



Mass Mailing of HIV Self-Tests to Persons Disproportionately Affected by HIV in the U.S.

CDC-RFA-PS22-2210

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Background

Why HIV Testing Matters

- **CDC is committed to accelerating efforts to end the HIV epidemic in the United States**
 - This includes supporting the Ending the HIV Epidemic in the U.S. initiative (EHE)
- **HIV testing is the bridge to treatment and prevention**
- **Strategies that deliver HIV testing and care in innovative, community-tailored ways will be critical to ending the epidemic**

CDC's HIV Self-Test Response

- **April 28, 2020 - Dear Colleague Letter**

- Allows for HIV Self-Tests (HIVSTs) to be procured using CDC funds (e.g., 18-1802, 20-2010)

- **May 15, 2020 - Dear Colleague Letter**

- Makes recommendations for Pre-Exposure Prophylaxis (PrEP) during COVID-19

HIV self-administered testing options

- **OraQuick® In-Home HIV test; a rapid HIVST**
 - U.S. Food and Drug Administration (FDA) approved, the HIVST specifically mentioned in the Dear Colleague Letter that allows for HIVSTs to be procured using CDC funds (e.g., 18-1802, 20-2010)
- **Self-collection kits, or “Mail-in” kits**
 - Various products are available on the internet
 - The test uses a self-collected Dried Blood Spot (DBS) sample for HIV testing
 - HIV testing of DBS is often combined with testing of other samples for other diseases
 - E.g., oral and rectal swabs collected to test for Chlamydia and Gonorrhea
 - Samples are sent to a lab to perform the testing, rather than performing the test at home

Rapid HIV Self-Testing

- **HIV self-testing**
 - The FDA-approved Oraquick® IN-HOME HIV TEST has been available since 2012
- **This HIVST is less sensitive than lab-based tests and is not recommended for persons initiating or taking PrEP**
- **Not the same test as the FDA-approved test used by providers**
 - OraQuick Advance test (provider administered test)



CDC's HIV Self-Testing Demonstration Project

- **CDC funded the distribution of the OraQuick® IN-HOME HIV Test**
- **Expanding on TakeMeHome program**
 - In 2021, as part of CDC's *Let's Stop HIV Together* campaign, CDC funded a national distribution of HIVSTs
 - Large-scale but targeted distribution of HIVSTs to populations disproportionately affected by HIV/AIDS
 - Assists CDC in its efforts to increase HIV testing among gay and bisexual men (MSM), transgender women (TGW), and racial and ethnic minorities

Characteristics and Outcomes of Demonstration Project

- **Participants could order one or two HIVSTs, to share with their peers or partners**
- **People with HIV (PWH) and those taking PrEP could order kits to give to others**
- **The project reached those who would benefit most**
 - 100,000 Self-Test were distributed in approximately 8 months
 - 55% of all orders were placed by MSM, TGW, Black women
 - 55% of self-tests were ordered from EHE Phase 1 jurisdictions
 - 26% reported never having been tested for HIV

Purpose of PS22-2210

- Increase one's knowledge of their HIV status
- Connect persons with a negative test result to PrEP services
- Connect persons with a positive test result to an HIV care provider
- Prevent new HIV infections in populations disproportionately affected by HIV

PS22-2210 Characteristics and Requirements

- **Direct-to-consumer approach**
- **Existence of portal to order self-tests**
- **A fully functional comprehensive distribution program for procurement, storage, processing orders and monitoring**
- **Distribute at least 175,00 HIVSTs each year for 5 years**
- **Focus on men who have sex with men (MSM), transgender women (TGW), and black cis-gender women**
- **Provide information in both English and Spanish**
- **Project will occur with close collaboration with CDC**

Marketing Developed by CDC

- **Distributed through social media in the Ending the HIV Epidemic in the U.S. Phase 1 jurisdictions**
 - Ads and images designed to appeal to audiences disproportionately affected by HIV



PS22-2210 Logic Model

Strategies and Activities	Short-term Outcomes	Intermediate Outcomes	Long-term Outcomes
<p><i>Strategy 1. Refine recipient's existing HIVST distribution program for purchasing and distributing HIVSTs to persons disproportionately affected by HIV in the U.S. and Puerto Rico</i></p> <p><i>Strategy 2. Implement HIVST distribution program and distribute HIVSTs to persons disproportionately affected by HIV in the U.S.</i></p>	<p>1. Culturally appropriate imagery and information developed by CDC available on the self-test ordering portal</p> <p>2. Fully functional comprehensive HIVST distribution program for procurement, storage, processing of orders and program monitoring</p> <p>3. Increased access to HIVSTs and prevention services including PrEP and STI testing among persons disproportionately affected by HIV</p> <p>4. Increased understanding of strategies to successfully deliver HIVSTs to populations disproportionately affected by HIV</p> <p>5. Increased understanding of user experience for HIV self-testing among populations disproportionately affected by HIV</p>	<p>1. Increased HIV testing among populations disproportionately affected by HIV</p> <p>2. Increased awareness of HIV infection among populations disproportionately affected by HIV</p> <p>3. Increased awareness of PrEP among populations disproportionately affected by HIV</p> <p>4. Increased initiation of PrEP among populations disproportionately affected by HIV</p>	<p>1. Increased linkage to HIV medical care for persons diagnosed with HIV</p> <p>2. Increased viral suppression among persons with HIV</p> <p>3. Increased PrEP use.</p> <p>4. Decreased HIV incidence</p>

PS22-2210 Strategies

- *Strategy 1. Refine recipient's existing HIVST distribution program for purchasing and distributing HIVSTs to persons disproportionately affected by HIV in the U.S. and Puerto Rico*
- *Strategy 2. Implement HIVST distribution program and distribute HIVSTs to persons disproportionately affected by HIV in the U.S.*

PS22-2210 Activities

Strategy 1.

