

HIV Testing



HIV testing kits in a vending machine in a university in Chengdu, Sichuan Province, China.

Reuters

Vending machines in commercial sex venues to increase HIV self-testing among men who have sex with men

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Results

During 18 months, 1,398 kits were dispensed. The survey was completed by 110 patrons (response rate =7.9%). Among those who reported that they used the test kit (n=96), 17 (17.7%) participants reported a first-time reactive HIV result. At the time of the survey, six participants with reactive results reported seeking confirmatory testing and linkage to care and four had initiated treatment. Two participants requested linkage-to-care assistance. Participants reported valuing the privacy and convenience of the vending machine but were skeptical on the accuracy of their result. The startup cost, including the purchase of two vending machines, was \$10,000 and the recurring cost (monitoring, test kits, personnel) was \$33.81 per kit vended.

HIV Testing in the United States

Key Dates in History of HIV Testing³

- 1981: First AIDS case reported
- 1984: Human immunodeficiency Virus (HIV) identified
- 1985: First test for HIV licensed (ELISA)
- 1987: First Western Blot blood test kit
- 1992: First rapid test
- 1994: First oral fluid test
- 1996: First home and urine tests
- 2002: First rapid test using finger prick
- 2003: Rapid finger prick test granted CLIA⁴ waiver
- 2004: First rapid oral fluid test (also granted CLIA waiver)
- 2006: CDC recommends routine HIV screening in U.S. health-care settings¹
- 2007: CDC launches Expanded HIV Testing Initiative in U.S.
- 2007: WHO/UNAIDS global guidelines recommend routine HIV screening in health-care settings⁵
- 2010: First HIV diagnostic test approved that detects both antigen and antibodies⁶

★ Who should be tested for STDs?

Note: Your doctor may recommend additional STD tests based on your sexual history, signs, symptoms, etc.

Population

Recommendations

Sexually active women ≤ 25 years

- Chlamydia testing every year

Sexually active men or women, who are not in a long term, mutually monogamous relationship
All men who have sex with men (MSM)

- Hepatitis B vaccination
- Annual HIV testing
- Chlamydia, as recommended by your health care provider
- Hepatitis A vaccination
- Hepatitis B vaccination

Sexually active men who have sex with men (MSM), who are not in a long term, mutually monogamous relationship

- Hepatitis A vaccination
- Hepatitis B vaccination

At least once every year:

- HIV
- Syphilis
- Chlamydia
- Gonorrhea

Pregnant women

- Chlamydia, at first prenatal visit
- Syphilis, at first prenatal visit
- HIV, as early as possible in the pregnancy
- Hepatitis B, during an early prenatal visit
- Hepatitis C, as recommended by your health care provider
- Gonorrhea, as recommended by your health care provider

Any person seeking STD evaluation or treatments

- Testing for HIV
- Hepatitis B vaccination
- Testing for Syphilis, Gonorrhea, Chlamydia, as recommended by your health care provider



When To Have An HIV Test?

CDC recommends people should have an HIV test if they fall into one or more of the following categories:

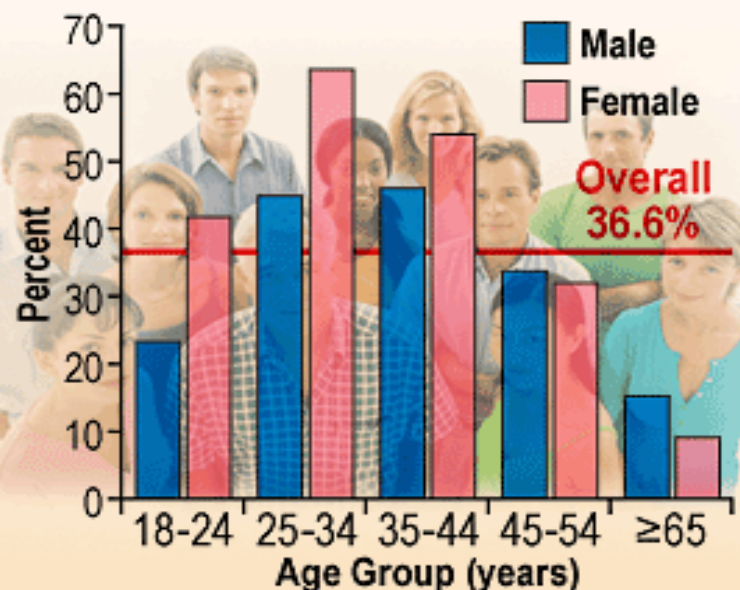
- ☐ Having three or more sexual partners in the last 12 months
- ☐ Have received a blood transfusion prior to 1985, or have a sexual partner who received a transfusion and later tested positive for HIV
- ☐ Not sure about one's sexual partner's risk behaviors
- ☐ Being a male who has had sex with another male
- ☐ Using street drugs by injection, especially when sharing needles and/or other equipment
- ☐ Having a sexually transmitted disease (STD)
- ☐ Being a healthcare worker with direct exposure to blood on the job

HIV Mandatory Testing in the US

Current U.S. laws enforce mandatory testing for the following populations:

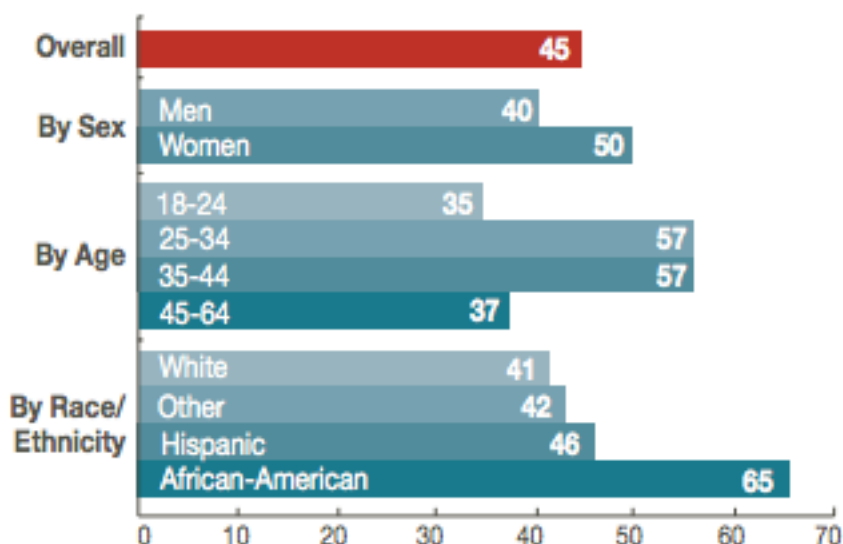
- ☐ Blood and organ donors
- ☐ Military applicants and active duty personnel
- ☐ Federal and state prison inmates under certain circumstances
- ☐ Newborns in some states

