



## NORTHWEST AIDS EDUCATION AND TRAINING CENTER

# Home HIV Testing

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# Rationale for Home HIV Testing

## HIV epidemic in U.S.

1.2 million people  
living with HIV

~**20%** unaware  
Of HIV status

Are responsible  
for ~**50%** new  
infections

## Why Is Testing Important?

Learning HIV status leads:

- decreased risk behaviors
- decreased infectiousness  
with ARVs

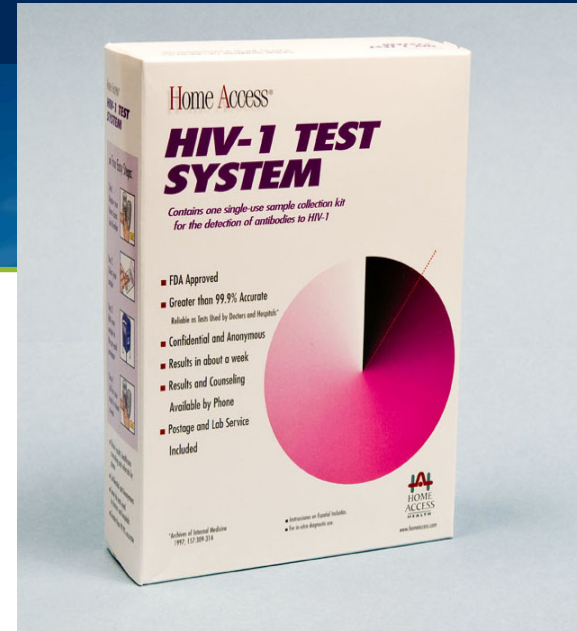
## How to ↑ Testing?

Increase:

- access to tests
- types of tests

# Home Access Home collection kit

- Approved in 1996  
174,316 tests  
called for results: 97%  
tested HIV+ 0.9%
- Behavioral data (44%)  
no prior test: 58%  
**HIV+/no prior test: 49%**



# Home use HIV tests

## Possible benefits

more timely diagnosis

## Possible risks

test misinterpretation

“point of sex” testing

↓ post-test counseling

delayed linkage to care

↓ STI screening

# OraQuick In-Home HIV Test - Contents



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# OraQuick In-Home HIV Test Phase III study results



Subjects who received kit  
5162

Subjects excluded (did not run  
test or return for Visit #3)  
104

Test System Failure  
subjects 5558

Subjects w/ Test System Failure  
59

Performance population  
5499

FDA Blood Products  
102<sup>nd</sup> Meeting, 5/12

SENSITIVITY analysis  
**114 (2.0%)**

SPECIFICITY analysis  
**5385**



# OraQuick In-Home HIV Test Phase III study results

5162 subjects received kit  
102 tested HIV+ by EIA



## ◎ SENSITIVITY

96 tested HIV+ by EIA

88 self-test + → **91.7%**

95% CI 84.2-96.3%

## ◎ SPECIFICITY

4903 true negative

4902 self-test - → 99.98%

95% CI 99.9-100%



# FDA-approved July 3, 2012

- ⦿ Rapid HIV antibody test
- ⦿ Performed on oral fluids
- ⦿ Read in 20-40 minutes
- ⦿ 3 month window period
- ⦿ Approved for ages 17 and older
- ⦿ Available for \$39.99 online and in pharmacies
- ⦿ 24/7 contact line for questions and referrals



# OraQuick In-Home HIV Test

## How will it be used?

### When should I use this test?

There is usually about **3 months** between when you get HIV and when tests can detect it. This test detects HIV infection if used **3 months after a risk event**. Using this test earlier than 3 months since a risk event may not produce an accurate result. If you test within the first 3 months, please test again after 3 months have passed. A "risk event" is defined by any of the below list of activities:

- Unprotected sex (vaginal, anal or oral)
- Sex with multiple partners
- Sex with someone whom you did not know their HIV status
- A man who had sex with another man
- Injected drugs or steroids, or shared needles or syringes
- Exchanged sex for money
- Been diagnosed or treated for Hepatitis, Tuberculosis or a sexually transmitted disease like Syphilis

You can also use this test:

- ✓ If you want to know your HIV status.
- ✓ If you are pregnant, test anytime.
- ✓ If you are age 17 or older.

