"SELF-TESTING":

A Strategy to Improve Access to HIV, Viral Hepatitis, and STI Testing

Webinar 4: Self-Testing: A Strategy to Improve Access to HIV, Viral Hepatitis, and STI Testing

April 6, 2021 | 3:00 PM – 4:30 PM

Agenda

- ✓ **CDC Introduction**
  - ✓ *Maria E. Alvarez (CDC)*
- ✓ **Self-Testing Toolkit**
  - ✓ *Liisa Randall (NASTAD) and Anne Gaynor (APHL)*
- ✓ **Self-Testing: Evaluating Test Performance/Validation**
  - ✓ *Marilyn Bibbs-Freeman (Division of Consolidated Laboratory Services, Virginia)*
- ✓ **Self-Testing in Texas: Lessons from the Field**
  - ✓ *Jenny McFarlane (Texas DSHS)*
- ✓ **Q&A/Open Discussion**

"SELF-TESTING":

A Strategy to Improve Access to HIV, Viral Hepatitis, and STI Testing

Self-Testing as a Public Health Tool

Self-testing may assist health departments to:

- Expand testing capacity
- Engage difficult to reach populations
- Support uptake of PrEP
- Address barriers to access

What's in the toolkit?

- Overview of Self-Testing Strategies
- Role of HIV, VH, and STI Programs
- Role of Public Health Laboratories
- Evaluating Self-Testing as Public Health Strategy
- Key Considerations for Implementing Self-Testing
- Considerations for PHLs Implementing Testing of Self-Collected Samples

What is "Self-Testing"?

- Point-of-Entry
  - Direct-access testing
  - Healthcare provider mediated
- Sample Collection, Sample Testing Method
  - Self-collected & self-tested
  - Self-collected & laboratory tested
  - Laboratory/facility-collected & laboratory tested

Testing Models

TABLE: TESTING MODELS, BY POINT OF ENTRY AND SAMPLE COLLECTION AND TESTING METHOD

	 SELF-COLLECTED, SELF-TESTED	 SELF-COLLECTED, LAB-TESTED	 LAB-COLLECTED, LAB-TESTED
DIRECT ACCESS			
	OraQuick purchased online or in pharmacy *Virginia DOH – HIV Self-Testing Program* *TakeMeHome™ national HIV home testing program*	Commercial kit purchased online (e.g. Binx, My Lab Box) *Texas Department of State Health Services permits contracted providers to purchase self-collection kits/services for distribution to clients*	Purchased online (e.g. Pixel by LabCorp, Quest Direct)
HEALTHCARE MEDIATED			
	OraQuick mailed to patient home from PCP	Service purchased online (e.g. Nurx), or via PCP *Iowa TelePrEP Program – bundle of PrEP monitoring tests*	Service purchased online (e.g. PlushCare)

Appendix A: Examples of Currently Available Commercial Tests and Testing Services

This is a summary of a number of commercial providers of tests and testing services grouped by point of entry and sample collection and testing method but may not comprehensive and not all methods may be available in all jurisdictions. Inclusion in this table is not an endorsement of any of the products or approaches.

Point of Entry	Sample Collection and Testing Method	Commercial Providers[a]	Tests Offered[b]	Sample Types (May vary by kit)	Insurance/Cost
DIRECT ACCESS	**Self-testing**	Consumer-purchased OraQuick	HIV-1/2	Oral swab	No insurance accepted (FSA may be accepted) Cost: ~$36-48
	Self-collection	Binx Health[5,6]	Chlamydia, Gonorrhea, HBV, HCV, HSV-2, HIV, HPV, Syphilis, Trichomoniasis	Dried blood spot; genital, throat, rectal swabs; urine	No insurance accepted Cost: $69 - $485
		CheckMate Healthcare[6-8]	Chlamydia, Gonorrhea, HCV, HSV-2, HIV-1/2, Syphilis, Trichomoniasis	Dried blood spot; vaginal swabs; urine	HSA/FSA accepted Cost: $63-$269
		EverlyWell[6,9]	Chlamydia, Gonorrhea, HCV, HSV-2, HIV-1/2, Syphilis, Trichomoniasis	Dried blood spot; vaginal swab; urine	No insurance accepted Cost: $69-$199
		iDNA[10]	Chlamydia, Gonorrhea, HCV, Herpes Virus 2, HIV-1/2, HPV, *Mycoplasma genitalium*, Syphilis, Trichomoniasis, Ureaplasma	Dried blood spot; vaginal swab; urine	No insurance accepted Cost: $78-$298
		Let's Get Checked[6,11]	Chlamydia, Gardnerella, Gonorrhea, HSV-1/2, HIV-1/2, HPV, *Mycoplasma genitalium*, Syphilis, Trichomoniasis, Ureaplasma	Dried blood spot; urine	No insurance accepted Cost: $55.30-$349
		My Home Tests (MTL)[12]	Chlamydia, Gonorrhea, HCV, HSV-2, HIV, HPV, *Mycoplasma genitalium*, Syphilis, Trichomoniasis, Ureaplasma	Dried blood spot; vaginal, oral, rectal swabs; urine	No insurance accepted Cost: $79-$399