The recipient will refine recipient's own existing HIVST distribution program for purchasing and distributing HIV self-tests to persons disproportionately affected by HIV in the U.S. and Puerto Rico.

Activity 1.

Collaborate with CDC to **refine** recipients existing HIVST distribution program, including procurement, storage, processing of orders, and program monitoring

These refinements to existing HIVST distribution program will be ongoing with consultation with CDC throughout the duration of the project 5-year period of performance

The refinements should ensure that tools (e.g., Urchin tracking module (UTM) codes and unique web-links linked to website traffic information in Google analytics) are able to capture information needed to conduct routine monitoring described in Strategy 2, Activity 3

PS22-2210 Activities

Strategy 1. Cont.

Activity 2.

Refine HIVST distribution program's registration and fulfillment web-portal to match the look and feel of CDC's Together marketing campaigns, in English and Spanish

Collaborate with CDC to ensure that it is consistent with the look and feel of CDC's Together marketing campaigns

The portal will be available in both English and Spanish

PS22-2210 Activities

Strategy 2.

Implement HIVST distribution program and distribute HIVSTs to persons disproportionately affected by HIV in the U.S.

Activity 1.

Procure and store HIVSTs for distribution

The recipient will purchase HIVSTs and effectively distribute free HIVSTs to populations disproportionately affected by HIV in the U.S.

PS22-2210 Activities

Strategy 2. Cont.

Activity 2.

Send HIVSTs to program participants using an approved shipping service

Send a limited number of HIVSTs (e.g., 1 to 4) to registered program participants in all 50 U.S. states and Puerto Rico

Fulfill orders for HIVSTs in 2 business days, and >95% are delivered within 7 days

System capable of limiting repeated requests for HIVSTs by a single user to predetermined timeframes (e.g., every 90-180 days)

System should identify individuals taking PrEP or ART. Allow ordering of kits with messaging to share tests with their peers – not for themselves

PS22-2210 Activities

Strategy 2. Cont.

Activity 3

Routinely monitor the program's reach to disproportionately affected populations, user's satisfaction, experience, test result interpretation, and linkage to other services, such as STI testing, PrEP evaluation and HIV treatment.

Conduct routine monitoring:

Determine geographic and demographic characteristics of persons being screened for eligibility prior to ordering HIVSTs online

Conduct routine cross-sectional evaluations:

Obtain information on use of the HIVSTs, access to other HIV services (after using the self-tests), user satisfaction and barriers

PS22-2210 Activities

Strategy 2. Cont.

Activity 4

Regularly review monitoring data with CDC to allow for refinement of the CDC marketing campaign

Monitor web-traffic using CDC-provided UTM codes and google analytics

Provide data on web-traffic & orders to CDC on a regular (weekly) basis and collaborate on review of these data

PS22-2210 Outcomes

Short-term:

- Culturally appropriate imagery and information developed by CDC located on the ordering portal
- Fully functional comprehensive HIVST distribution program for procurement, storage, processing of orders and program monitoring
- Increased access to HIVSTs and prevention services including PrEP and STI testing among persons disproportionately affected by HIV
- Increased understanding of strategies to successfully deliver HIVSTs to populations disproportionately affected by HIV
- Increased understanding of user experience for HIV self-testing among populations disproportionately affected by HIV

Intermediate:

- Increased HIV testing among populations disproportionately affected by HIV

PS22-2210 Evaluation Criteria

Approach:

- Description of a process for revising their own existing HIVST distribution program, including the integration of CDC's advertising materials and strategies into their web-portal
- Description of the process by which data from ongoing program monitoring will be used to inform revisions of the CDC advertisement and recruitment strategy to ensure communications materials and strategies do not become stale and ineffective
- Description of the online screening and registration process to ensure that appropriate participants are enrolled into the program, prevent fraudulent enrollment, and manage participant information securely
- Description of the process for procuring and storing HIVSTs and the fulfillment process to ensure shipping within 2 business days and delivery of materials to program participants within 7 days
- Description of the work plan for Year 1 of the project

PS22-2210 Evaluation Criteria

Evaluation and Performance Measurement:

- Description of current ability to use existing data systems and how advertising materials and strategies are effective in reaching priority populations and increasing demand for HIVSTs
- Description of anticipated revisions to existing monitoring and evaluation processes to ensure that all priority populations are effectively reached.
- Description of current system to conduct scheduled cross-sectional program evaluation to:
 - Monitor user satisfaction
 - Determine how the HIVSTs are used (by user or given away)
 - Use of other HIV services after use of a self-test
 - Method for conducting the follow-up surveys
- Description of current evaluation questions and how they are addressed by the data collected
- Description of anticipated modifications to program evaluation procedures to evaluate the success of the project

PS22-2210 Evaluation Criteria

Capacity:

- Description of the existing HIVST distribution program that includes procurement of HIVSTs, storage of HIVSTs, registration and distribution of materials to populations disproportionately affected by HIV in the US.
- Description of prior experience with programs that advertise to the priority populations described in the announcement (e.g., Black and Hispanic MSM, Transgender persons and Black cis-gender women)
- Description of the capacity to maintain and continuously update a secure HIVST distribution program
- Description of the capacity to ensure delivery of at least 175K tests to program participants within 7 days of ordering a test
- Description of the capacity to conduct ongoing program monitoring and evaluation

Key Takeaways

- **CDC is committed to accelerating efforts to increase prevention of HIV infections among populations disproportionately affected by HIV in the US**
 - This includes supporting the Ending the HIV Epidemic in the U.S. initiative
 - Increase HIV testing to diagnose all people with HIV as early as possible

Questions?

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For more information, contact CDC
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The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.





Thank you