### When should I NOT use this test?

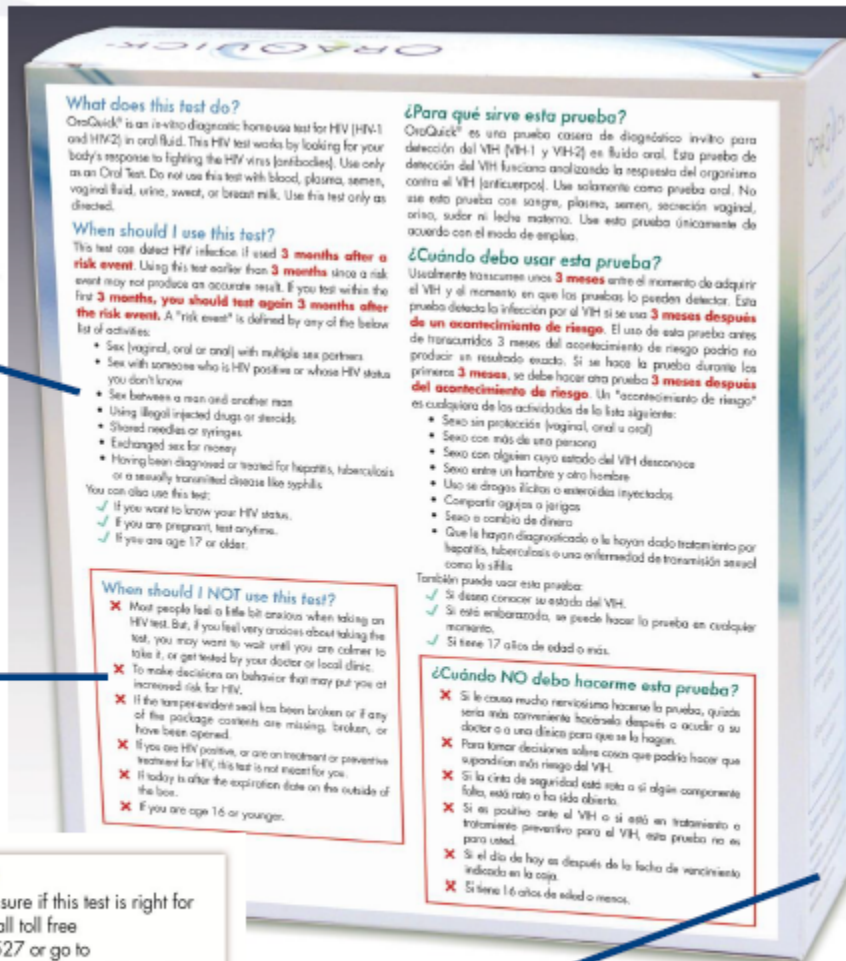
- ✗ Most people feel a little bit anxious when taking an HIV test. But, if you feel very anxious about taking the test, you may want to wait until you are calmer to take it, or get tested by your doctor or local clinic.
- ✗ To make decisions on behavior that may put you at increased risk for HIV.
- ✗ If the tamper-evident seal has been broken or if any of the package contents are missing, broken, or have been opened.
- ✗ If you are HIV positive, or are on treatment or preventive treatment for HIV, this test is not meant for you.
- ✗ If today is after the expiration date on the outside of the box.
- ✗ If you are age 16 or younger.

### Questions?

If you are not sure if this test is right for you, please call toll free 1-866-436-6527 or go to [www.oraquick.com](http://www.oraquick.com) for more information.

### ¿Alguna pregunta?

Si no sabe con seguridad si esta prueba es adecuada para usted, por favor llame gratis al 1-866-436-6527 o visite [www.oraquick.com](http://www.oraquick.com) para más información.