Evaluating Self-Testing: Benefits and Drawbacks

- Population-level factors
  - Incidence, prevalence
  - Co-morbidities
- Individual-level factors
  - Appropriateness of test(s)
  - Access, convenience, cost
  - Ease, ability to use/receive results
  - Linkage to supplemental testing, treatment, support
- Program-level factors
  - HD capacity, resources
  - PHL capacity, resources

Evaluating Self-Testing as a Public Health Strategy

Self-testing is a tool to reach individuals who are hesitant or unable to attend traditional healthcare facilities or public health testing and linkage programs. Health departments may consider implementing self-testing programs to strengthen their testing and linkage programs. In determining whether to implement a self-testing program and which model(s) are most appropriate, health departments should consider several factors, presented below in Table 1.

TABLE 1: BENEFITS AND DRAWBACKS OF IMPLEMENTING A SELF-TESTING PROGRAM

POPULATION-LEVEL FACTORS	Benefits	Drawbacks
• HIV, viral hepatitis, and STI incidence and prevalence • HIV, viral hepatitis, and STI co-morbidity	• May increase uptake of testing in priority populations • May enhance access to and utilization of testing in medically underserved populations, or populations who would not otherwise be able to access testing • May enable access to testing services where health care and public health services have been disrupted, e.g. due to pandemic COVID-19 • Some test kits/services offer multiple or bundled tests appropriate for co-occurring conditions • Some test kits/services are available to minors ages 13 years and above	• Certain available tests may not be able to diagnose acute HIV infection • Available test kits/services may not provide the tests best aligned with population needs to identify potential co-infections • Supplemental testing, ordered by a healthcare provider and conducted by a laboratory, may be required to diagnose current infection (e.g. HIV, HCV, syphilis) • Test results may not be available to public health surveillance program, e.g. HIV self-test results may be known only to the consumer

Evaluating Self-Testing: Test Performance

- FDA-approved/cleared Self-Collection Device/Test
  - OraQuick HIV Home Test (Oral Fluid)

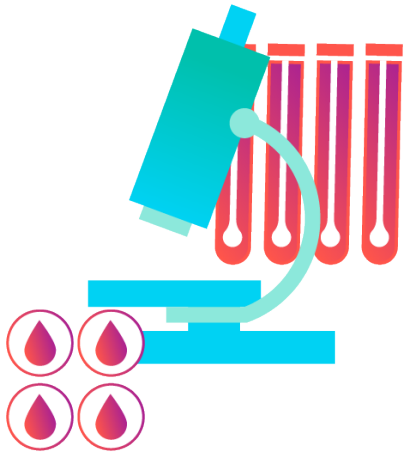
- **All other tests/ testing services that use self-collected specimens outside a clinical setting are considered Laboratory Developed Tests (LDT)**

- Any laboratory that accepts and tests self-collected samples (not included in the FDA-approved or cleared method) must have performed a validation that meets the requirements of the regulatory agency that allows them to perform clinical testing.

Role of the Public Health Laboratory

- **Evaluate and provide guidance on commercially available collection kits/testing laboratories for "self-testing"**
  - *Review available testing options*
  - *Ensure testing meets HD needs and quality*
  - *Review performance data and reporting language*

AND/OR



- **Serve as the laboratory performing testing**
  - *May include collection kit production/distribution*
  - *Evaluating/validating self-collected specimens from clinical/non-clinical setting*

Considerations for Public Health Laboratories

- Capacity to perform testing on self-collected samples
- Capacity for collection kit assembly & distribution
- Reporting

Tip Sheet: Implementing HD Self-Testing

This tip sheet summarizes key issues and strategies that health departments should address as they consider implementation of self-testing.

