HIV TESTING DEMO

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AIDS Activities Coordinating Office

Prison AIDS Project

The Center for Disease Control (CDC) is one of the major operating components of the Federal Government's Department of Health and Human Services.

The CDC operates the **National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention**. Their objective is to maximize public health and safety nationally and internationally through the elimination, prevention, and control of disease, disability, and death caused by HIV/AIDS, viral hepatitis, STDs and TB

CDC provides oversight and funding for testing in the United States.

Center for Disease Control (CDC) Recommendations for HIV Testing

CDC has made guidelines for patients in all health-care settings and especially for pregnant women

CDC Recommendations for Patients in All Health-Care Settings

- HIV screening is recommended for patients in all health-care settings after the patient is notified that testing will be performed unless the patient declines (opt-out screening).
- Persons at high risk for HIV infection should be screened for HIV at least annually.
- Separate written consent for HIV testing should not be required; general consent for medical care should be considered sufficient to encompass consent for HIV testing.
- Prevention counseling should not be required with HIV diagnostic testing or as part of HIV screening programs in health-care settings.

CDC Recommendations for Pregnant Women

- HIV screening should be included in the routine panel of prenatal screening tests for all pregnant women.
- HIV screening is recommended after the patient is notified that testing will be performed unless the patient declines (opt-out screening).
- Separate written consent for HIV testing should not be required; general consent for medical care should be considered sufficient to encompass consent for HIV testing.
- Repeat screening in the third trimester is recommended in certain jurisdictions with elevated rates of HIV infection among pregnant women.

Important Terms To Know About HIV Testing

Antibody Test

Window Period

ELISA/EIA and Western Blot

Rapid and Conventional Testing

Pennsylvania ACT 148 and Act 59

Confidential and Anonymous Testing

Negative/Non Reactive

Preliminary Positive/Reactive

Confirmed Positive

What is an Antibody Test?

There is no such thing as an AIDS TEST!

There is however Antibody testing. It is a relatively inexpensive tool to determine if an individual has been exposed to HIV. It is a routine diagnostic test that can detect the presence of HIV antibodies. You can only have HIV antibodies if you have been infected.

What is the Window Period?

A period of time that the body needs to develop measurable HIV antibodies after infection and it varies from one person to another. After potential exposure the window period range can be from three weeks up to six months.

ELISA/EIA vs. Western Blot test

•**ELISA** (enzyme-linked immunosorbent assay) and **EIA** (enzyme immunoassay) were for the first type of HIV antibody screening tests. They are highly sensitive. Their accuracy is typically above 99%.

•**Western Blot** is another type of antibody detection test. This test is used to provide more detail information than ELISA/EIA. It is used to confirm the ELISA/EIA result.

Should I Take a Rapid or a Conventional Test?

- **Rapid** (point-of-care) and **Conventional** tests are both **ELISA** diagnostic tools.
- The difference is that **rapid** test results can be ready in as little as 10 minutes.
- These tests can give an individual a preliminary response to the question – “Am I infected?”
- Using a rapid test product allows for more flexibility for testing sites.
- The rapid test is not considered the final determination because it requires a follow-up confirmatory **Western Blot**.
- **Conventional** tests are sent to a lab and require follow-up visit for results.
- Both types of test can be conducted using oral fluid or blood product.

Some individuals are uncomfortable with the idea of a rapid test. The option of a conventional test is still readily available. The wait time is a little longer for the results.

IT'S THE LAW!

PENNSYLVANIA ACT 148 AND ACT 59

Pennsylvania's Confidentiality of HIV-Related Information or Act 148 addresses the protocol for HIV testing in PA. In 2011, changes (known as ACT 59) were made to align testing closer to CDC guidelines.

- Negative test results no longer need to be given in person
- Written informed consent is not required for an HIV Test
- Heath care provider's need to document patient's consent or refusal
- Counseling before a test is not required, however needs to be explained

Is the Test Confidential or Anonymous?

Confidential

- Individuals are identified by name
- Test site can contact the individual
- Results cannot be released legally without the authorization of the individual tested.

Anonymous

- Individuals not required to give their names.
- They must return to test site for results.

Possible Test Results

- **Negative/Non Reactive** – no HIV antibodies were detected, however if an individual is still within their **window period** follow-up testing is highly recommended (up to 6 months after potential risk)

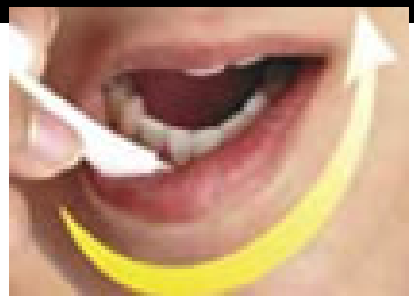
- **Preliminary Positive/Reactive** – reaction detected in the **ELISA** and confirmatory testing needs to be conducted

- **Confirmed Positive** – an individual has received a positive **Western Blot** result

Demonstration Time

Step 1 - Collect sample.