Adults Aged ≥ 18 Who Had Ever Been Tested for HIV*, by Age Group and Sex, 2007



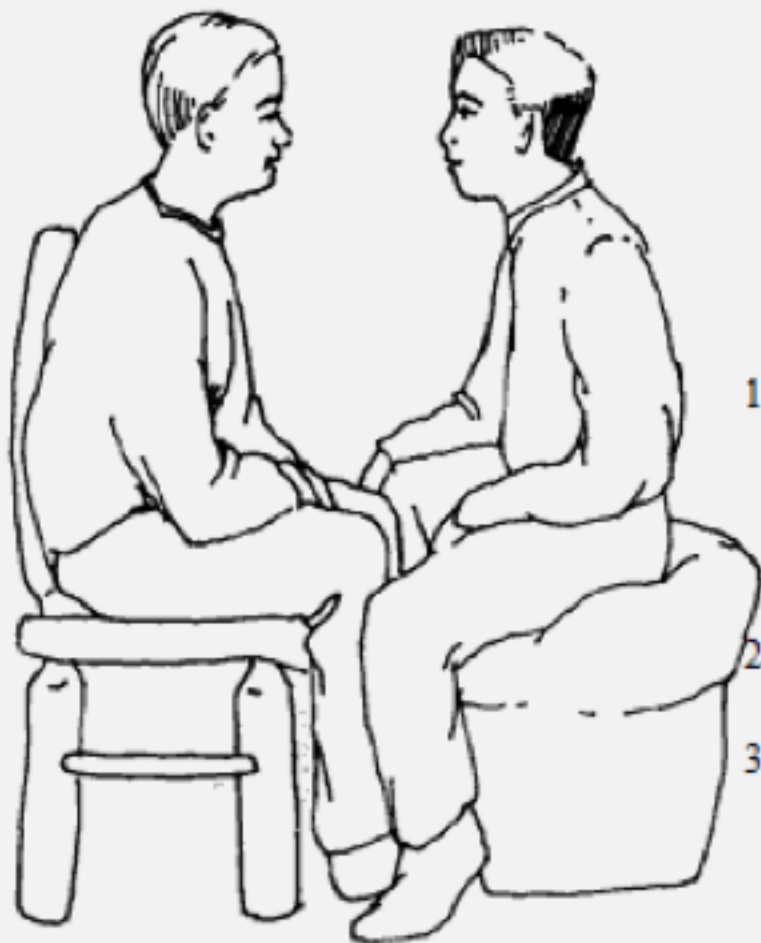
*Human Immunodeficiency Virus

Percentage of People Who Have Ever Been Tested for HIV, Overall and by Population, 2010



HIV Counseling, Testing & Support

Before You Take the Test



Taking the HIV test can help you, but it is a big step. You should think about how having HIV could affect your life. These steps can help you prepare to take the test.



1. **Consider telling someone you trust that you are having the HIV test.**

Support of a family member or friend can mean a lot.

2. **Find out how private your test results will be.**

Ask the clinic if anyone but you can learn your test results.

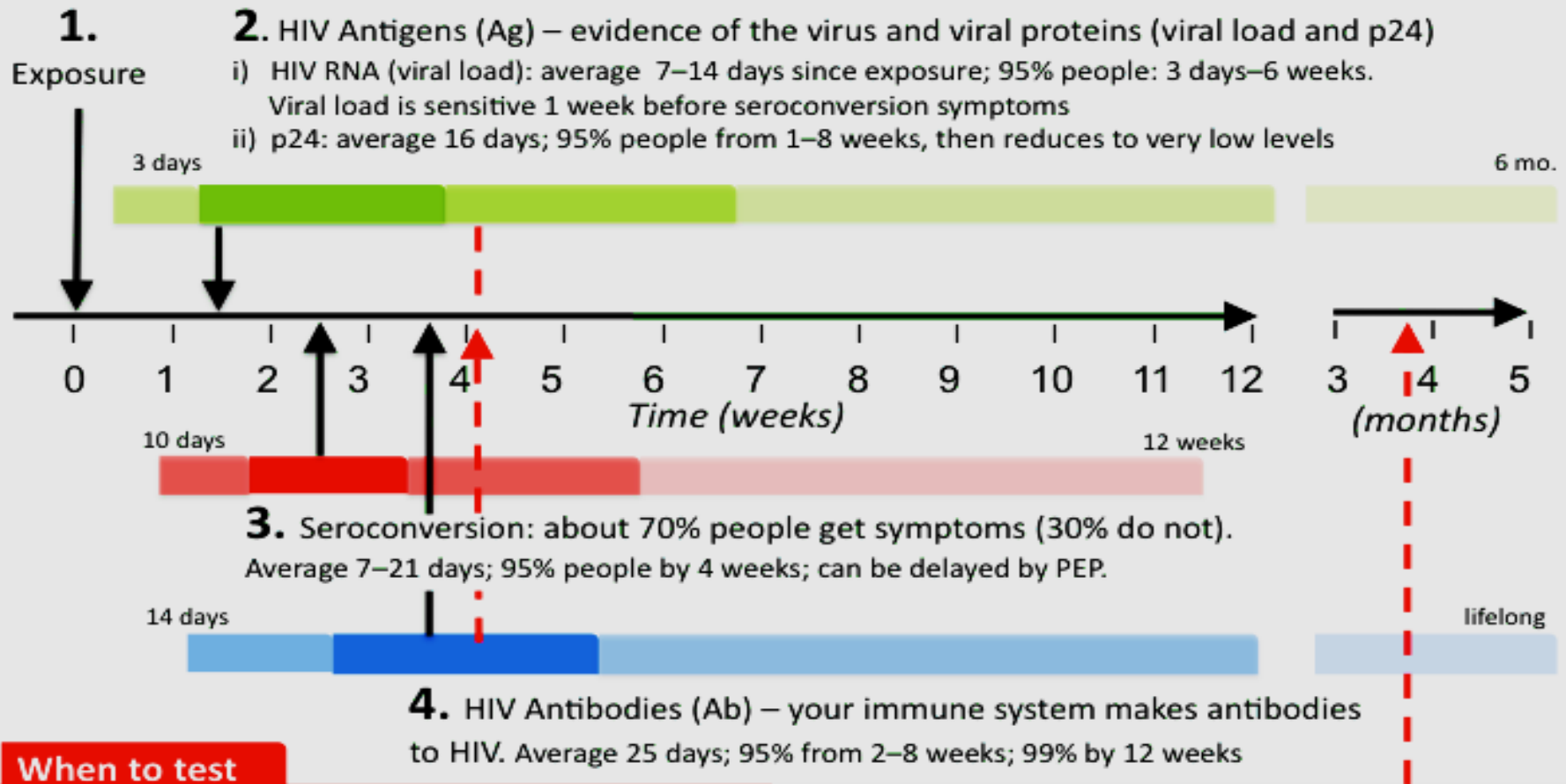
3. **Set a time to get your results.**

Don't put it off. The test can only help you when you find out what it shows.

When can I take a HIV Test?

Time from HIV sexual exposure until HIV can be detected

NOTE: Times are approximate and average. A small percentage of people generate responses earlier or later, shown by lighter bars.