Accessing Target Populations

- Identify which testing kits and testing services are already available in the jurisdiction, and which populations may be accessing them.
- Collaborate with community advisory groups and other stakeholder groups to identify and adopt the models of self-testing appropriate to addressing community needs and priorities.
- Leverage health communications campaigns or other social media to increase awareness of the value of testing and resources for obtaining low- or no-cost testing, including self-testing.

Alignment with Public Health Priorities and Population Needs

- Coordinate across health department programs to identify areas self-testing may enhance program initiatives (e.g. integration) and contribute to achievement of program objectives.
- Consult with test kit manufacturers, or testing services to help consumers obtain the tests and samples appropriate to their risk and circumstance.
- Collaborate with the public health laboratory, test kit manufacturers, or testing services to design a "custom" test bundle, including sample types and supplemental tests.
- Identify and implement strategies to assist consumers to access local resources to link to treatment, prevention, partner notification, and other support services. This may include coordination with test kit manufacturers or testing services.

Quality Testing

- Identify the specific tests performed by testing services or laboratories.
- Confirm that tests are validated for each sample type.
- Evaluate performance data for each test, and for each sample type.
- Develop and provide materials and resources that assist consumers in sample collection and submission, and performing a test.
- Identify and implement strategies that ensure consumers obtain and accurately interpret test results, including need for follow-up and supplemental testing. This may include coordination with test kit manufacturers or testing services.

Disease Surveillance and Program Monitoring

- Communicate and collaborate with your public health laboratory, test kit manufacturers, or testing services and their affiliated laboratories, to obtain data about consumers using test kits or testing services, including test results.
- Support or establish electronic reporting of test results (e.g. via laboratory reporting).
- Implement a process to follow-up with consumers after distribution of In-Home HIV Test kits to ascertain test results to support disease surveillance and partner notification.

Feasibility

- Investigate state and local laws and regulations that impact self-testing.
- Negotiate with test kit manufacturers or testing services for reduced costs to consumers, or purchase kits or services on behalf of consumers at reduced costs, as part of a self-testing program.
- Collaborate with your public health laboratory to provide services for self-testing, possibly at a lower cost than commercial providers.
- Coordinate across health department programs to leverage resources and expertise needed to implement a self-testing program including kit assembly and distribution, data collection and evaluation, health communications, and consumer support.

Key Considerations

- Advance public health goals, objectives
- Address population- and client-level needs
- Provide quality testing
  - From proper sample collection to reporting clear results and everything in between also referred to as: Pre-analytic, Analytic, Post-Analytic
- Facilitate disease surveillance
- Enable appropriate monitoring, evaluation
- Feasible
  - Legal, regulatory
  - HD, PHL resources
  - HD, PHL capacity

Contact

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Evaluating Test Performance/Validation

Marilyn Bibbs Freeman

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DCLS

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Self-Testing: Evaluating Test Performance

Marilyn Bibbs Freeman, Ph.D, M(ASCP)

April 6, 2021

Objectives

- **Importance of verification/validation**
- **Verification/validation terminology**
- **High-level overview of verification/validation process**
- **Quality and process considerations for self-collection and/or self-testing**

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General Definitions

- **<u>Validation</u>: The process of establishing the performance characteristics and limitations of a test system and the identification of the influences which may change these characteristics and to what extent (In house developed, Non-FDA methods)**
- **<u>Verification</u>: The evaluation of a test system to assure it complies with regulations, requirements or manufacturer specifications (FDA approved methods)**

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Must I Verify/Validate????

- The entire testing process must be verified or validated
  - Collection process, sample type, sample media, shipping process, testing process, each organism desired

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Says Who?