# Home testing: Unanswered questions

Will...

- people use a home test?
- more people test/test more?
- home tests delay linkage to care?
- sex partners test together?
- “point of sex” testing increase HIV transmission?



## Study Design & Methods

# The iTest Study: Objectives



**iTEST**  
HOME HIV TESTING  
**STUDY**

## Primary Objectives

- 1) Test frequency in subjects randomized to:  
    self-testing OR  
    standard clinic-based testing
- 2) Differences in sexual behavior

## Secondary Objectives

STI acquisition, accuracy, acceptability, ease of use

# The iTest Study: Key points



**iTEST**  
HOME HIV TESTING  
**STUDY**

246 subjects followed for 15 months

In-person training

Given one kit at a time

Additional kits mailed as necessary

Taken off study if kit used on someone else

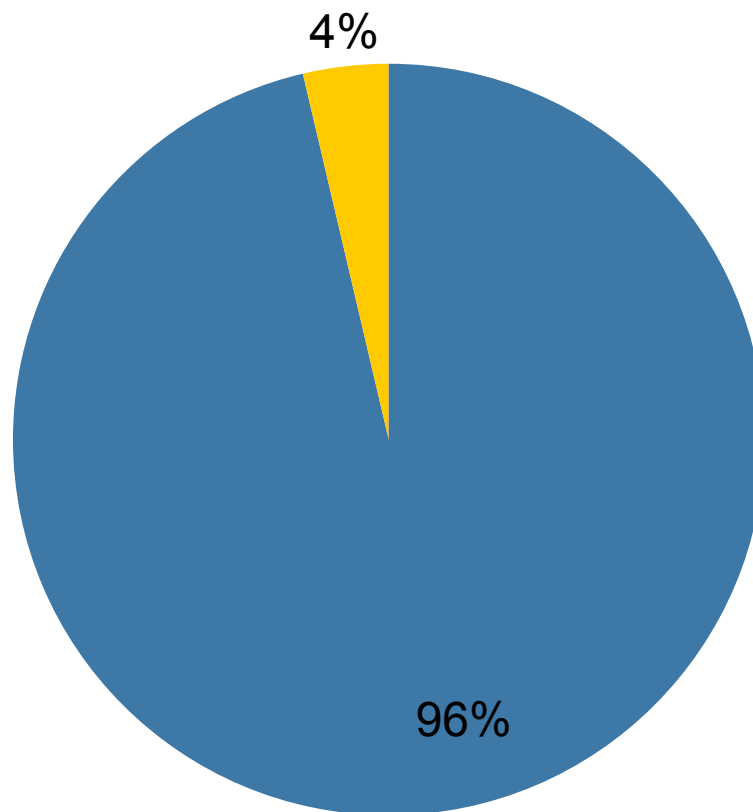
24-hour contact line

# The iTest Study: Ease of Use



**iTEST**  
HOME HIV TESTING  
**STUDY**

## How easy was it to use the home self-testing kit?



From 109 post-testing surveys reporting home self-testing:

- Very easy
- Somewhat easy
- Somewhat hard
- Very hard

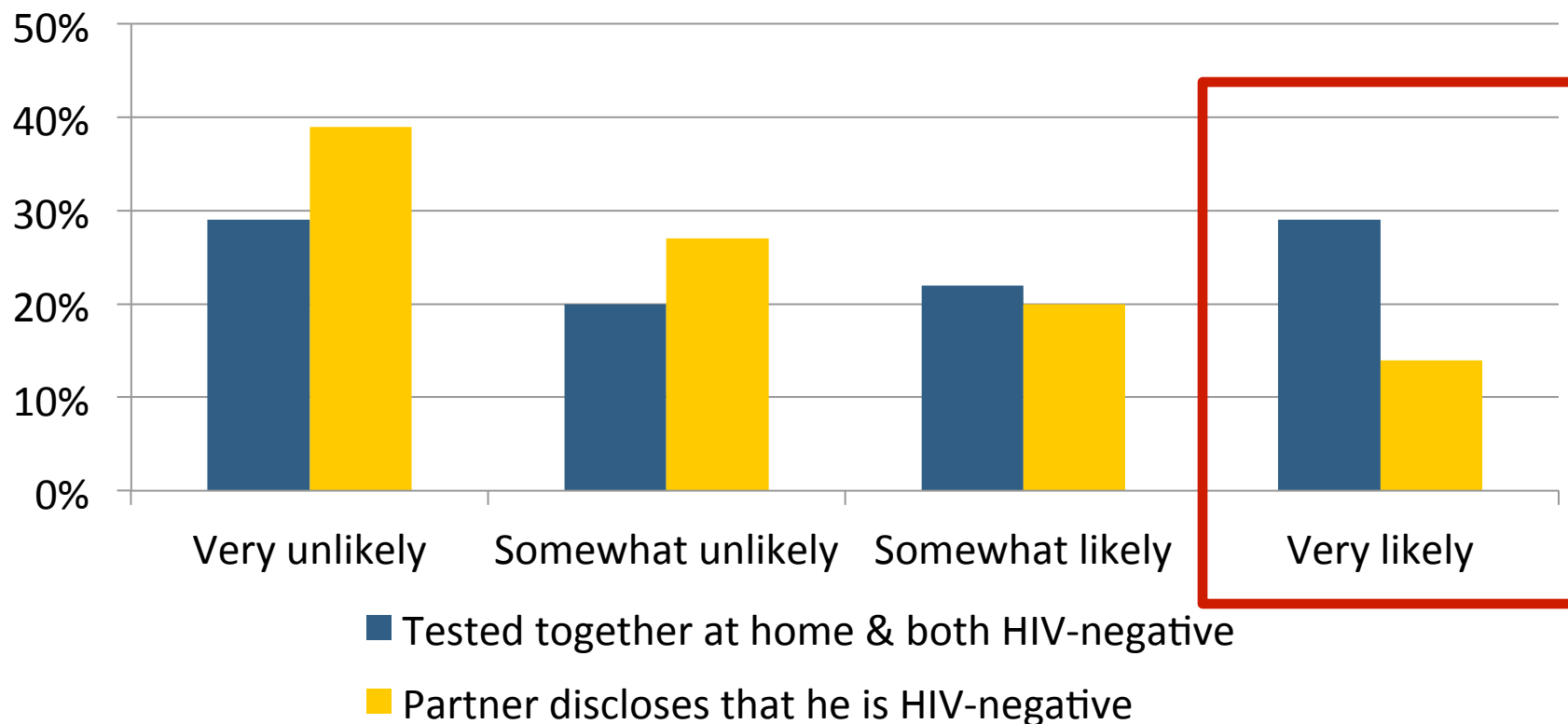


# The iTest Study: Point of sex testing?



**iTEST**  
HOME HIV TESTING  
**STUDY**

## Likelihood of unprotected anal sex with a new sex partner based on how HIV status was learned



# The iTest Study: Partner testing case report



iTEST  
HOME HIV TESTING  
STUDY

27yo MSM not in our study sought confirmatory testing at PHSKC STD clinic for a reactive home test.

2mo prior, he had UAI with a study subject.

After sex, the subject offered to test him.

The case had a reactive test.

- GOOD:      accurate  
                 subsequent condom use
- BAD:        did not get confirmatory testing  
                 delayed entry to care  
                 no PEP for our subject

# Background

## PHSKC Pooled HIV NAAT Program

MSM screened by POC test (Sep 03-Dec 10), n=16,049

	# HIV-positive	Cumulative HIV-positive	Cumulative "Sensitivity"
OraQuick	314 (2.0%)	314	77%
EIA	40 (0.3%)	354	87%
NAAT	52 (0.3%)	406	100%

# Consequences of home tests replacing clinic tests?