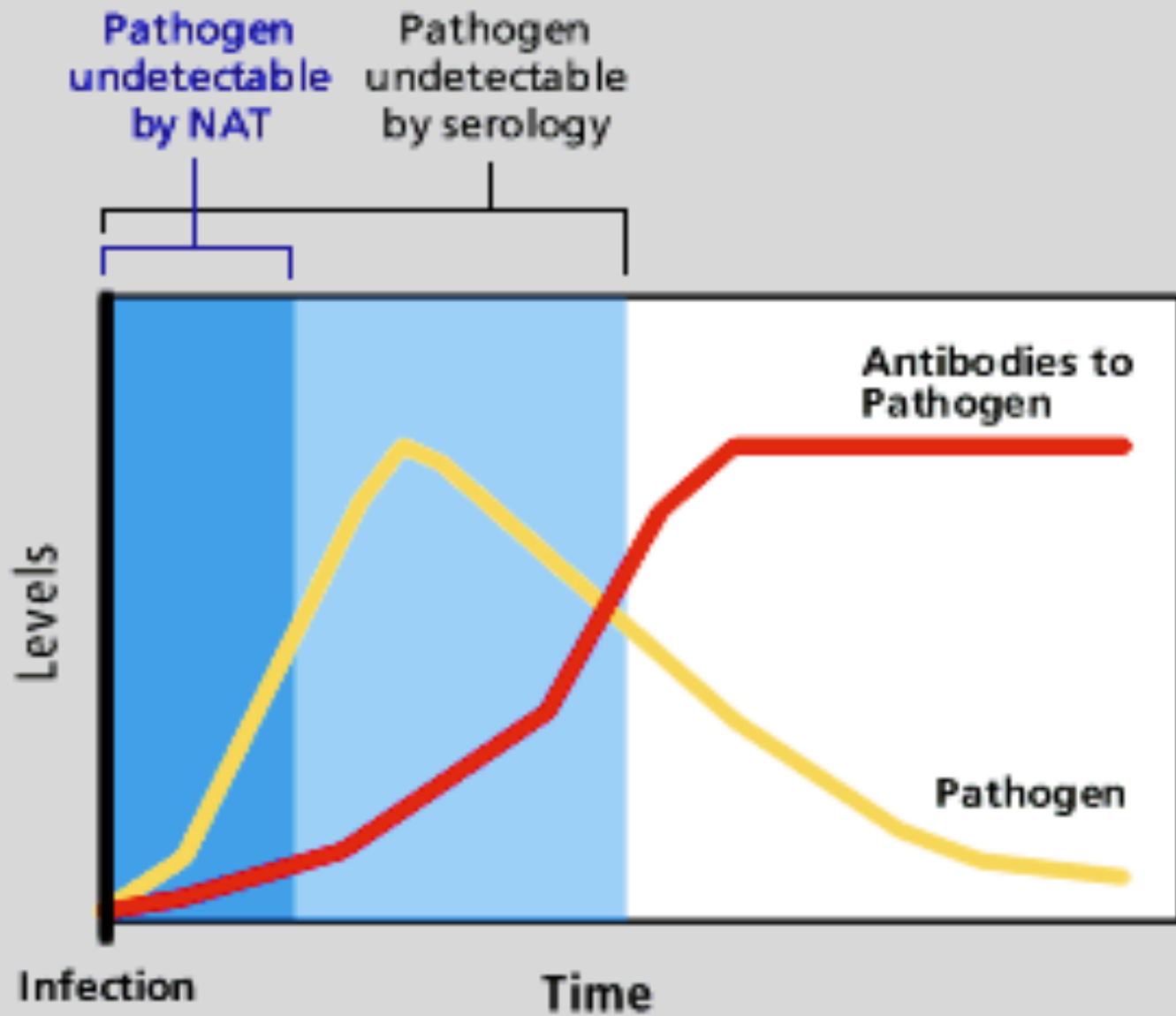


Viral load tests *can* detect HIV one week before symptoms, but are not used routinely.

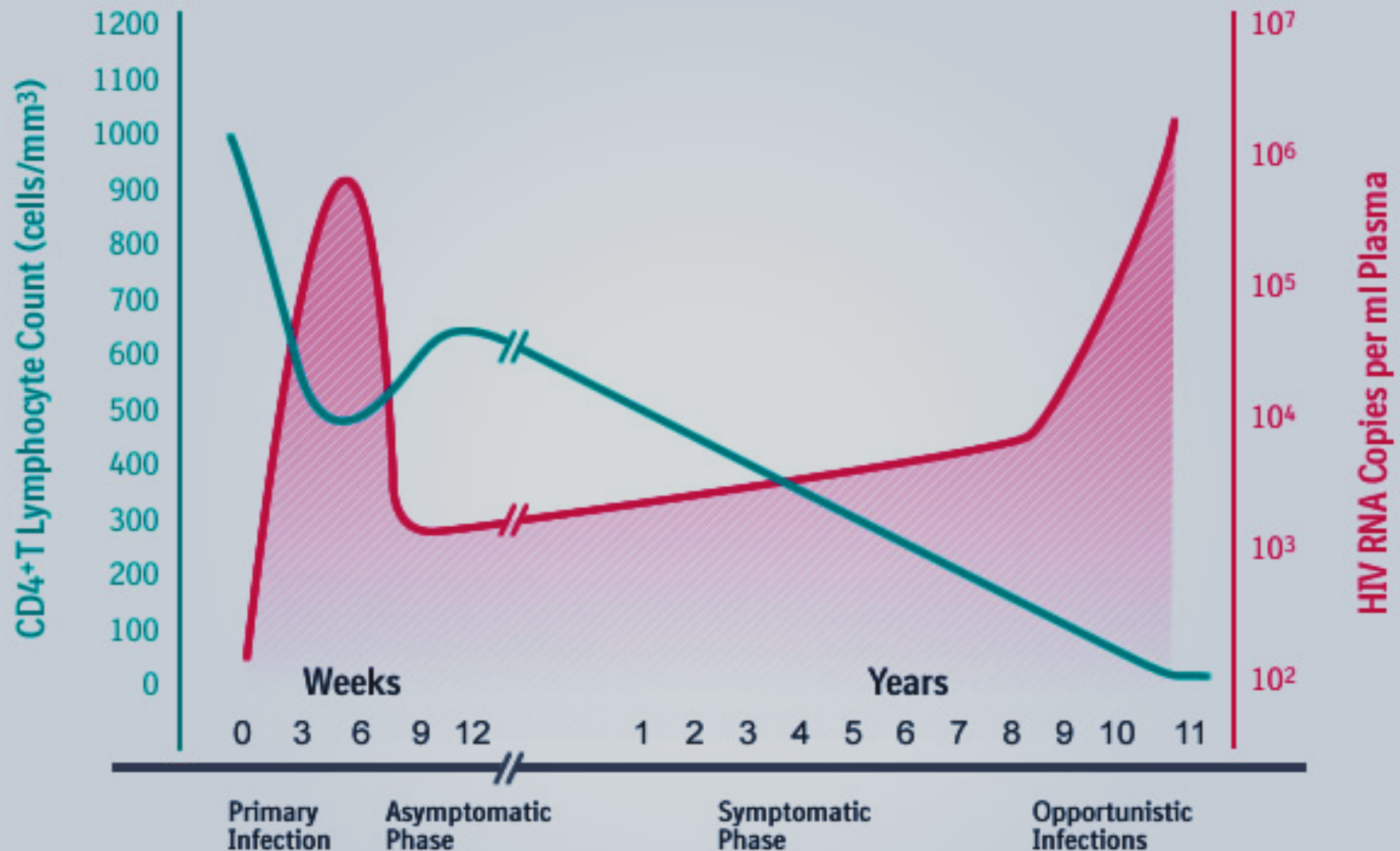
4th generation (Ab/Ag) HIV tests detect 95% of infections within 4 weeks. UK guidelines recommend testing at 4 weeks. Confirm with a second test after three months later as 5% of people take longer.

Confirm a negative result with a second test three months after your first test.