- **Clinical Laboratory Improvement Amendments (2004)**
  - **§493.1253 (Performance verification requirements, LIS)**

- **College of American Pathologists (2020)**
  - **All Common Checklist (Performance verification)**
  - **Lab General Checklist (LIS requirements)**

- **Others…….**

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Verification/Validation Definitions

- **Accuracy: The degree to which the result of a measurement, calculation or specification conforms to the correct value or a standard**
- **Precision: Refers to how close two or more measurements are to each other, regardless of whether they are accurate or not**
- **Reportable Range: The span of test result values over which the laboratory can establish or verify the accuracy of an instrument or test system measurement response**
- **Reference Range (Normal Range): The range of test result values expected for a designated population of individuals**

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Verification/Validation Definitions

- **Analytic Sensitivity: The lowest concentration or amount of an analyte that can be measured and distinguished from a blank (i.e. minimum detection limits)**
- **Analytic Specificity: The ability of an instrument or test system to measure the intended organism or substance, rather than others, in a sample (i.e. cross-reactivity, interference)**
- **Diagnostic (Clinical) Sensitivity: The ability of a test to correctly detect an analyte when it is present**
- **Diagnostic (Clinical) Specificity: The ability of a test to correctly detect the absence of an analyte when it is not present**

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How????

	Not FDA Modified	FDA Modified or LDT
Accuracy	X	X
Precision	X	X
Reportable Range	X	X
Reference Range	X	X
Analytical Sensitivity		X
Analytical Specificity		X
LIS	x	X

- At this time, nearly all self-testing is considered a laboratory developed test
- Currently, FDA approves methods that start the validation process at the self-collection step and continues through the final interpretation and reporting.
- Only OraQuik for HIV is FDA-approved for self-testing, but no other STI's
- Limited clinician-mediated (observed) self-collection for STI

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Considerations: Kit Preparation

- **In-house**
  - **Procurement process**
  - **Materials**
  - **Inventory space**
  - **Inventory tracking/traceability**
  - **Internal QA procedures**
- **External vendor**
  - **Questionnaire**
  - **ISO 9001**
  - **Fulfillment practices**
  - **Availability**
  - **References**

- **In-house or Vendor**
  - **Who can order**
  - **Ordering process**
  - **Storage req.**
  - **Shipping container**
  - **Kit tracking**
  - **Shelf-life**
  - **Clear labeling, esp. expiration dates**
  - **Phone support**
  - **Computer support**
  - **Start the clock**

Considerations: Self-collection

- **Provider mediated or self-collected**
  - **Training videos**
  - **Sample type**
  - **Environmental conditions - temp, humidity**
  - **Collection location – home or other controlled setting**
  - **Instructions – collection, packaging, shipping, reporting**
  - **Sample tracking (if tested in lab)**
  - **Rejection criteria**
  - **Accessibility**
  - **Support services**
  - **Submission form or electronic submission**
  - **Clear expiration dates**
  - **Sample handling, storage, and shipping**
  - **Timed reminders**

A sample is only as good as the collection performed and appropriate shipping and handling can affect results.

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Considerations: Testing

Lab

- FDA approved or not
- Accuracy
- Precision
- Reportable range
- Reference range
- Analytical sensitivity
- Analytical specificity
- Reporting structure
- Quality indicators
- Prevalence
- Rejection criteria

At-home

- Training instructions or video
- Ease of use
- Storage conditions for device
- Clear labeling, esp. expiration dates
- Interpretation
- Prevalence
- Rejection criteria

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Considerations: Interpretation/Reporting

- **Clear instructions with pictures**
- **Video tutorial**
- **Upload picture of result for interpretation**
- **Digital, manual reporting to a clinician**
- **HIPAA**
- **Follow-up with a clinician**

How results are handled after testing can impact action in the form of treatment and prevention strategies

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Things to Ponder

- **If you cannot verify or validate all parts from kit prep to result reporting, can you validate each piece individually with a pilot study?**
- **Collection kits that improve quality, will sometimes conflict with safety (i.e. MTM).**
- **Could vendors survey users prior to kit shipment to reinforce some of the more critical quality parameters?**
  - **Correct kit ordered, shipping conditions, storage conditions, reporting**
- **Could a reimbursement of fees be considered if patients follow-up with a clinician as a way to incentivize follow-up?**
- **Could integration of quality monitors be helpful in identifying trends that could impact the overall quality of testing?**
  - **Transport time, result reporting percentages, test rejections**