Swab between the teeth and upper and lower gum .



Step 2 - Insert the device into the buffer

Step 3 - Read between 20 and 40 minutes.

Non-Reactive
Line in the C Zone

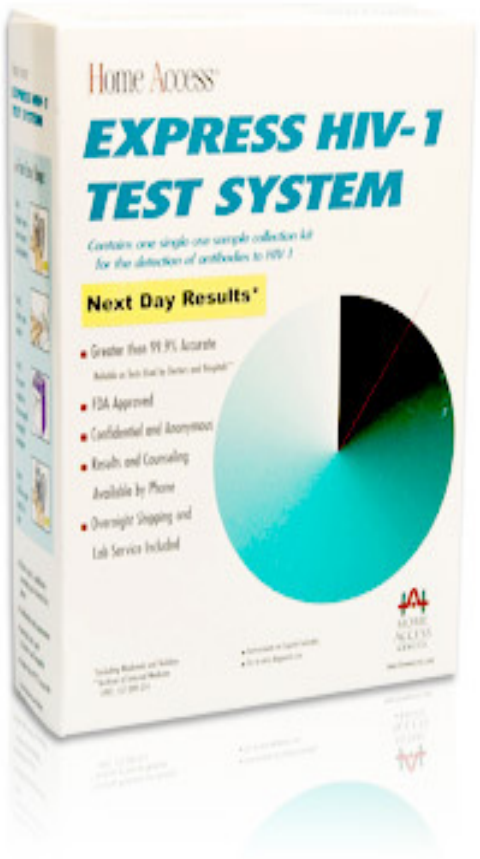
Preliminary Positive
Line in the C and T Zones

OraSure Technologies, Inc.

You can use oral fluid with their conventional test

You can use oral fluid and blood with their Rapid HIV 1/2 test. Test results are available in 20 to 40 minutes

WHAT OTHER TESTS ARE AVAILABLE?



The Home Access® Express (next day) HIV-1 Test System

FDA Approved - The only U.S. Food and Drug Administration approved HIV-1 test system.

Accurate - Clinically proven to be more than 99.9% accurate.

Anonymous - You are identified only by a code number that comes with your kit

Help Line - Toll-free telephone support for test and result questions.

Timely - Your results are available the day your sample arrives at our laboratory (excluding weekends and holidays).

Easy – A non-invasive, simple fingerstick sample is all that is needed

Three Simple Steps

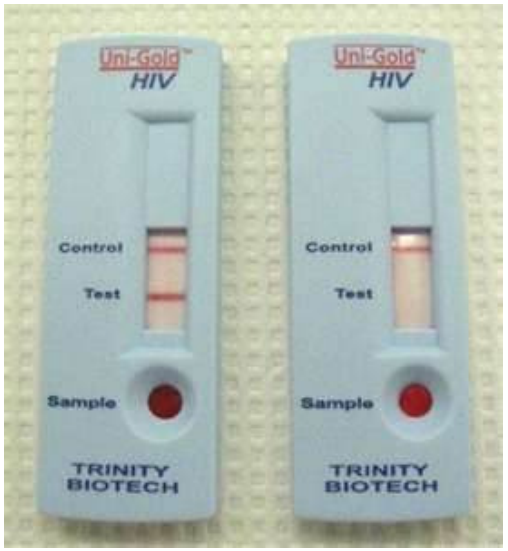
Add one drop of patient sample

Add four drops of wash solution

Read results in only 10 minutes

Uni-Gold™
Recombigen® HIV

This is a whole blood venipuncture or finger stick test with results in 10 minutes

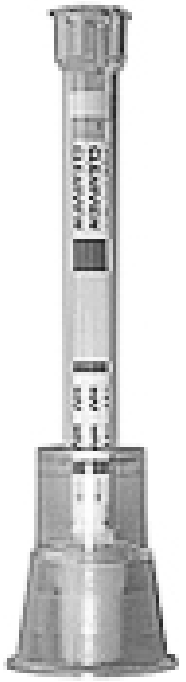


REVEAL® G3

Is the fastest point-of-care rapid HIV-1 Test in the U.S. and it uses blood. This type of test is used mostly in hospitals.