Pathogen detection window period



Progression of HIV Infection: CD4 cells and Viral Load



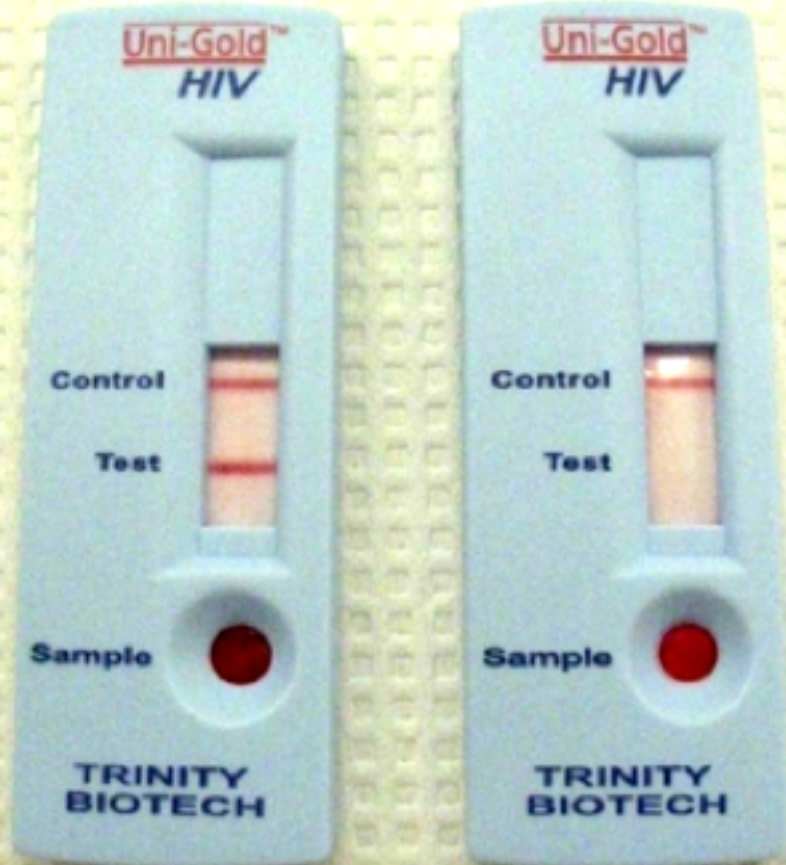
Types of HIV Tests

There are 3 broad categories of HIV tests

- 1. Screening tests-** highly sensitive; results may be positive in a small percentage of uninfected individuals
 - A. ELISA (Urine and serum [blood samples])
 - B. Rapid tests (Blood, oral fluid)
 - C. “Home Testing Kits”: currently only the [Home Access HIV-1 Test System](#) is approved by the [FDA](#)
- 2. Confirmatory test**

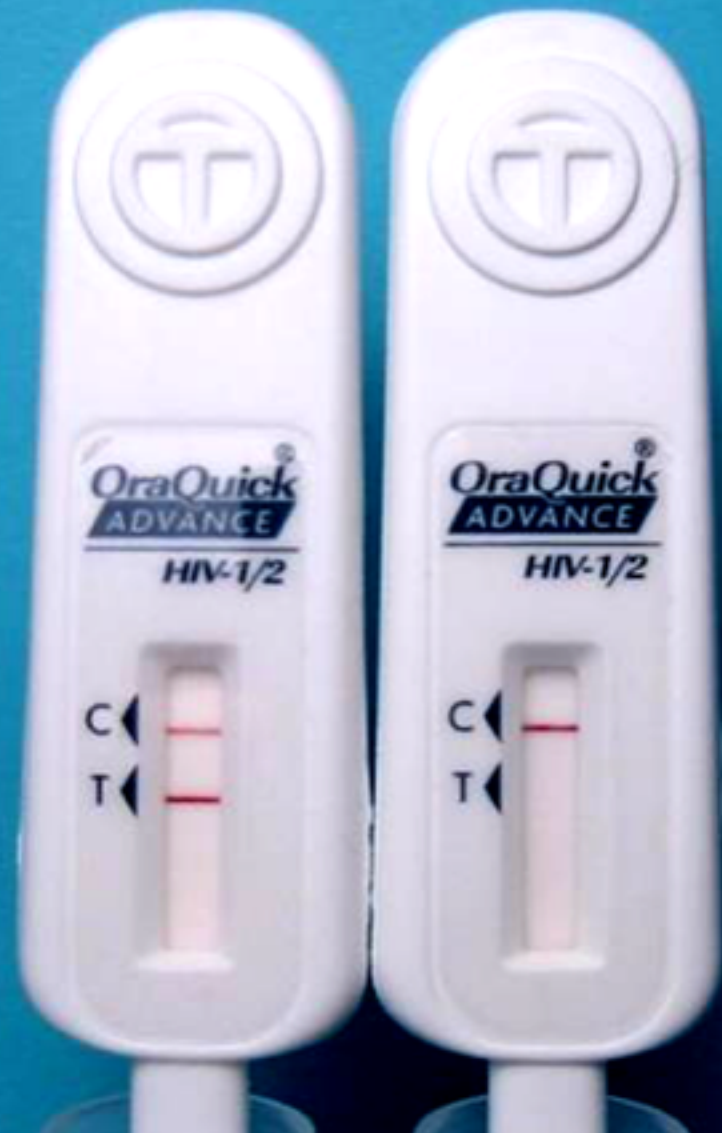
Western Blot
- 3. Tests of HIV progression and tropism**
 - A. [HIV viral load](#)
 - B. [CD4 cell count](#)
 - C. [Tropism Test](#) - CCR5, CXCR4, or dual/mixed.

Rapid HIV Tests



CDC

A rapid HIV test. The one on the left shows a positive result.



New HIV Test

Abbott ARCHITECT HIV Ag/Ab Combo

Applicant: Abbott Laboratories

Product: ARCHITECT HIV Ag/Ab Combo

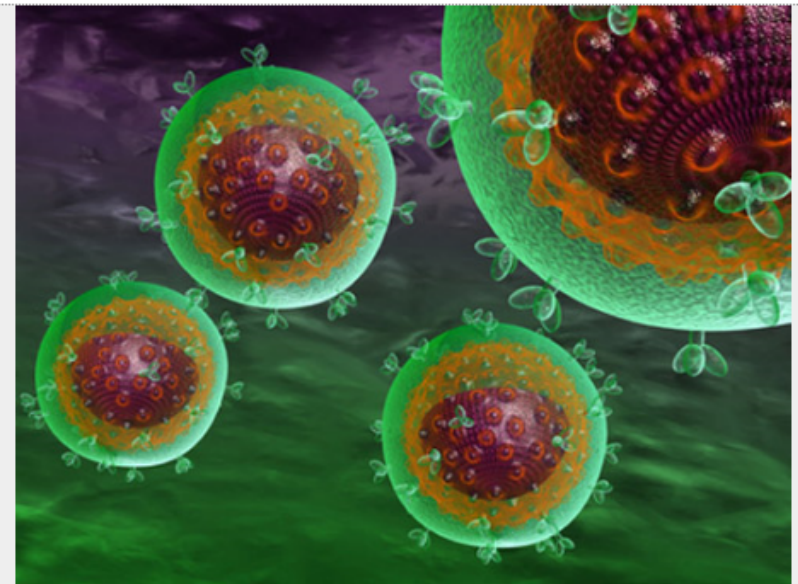
PMA number: BP090080/0

Indication for Use: As an aid in the diagnosis of HIV-1/HIV-2 infection, including acute or primary HIV-1 infection

Approval Date: 6/18/2010

GEN news highlights: Jun 21, 2010

FDA Sanctions Abbott's Test that Detects HIV Antigen and Antibodies



Assay identifies HIV p24 antigen and antibodies to HIV-1 group M and group O and/or HIV-2. [© 4designersart - Fotolia.com]

- ☐ AB-only tests miss up to 10% of HIV infections in some high- risk populations
- ☐ Detects the HIV p24 antigen (direct presence of HIV).
- ☐ “The most sensitive third-generation antibody tests will pick up about 42% of acute-phase infections, whereas the new combination assay picks up about 90% of those in the acute phase,” -Abbott Senior Director, Gerald Schochetman