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General Definitions

- **Certification/Accreditation: A process that recognizes a business as qualified to perform accurate, reliable, and timely laboratory testing based on federal law (certification) or other defined and accepted guidelines (accreditation)**
- **Complexity: FDA categorizes a test based on 7 criteria to define the level of complexity – waived, moderate, high**
- **Health Insurance Portability and Accountability Act (HIPAA): Federal regulation that defines how protected health information must be handled, managed, and secured**
- **Laboratory Developed Test (LDT): A laboratory test manufactured by and used within a single laboratory**

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General Definitions

- **<u>Quality Indicator (Monitors)</u>: An observable measure applied to any aspect of the laboratory testing process to assess performance**
- **<u>Clinical Laboratory Improvement Amendments (CLIA)</u>: Federal law used by the Center for Medicare and Medicaid Services (CMS) to regulate any laboratory testing done on human samples (research and forensic testing excluded)**
- **<u>College of American Pathologists Accreditation</u>: An accreditation authority deemed by CMS to inspect clinical labs in lieu of CLIA certification**

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Self- Testing Lessons from the Field

Jenny McFarlane

Texas Department of State Health Services

TEXAS
Health and Human Services

Texas Department of State Health Services

Texas Department of State Health Services Home Testing and Home Self-Collection Guidance

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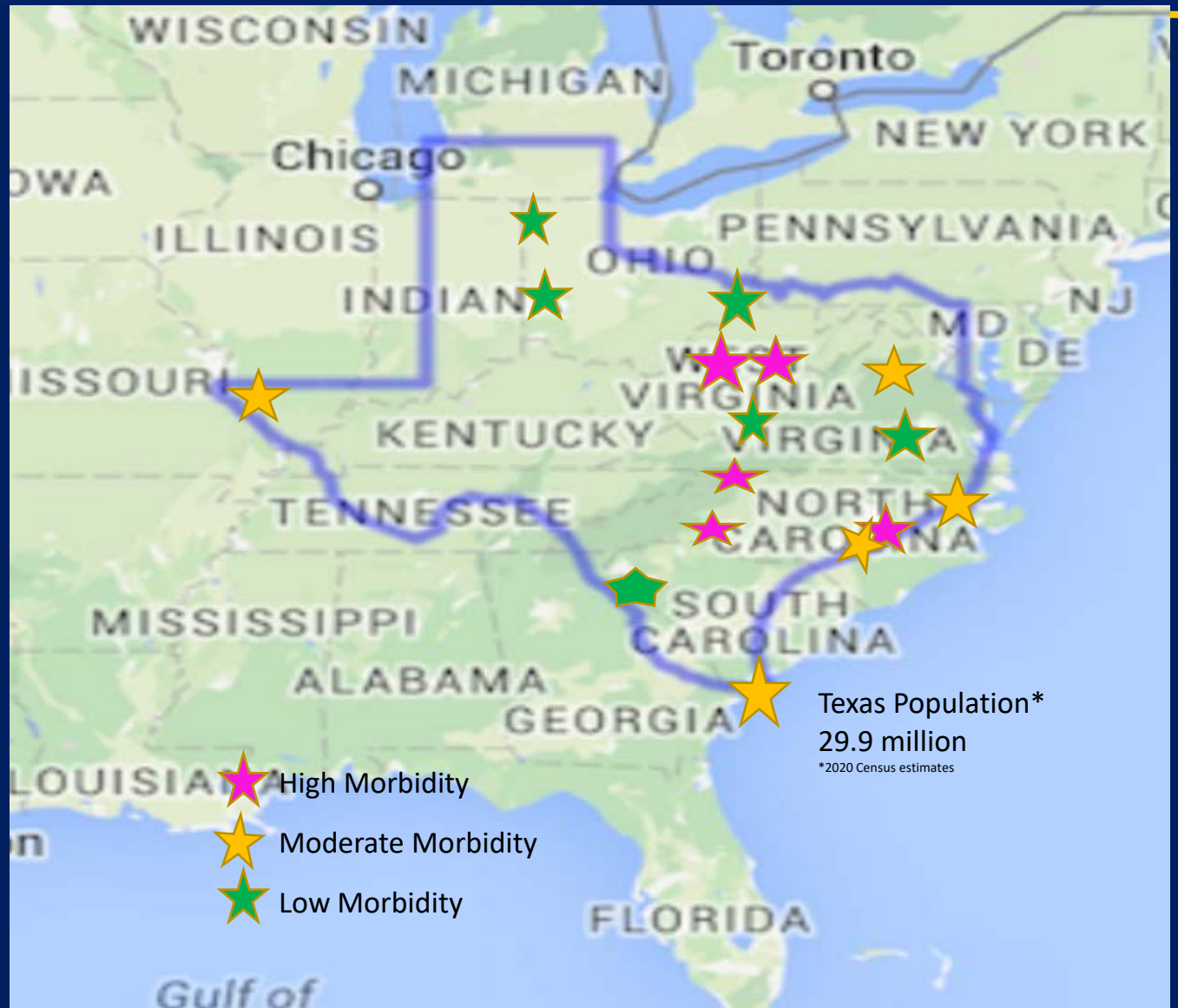
What does it mean to support HIV and STD screening in Texas? Large, Diverse, and Expansive State!



