
Of these 4,180 patients, 84.1% (n=3,515) reported preference for the self-collected option.



QCP patients selecting self-collect testing were slightly more likely to have a PrEP follow-up in the ensuing 6 months, with self-collect testers 1.14 times more likely to have at least one follow-up compared to those choosing blood draw (Prevalence ratio 1.144; 95% CI: 0.995, 1.316)

Lab Choice	Total	N	%
Self-collect	1782	888	**49.8**
Blood draw	287	125	**43.6**

LOWERING BARRIERS TO TESTING

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.

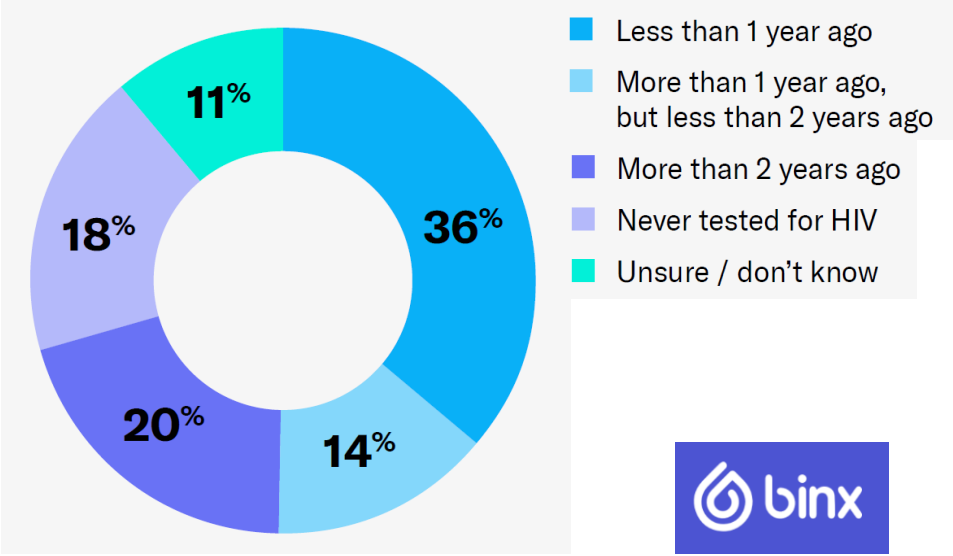
Methods: In summer 2020, the District of Columbia Department of Health launched GetCheckedDC.org for District of Columbia residents to order home-based oral HIV antibody test and urogenital, pharyngeal, and rectal chlamydia and gonorrhea tests. Initial and follow-up surveys were completed by individuals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

LOWERING BARRIERS TO TESTING

The Binx *everywhere* STI Collection Program & Alabama DPH in collaboration with Binx Health, reviewed 4-12/2021

49% had never been HIV tested >2 yrs ago / never / uncertain

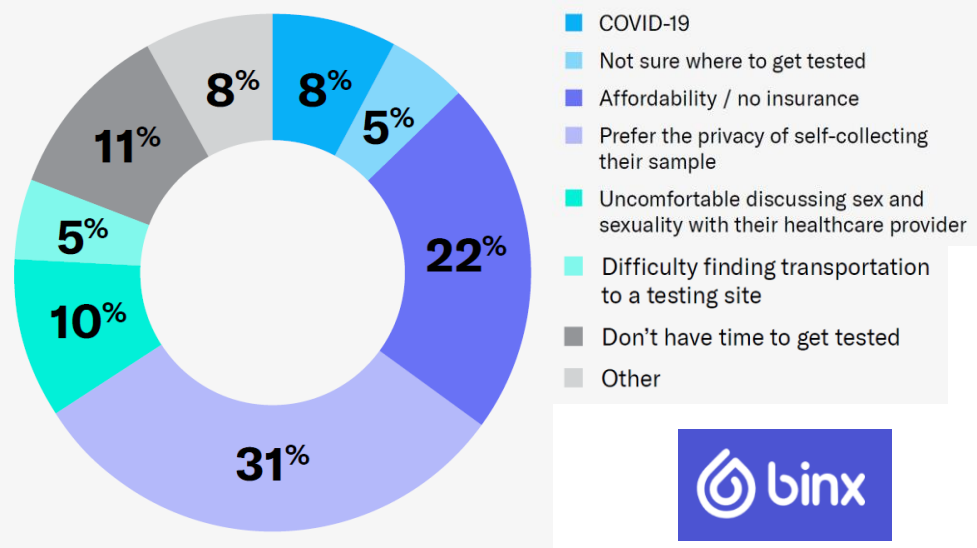


1,866 kits requested, 41% of which were returned (92.5% received within 30 days), with 5.2% CT+, 3.2% NG+. Alabama has 8th highest CT rate, 3rd highest NG rate, and 15th highest primary / secondary syphilis rate in U.S.

LOWERING BARRIERS TO TESTING

The Binx *everywhere* STI Collection Program & Alabama DPH in collaboration with Binx Health, reviewed 4-12/2021

Significant stigma and practical/financial barriers to HIV testing



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CONCLUSIONS

- Self-collect testing served **one in 7 US PrEP users in 2021** and **was used disproportionately among those** at high risk of HIV infection: young people, men, and people in the US South.
- Those seeking telePrEP in the South and rural areas were **more likely to be HIV-positive**.
- TelePrEP **addresses barriers to PrEP access**, including limited accessibility, stigma, and safety concerns during the COVID-19 pandemic.
- TelePrEP **contributes to supporting PrEP use and persistence** in the most vulnerable US PrEP users.

CONCLUSIONS FOR AN INTERNATIONAL AUDIENCE

- Remote care and collection addresses **stigma, safety, and privacy issues** that may facilitate access to care in vulverable populations
- Experience with and openness to **remote self-collected and guided specimen collection** internationally, though regulatory requirements vary globally
- Digital resources required for continuous remote care may not be consistently available and may be **exacerbated by economic inequities** that needto be solved for
- In varied settings, **specimen stability validation** may be required

Dr. Hall wishes to thank co-authors Drs. Eric Hall & Patrick Sullivan for their assistance with data analysis.