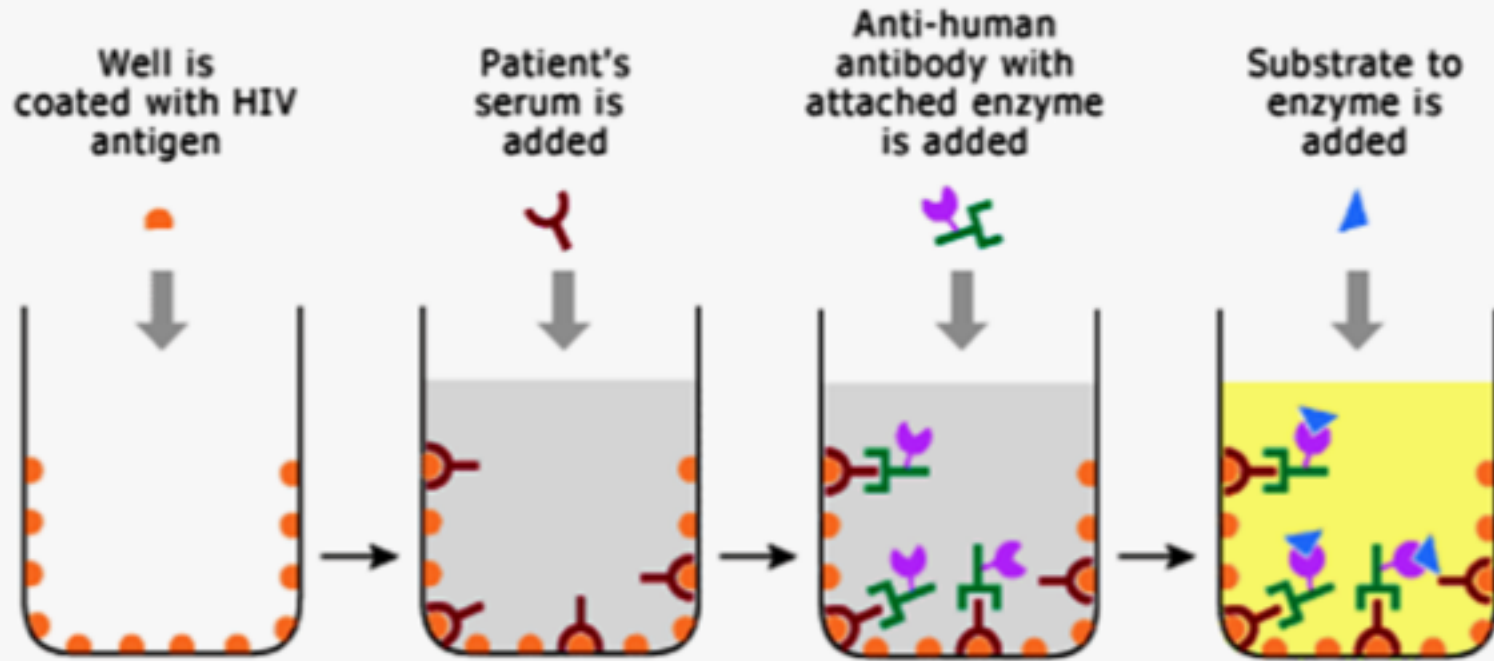
Types of HIV Tests

Type of test	What the test look for?		
	RNA/ DNA *	Anti- gen	Anti- body
PCR/viral load	•		
p24 only test (Ag)		•	
4th generation antigen/antibody (Ag/Ab) tests (p24+ ELISA, ELI, MEIA/ELFA/ECLIA): includes Architect, Duo, Combo/Combi etc		•	•
1st/2nd/3rd generation antigen only tests (ELISA, ELI, MEIA/ELFA/ECLIA): includes TriDot etc			•
Rapid tests: finger prick and oral swab test are antibody only: includes OraQuick.			•
Western blot tests look for antibodies to specific HIV proteins. They confirm a positive HIV antibody test result.			•
* Viral genetic material			

How The HIV Screening Test Works



Testing of blood
for HIV antibodies

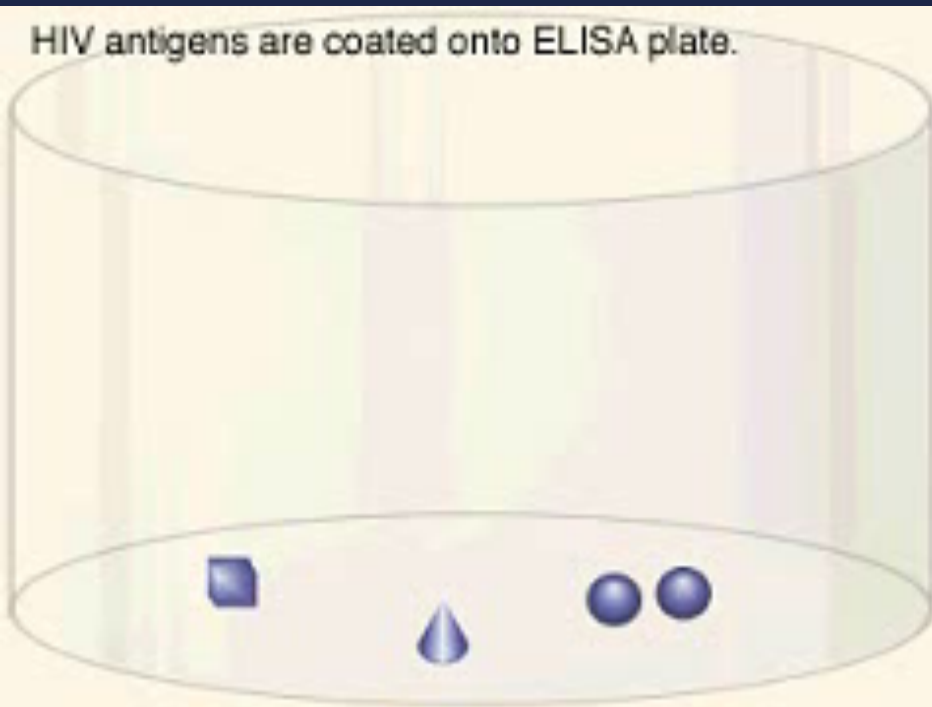


The ELISA Test: A color change in the final step indicates that the patient has HIV antibodies in their bloodstream.



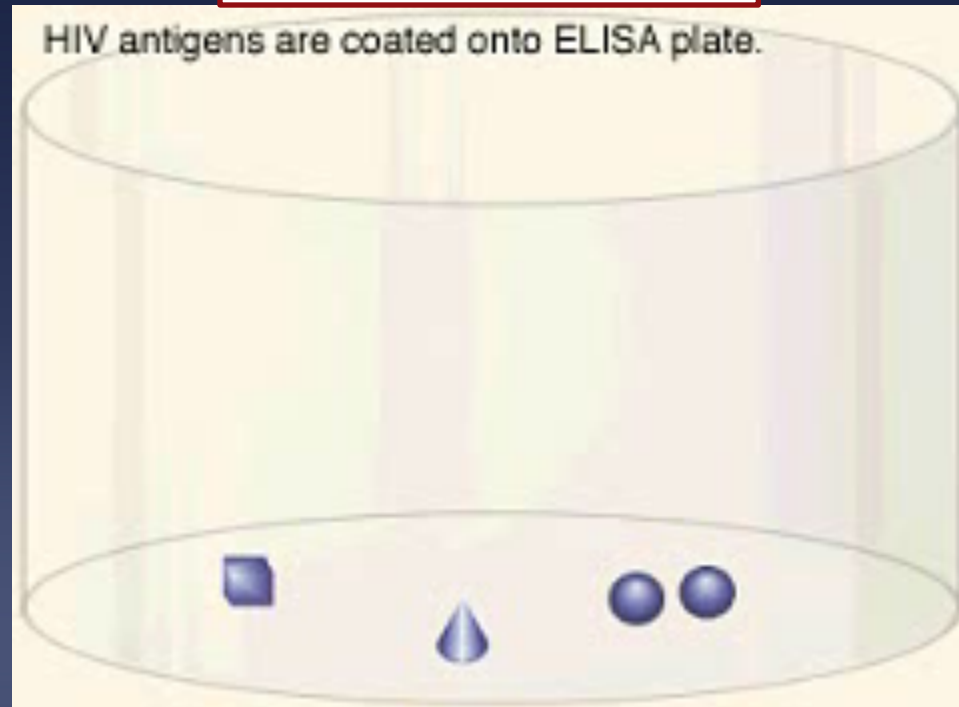
The ELISA Method – Animated

Negative ELISA Test



Partially purified, inactivated HIV antigens pre-coated onto an ELISA plate

Positive ELISA Test



Patient serum which contains antibodies. If the patient is HIV+, then this serum will contain antibodies to HIV, and those antibodies will bind to the HIV antigens on the plate.