Testing Portfolio

- Regional and local health departments - Sexual Health Clinics including PrEP/nPEP services and Public Health Follow-Up
- HIV Prevention Programs – Focus based testing, Routine HIV screening, Sexual Health Clinics including PrEP/nPEP services

Impetus and Hesitations

- COVID
- Requests from funded programs
- Community planning inquiries
- Ending the Epidemic 20-2010
- Get out of the Stone Age!
- Capacity
- Procurement
- Data collection
- Disease Reporting
- Supplemental Testing,
- Eligible populations
- Detect early infection - Blood!

To do it - we better elicit input, learn from the community, other jurisdictions, and develop guidance!

DSHS Commitments

- Cross HIV and STD collaboration
- Provide written Interim Guidance
- Web-based training
- Review and provide input on implementation and policies
- Facilitate peer-to-peer support
- Training on HIV test technology and testing markers (RNA, DNA, p24, HIV 1/2 Ab IgG and IgM), and the HIV diagnostic algorithm
- Access to kits for populations with greatest vulnerabilities
- 20-2010 supported web-based distribution program to ADD HIV Self-Test kits
  - **TexasWearsCondoms.com**

HSDA	Core Priority Populations	Optional Additional Populations
Area 1		
1A - Austin	Hispanic MSM, Black MSM, White MSM, transgender persons	
1B - Dallas	Hispanic MSM, Black MSM, White MSM, Black heterosexual women, transgender persons	**Black heterosexual men, Hispanic heterosexual women, people who inject drugs (PWID); MSM who inject drugs (MSM/PWID)**
1E - Fort Worth	Hispanic MSM, Black MSM, White MSM, Black heterosexual women, transgender persons	
1C - Houston	Hispanic MSM, Black MSM, White MSM, Black heterosexual women, transgender persons	
1D - San Antonio	Hispanic MSM, Black MSM, White MSM, transgender persons	**PWID**
Area 2		
Beaumont – Port Arthur	Black MSM, Black heterosexual women, transgender persons	**PWID**
Brownsville	Hispanic MSM, transgender persons	**Hispanic heterosexual men and women**
El Paso	Hispanic MSM, transgender persons	
Galveston	Hispanic MSM, Black MSM, White MSM, transgender persons	
Tyler-Longview	Black MSM, White MSM, Black heterosexual women, transgender persons	
Area 3		
Amarillo	Hispanic MSM, White MSM, transgender persons	
Bryan-College Station	Hispanic MSM, Black MSM, White MSM, transgender persons	
Corpus Christi	Hispanic MSM, White MSM, transgender persons	
Laredo	Hispanic MSM, transgender persons	**Hispanic heterosexual women**
Lubbock	Hispanic MSM, White MSM, transgender persons	
Lufkin	Black MSM, Black heterosexual women, transgender persons	**PWID**
Midland-Odessa	Hispanic MSM, White MSM, transgender persons	
Temple-Killeen	Black MSM, White MSM, transgender persons	
Waco	**Black MSM, White MSM, Black heterosexual women, transgender persons**	

Purpose of the Interim Guidance

- Offer waiver for 2014 DSHS Policy - The Use of Testing Technology to Detect HIV Infection
  - Blood sample collection requirement
- New guidance intended for programs funded or otherwise supported by the Department of State Health Services (DSHS) TB/HIV/STD Section.
  - Creation of policies for the use of FDA approved home testing kits for HIV, and Laboratory Developed Tests (LDTs) for self-collection kits for HIV, STDs, HCV and tests required for PrEP prescriptions.