Clearview® COMPLETE HIV 1/2
Clearview® COMPLETE HIV 1/2 STAT-PAK

These rapid test detect antibodies for HIV 1 and 2 in blood with results in 15 minutes



Check for HIV 1+2 at home in total privacy, your test results will be available to you within minutes. This product is certified by the World Health Organization and is used extensively Worldwide as the front line clinical field testing kit. Not FDA approved.

FDA-Approved Rapid HIV Antibody Screening Tests

February 4, 2008

	FDA Approval Received	Specimen Type	CLIA Category*	Sensitivity** (95% CI)	Specificity** (95% CI)	Manufacturer	Approved for HIV-2 Detection?	List Price Per Device^	External Controls
OraQuick ADVANCE Rapid HIV-1/2 Antibody Test	Nov 2002	Oral fluid	Waived	99.3% (98.4-99.7)	99.8% (99.6-99.9)	OraSure Technologies, Inc. www.orasure.com	Yes	$17.50	Sold Separately ($25 each)
		Whole Blood (finger stick or venipuncture)	Waived	99.6% (98.5-99.9)	100% (99.7-100)				
		Plasma	Moderate Complexity	99.6% (98.9-99.8)	99.9% (99.6-99.9)				
Uni-Gold Recombigen HIV	Dec 2003	Whole blood (fingerstick or venipuncture)	Waived	100% (99.5-100)	99.7% (99.0-100)	Trinity Biotech www.unigoldhiv.com	No	$15.75 *$8.00-*	Sold Separately ($26.25 each)
		Serum & Plasma	Moderate Complexity	100% (99.5-100)	99.8% (99.3-100)				
Reveal G-3 Rapid HIV-1 Antibody Test	Apr 2003	Serum	Moderate Complexity	99.8% (99.2-100)	99.1% (98.8-99.4)	MedMira, Inc. www.medmira.com	No	$14.00	Included
		Plasma	Moderate Complexity	99.8% (99.0-100)	98.6% (98.4-98.8)				

- *"Public health" price for public health programs that are recipients of CDC funds for expanded HIV testing*

* Clinical Laboratory Improvement Amendments: CLIA regulations identify three categories of tests: waived, moderate complexity, or high complexity

** Sensitivity is the probability that the test result will be reactive if the specimen is a true positive; specificity if the probability that the test result will be nonreactive if the specimen is a true negative. Data are from the FDA summary basis of approval, for HIV-1 only. For HIV-2 information, see package inserts.

^ Actual price may vary by purchasing agreements with manufacturers

Note: Trade names are for identification purposes only and do not imply endorsement. This information was compiled from package inserts and direct calls to manufacturers.

Prepared by Kali Stanger & Frances Margolin at HRET; Margaret Lampe, Jill Clark, and Bernard Branson at CDC.

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MultiSpot HIV-1/HIV-2 Rapid Test	Nov 2004	Serum	Moderate Complexity	100% (99.94-100)	99.93% (99.79-100)	BioRad Laboratories www.biorad.com	Yes – differentiates HIV-1 from HIV-2	$25.00	Included
		Plasma	Moderate Complexity	100% (99.94-100)	99.91% (99.77-100)				
Clearview HIV 1/2 STAT-PAK	May 2006	Whole Blood (finger stick or venipuncture)	Waived	99.7% (98.9-100)	99.9% (99.6-100)	Inverness Medical Professional Diagnostics www.invernessmedicalpd.com	Yes	$17.50 *$8.00-*	Sold Separately ($50/set)
		Serum & Plasma	Non-waived	99.7% (98.9-100)	99.9% (99.6-100)				
Clearview COMPLETE HIV 1/2	May 2006	Whole Blood (finger stick or venipuncture)	Waived	99.7% (98.9-100)	99.90% (99.6-100)	Inverness Medical Professional Diagnostics www.invernessmedicalpd.com	Yes	$18.50 *$9.00-*	Sold Separately ($50/set)
		Serum & Plasma	Non-waived	99.7% (98.9-100)	99.9% (99.6-100)				

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Prepared by Jeanette Lyons & Frances Margolin at HRET; Margaret Lampe, Jill Clark, and Bernard Branson at CDC.

Have you had your HIV test?

Call 800-985-2437

Or text PA plus zip code to 36363

THANK YOU!!!

A special thanks to the PRISON AIDS PROJECT TEAM

REFERENCE

www.cdc.gov

www.orasure.com

www.unigoldhiv.com

www.medmira.com

www.biorad.com

www.invernessmedicalpd.com

www.homeaccess.com/ExpressHIV_Test.asp