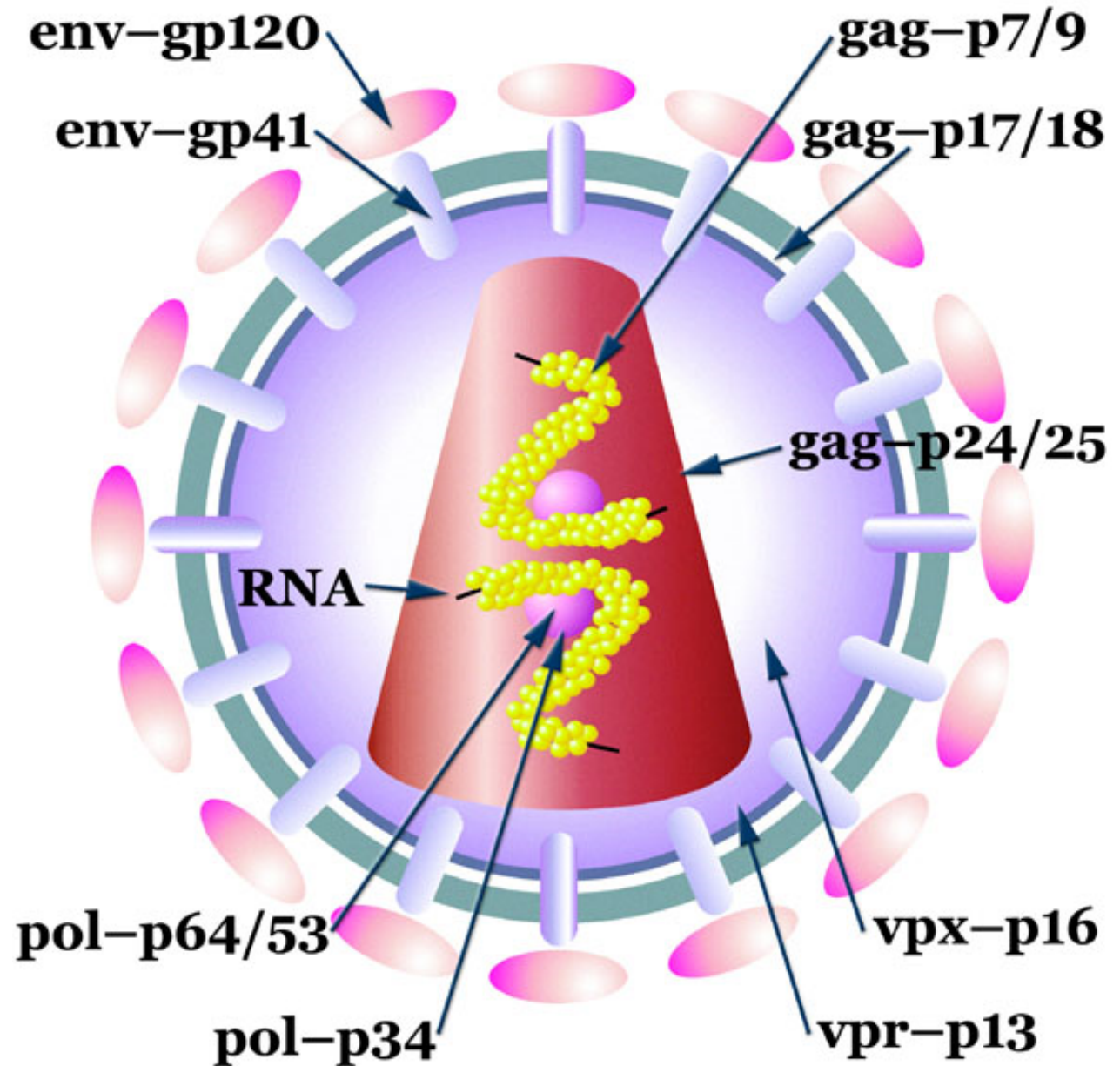


Anti-human immunoglobulin coupled to an enzyme. This is the second antibody, and it binds to human antibodies.



Chromogen or substrate which changes color when cleaved by the enzyme attached to the second antibody.