Overview of Guidance-Background

- Purpose to increase access to HIV, STD, and HCV testing and linkages to medical treatment and other prevention services, including the tests required for PrEP prescriptions.
- No endorsement of a specific test technology, manufacturer, or laboratory.
- Do not open the kits prior to distribution or replace, alter, or remove the instructions and inserts. May add locally relevant materials including local phone numbers and contact information for support and referrals.

Overview of Guidance-Required Items

- DSHS supported programs may distribute home testing kits or self-collection kits to eligible individuals.
- Programs must develop and maintain a DSHS-approved policy, containing:
  - Identify eligible populations receiving test kits;
  - Identify the home testing and/or self-collection kit(s) and describe how it is suited for the eligible population;
  - Identify funding for the purchase of tests, staff time, postage, and other related costs;
  - Describe the security of program reporting data and the confidentiality of client information;
  - Describe the informed consent process;
  - Describe the kit shipping, storage, maintenance, and inventory and quality control measures;

Overview of Guidance-Describe the Following:

- Test kit tracking process;
- Documentation and tracking of:
  - Demographic
  - Priority population groups
  - Test result(s)
  - Linkage data
- Notification of:
  - Test results
  - Referrals for confirmatory testing
  - Referrals to and confirmation of medical tx and partner services
  - Referrals and tracking for other prevention services
- Required staff training(s):
  - Home testing and self-collection kits
  - How information to persons requesting tests will be shared;
- Access to and reporting of test results to the local HA
- Listing incentives
  - Knowing how to share during interactions with persons being tested.

We are learning!

- Decentralization-The local/regional health departments need to identify funding and navigate their own procurement processes.
- Cost-The overall cost of at-home self-collected STI lab tests is higher than STI test processing at public health labs.
- Validated Laboratories- Self-collection kits require identifying a lab that has been validated and negotiating cost.
- COVID-19-The local/regional health departments are involved in the on-going response to the pandemic.
- Data Collection – for STI programs THISIS, HIV Prevention – Eval Web

Immediate Outcomes

- Nine HIV Prevention programs submitted checklist and procedures
- 4 have submitted data:
  - Preliminary data 94 tests, no preliminary positives.
  - Mostly MSM (Latino, Black, White)
  - Black women who have sex with men and Latina women who have sex with men
  - Few PWID
- As of 3/31/3021, no programs have contracted with self-collection lab or provider.
- TexasWearsCondoms.com is LIVE!
  - RedCap Survey determines if person is eligible to receive test.

All Agencies							
	Race / Ethinicity						
Priority Population	Hispanic	White	Black/African American	Asian	American Indian or Alaska Native	Don't Know	Total
MSM	40	16	5	5	1	5	72
Heterosexual female	9	3	5				17
Heterosexual male	2						2
IDU		2					2
No sexual contact or IDU past 5 years		1					1
Total	51	22	10	5	1	5	94

texaswearscondoms.com/at-home-hiv-test-kit/

TEXAS WEARS CONDOMS

Home | Free Condoms | At Home HIV Test Kit | Get Educated | Get Tested | FAQ | Contact Us

At Home HIV Test Kit

Hey Texans! We're very excited to offer FREE at-home HIV test-kits to eligible Texas residents throughout 2021. Click on the link below to fill out a short screener to see if you're eligible. If you qualify, we'll contact you to confirm your address and other details and ship out your test kit for FREE (including free shipping, of course). Our test-kit package will come in a plain brown box that does not identify what's inside, and we'll even include a handful of condoms & lubricants (for a full condom request, please place an order through our site using the current process).

If you get tested using one of our kits, we ask that you take a survey with us afterwards so we can collect your test results and offer you resources. This survey will be done over the phone and through email- we're even throwing in a gift card for your time (spoiler alert, the gift card is between $24.99 and $25.01 and the retailer rhymes with Spamazon).

CLICK HERE TO SEE IF YOU QUALIFY!

Qualify

Order

Test

Survey

Thank you!

Home Testing and Home Self-Collection Guidance

✓ Discussion/Q&A

Please feel free to use the chat function or unmute yourself to ask questions to the presenters

Contact Information

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