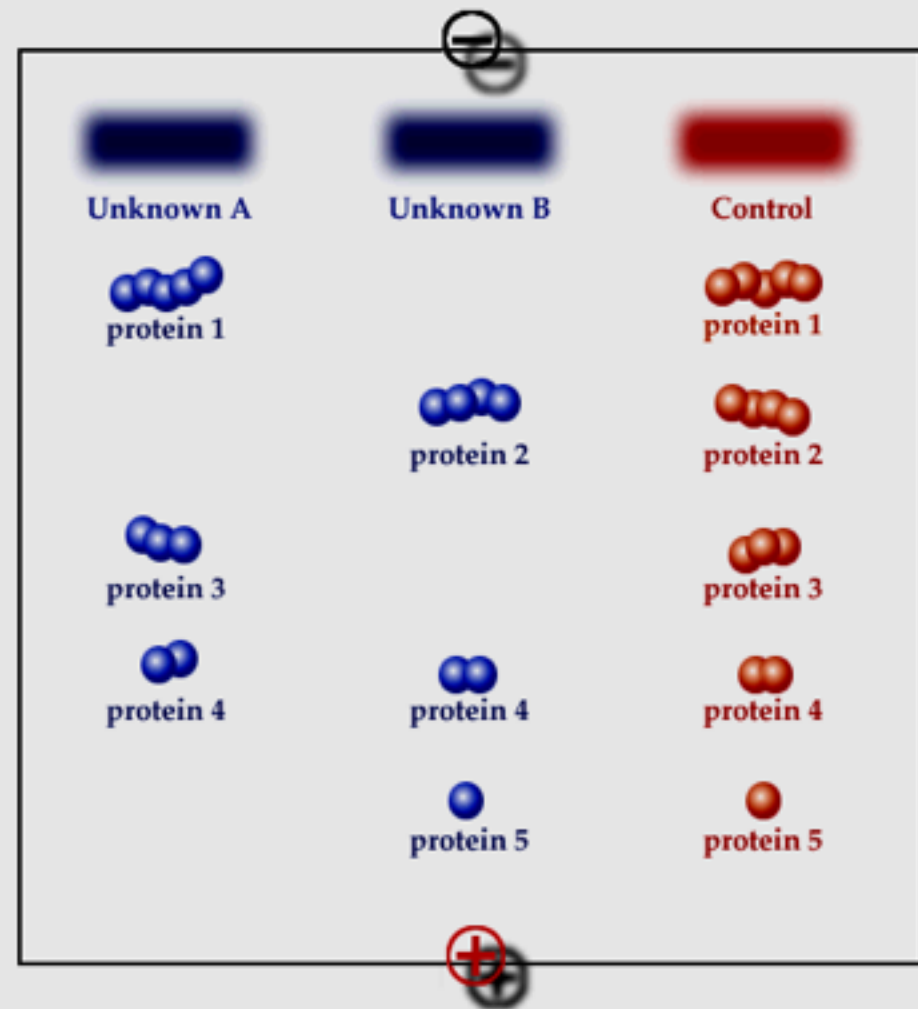
HIV Proteins



Western Blot and Specific HIV Proteins

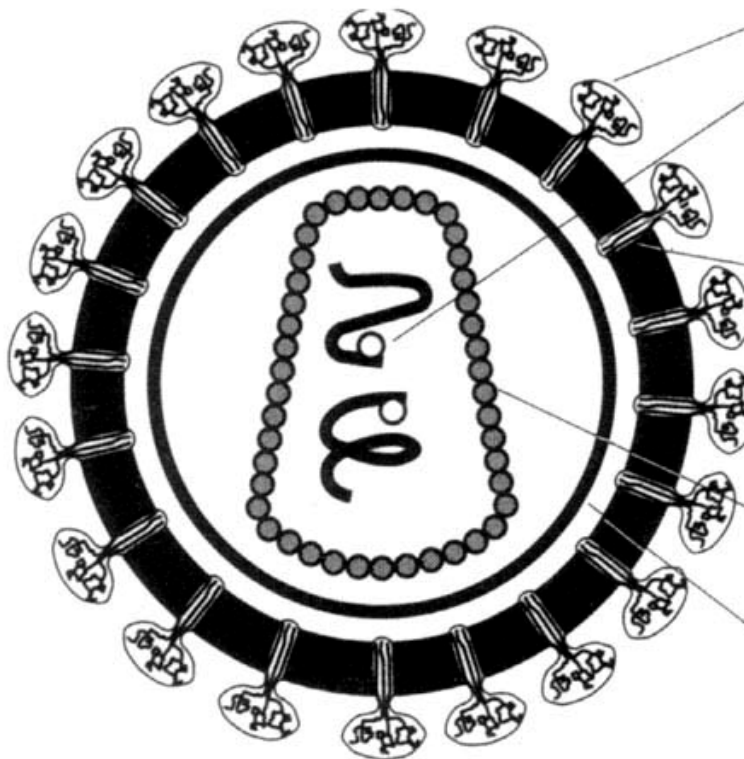
No bands present	Negative
Bands at either p31 OR p24 AND bands present at either gp160 OR gp120	Positive
Bands present, but pattern does not meet criteria for positivity	Indeterminate

gp160	viral envelope precursor (<i>env</i>)
gp120	viral envelope protein (<i>env</i>) binds to CD4
p24	viral core protein (<i>gag</i>)
p31	reverse transcriptase (<i>pol</i>)

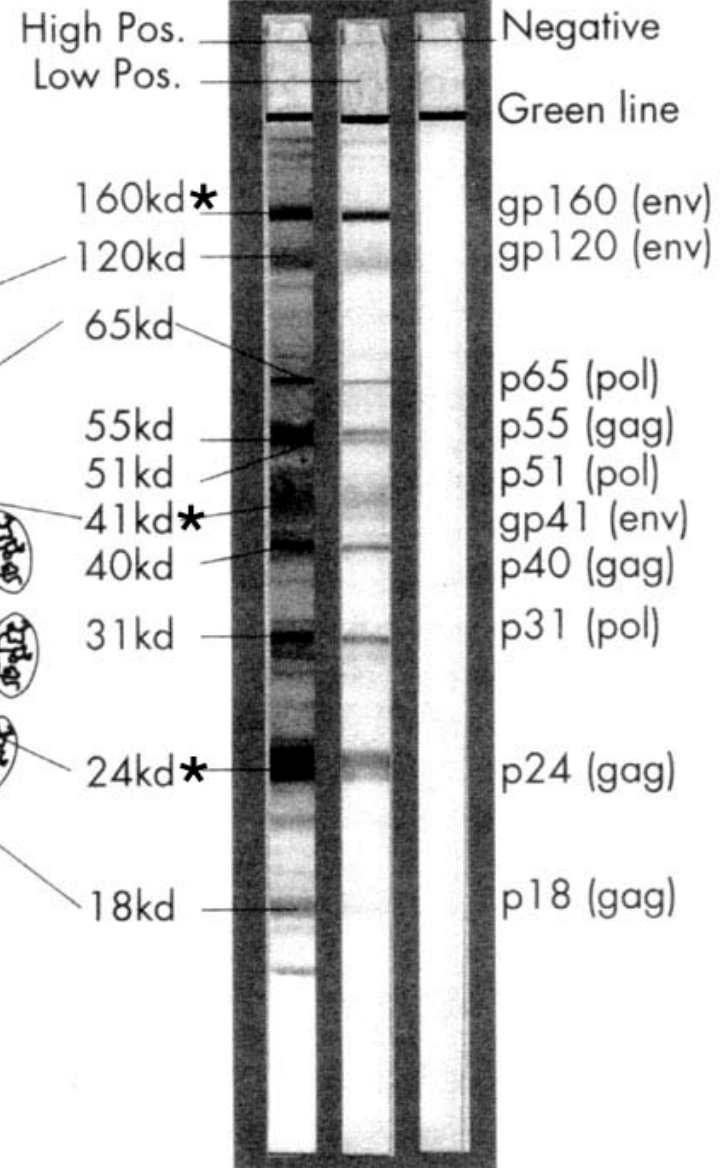


Western Blot: Relevant Protein Location

ANATOMY OF HIV-1

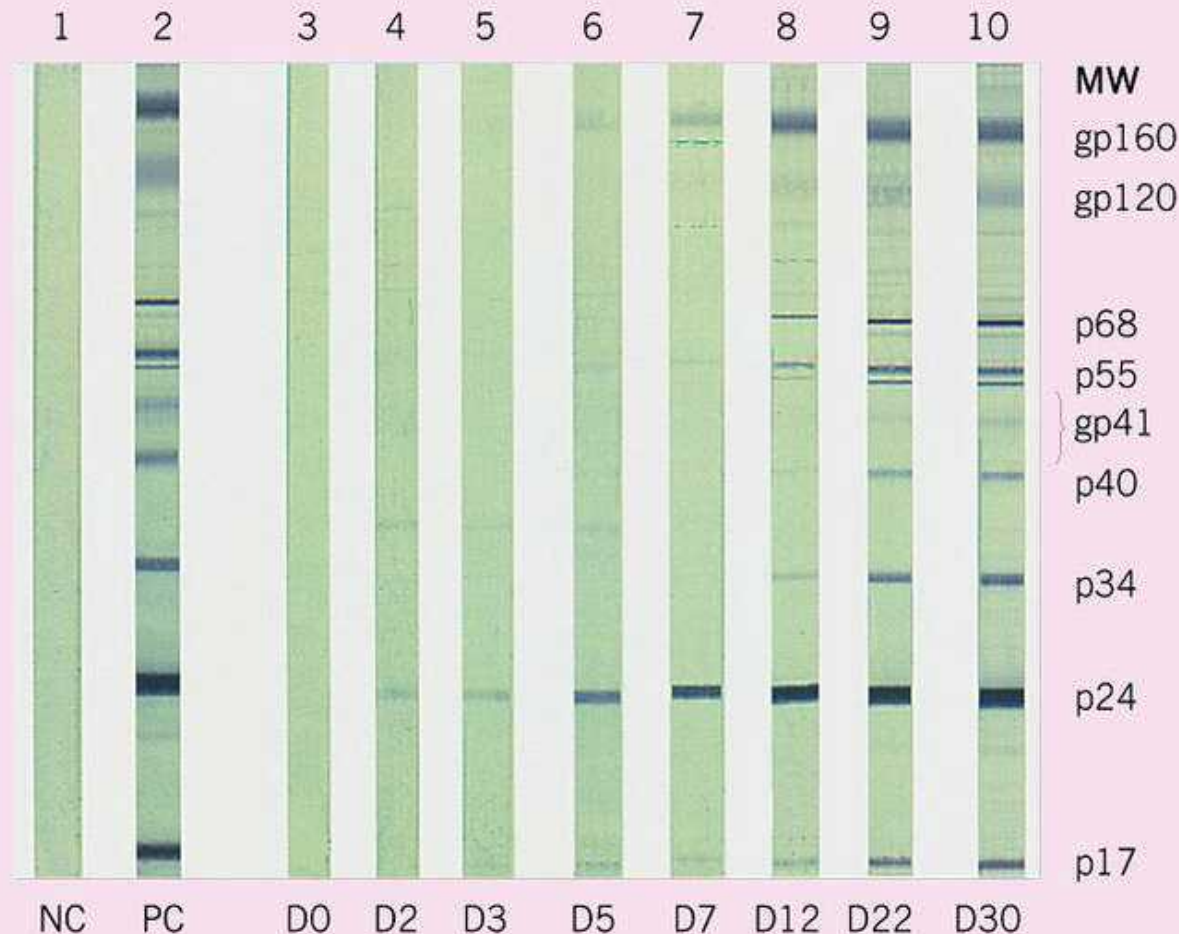


HIV-1 ASSOCIATED BANDS



Progression of HIV Infection

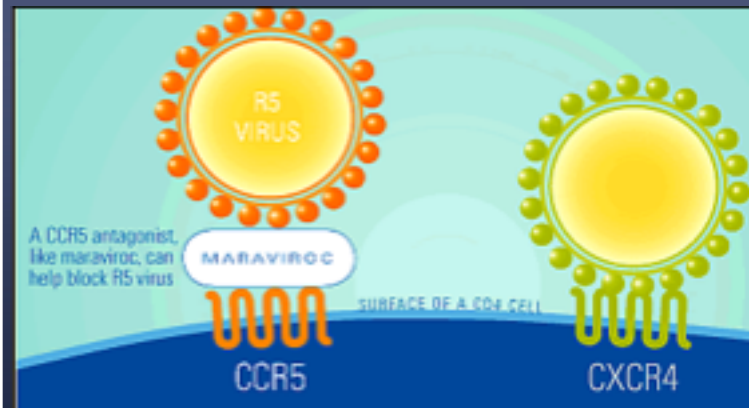
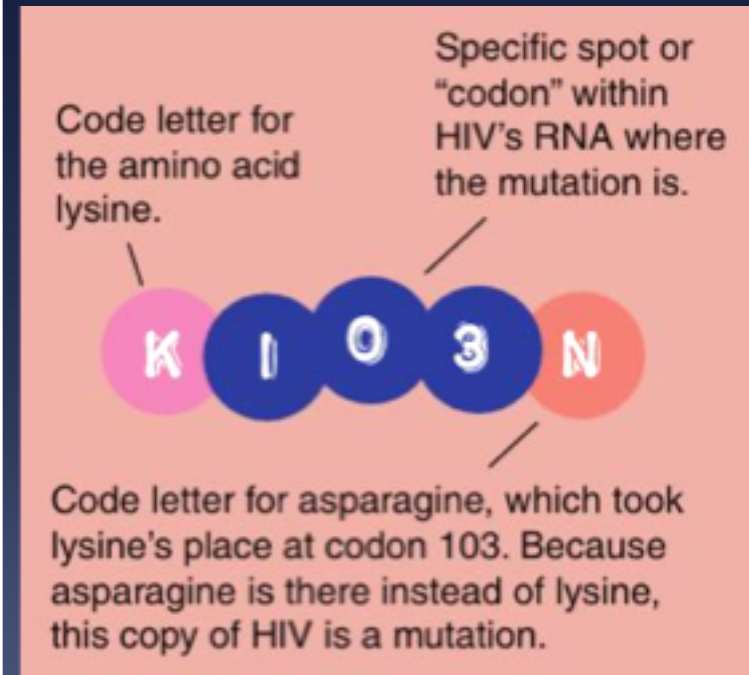
WESTERN BLOT REACTIVITY IN ONE HIV-1 SEROCONVERTER



The column marked "PC" is an HIV-positive test result and the column marked "NC" is an HIV-negative test result. Column 3 to Column 10 are tests performed on a single person beginning with the day when the person was first exposed to HIV (Column 3, Day 0) to when the person had a full-blown HIV infection (Column 10, Day 30).

HIV Resistance and Tropism Test

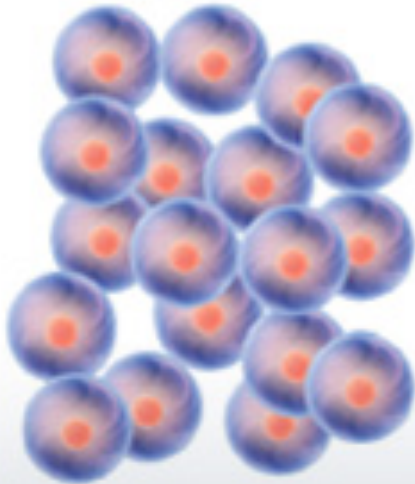
- ❑ Resistance decreases the ability of drugs to control HIV & affects treatment options
- ❑ **Genotype test** – Checks for mutation in HIV that cause drug resistance
- ❑ **Phenotype test** - challenges virus with all HIV drugs (in a test tube)
- ❑ **Virtual phenotype test** - genotype test that uses phenotype information to predict which drugs will be effective against HIV (and its mutations)



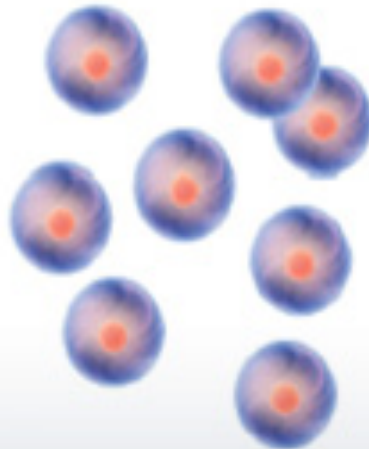
CD4 T Cell Count and HIV

Here is what your T-cell count can tell you

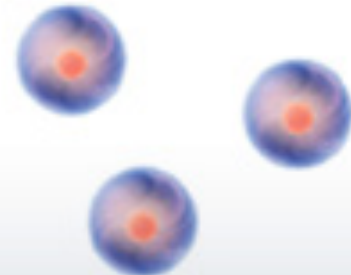
More than
500 cells/mm³
Your immune system
is **normal**



200-500 cells/mm³
Your immune system
may be **weakened**



Less than
200 cells/mm³
Your immune system is
very weak. You are at high risk
for getting an opportunistic
infection – an infection that
develops only when the
immune system is weak

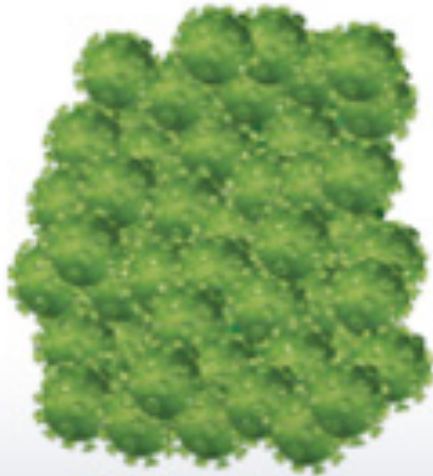


HIV Viral Load Test

Here are 3 examples of viral load levels

High

For example, greater than or equal to 100,000 copies/mL



Low

For example, fewer than 10,000–30,000 copies/mL



Undetectable

For example, either less than 400 or less than 50 copies/mL, depending on the test used

