CLINICIAN CONSULTATION CENTER
National rapid response for HIV management and bloodborne pathogen exposures.

Frequently Asked Questions about HIV Testing

What are the current recommendations for HIV testing?

- One-time HIV screening for all persons aged 15-64 is recommended by the US Preventive Services Task Force (USPSTF), as part of regular medical care. The CDC recommends one-time routine screening for all persons aged 13-64.
  - HIV screening tests are adminstered on an "*Opt-out*" vs. "*Opt-in*" basis. "*Opt-out*" *consent* refers to general informed consent for medical care notifying the patient that an HIV test will be performed unless the patient declines, and should be considered adequate informed consent for HIV testing.
  - This routine screening does not require pretest counseling or separate written consent from the patient***** as had been the practice for "*Opt-in*" testing.
- All pregnant women.

*****Please check the Compendium of State HIV Testing Laws on our website to see if your states's HIV testing laws are compatible with these recommendations: www.nccc.ucsf.edu.

Are there additional considerations for high risk persons?

Persons at high risk for infection should be tested annualy or more frequently, based on their risk status or risk activity. Those at elevated risk include:

- people with many sex partners
- sex workers or people who exchange sex for drugs or money
- people who inject drugs and share needles or syringes
- people having unprotected sex with an HIV+ partner or partner of unknown status

When should pregnant women be tested for HIV?

The CDC recommends routine prenatal HIV screening for all pregnant women during the 1st trimester, with a repeat 3rd trimester screening for women at risk for HIV infection or in areas with an HIV prevalence >1%. Rapid HIV tests should be offered at labor and delivery to any woman without a documented 1st and/or 3rd trimester HIV test and to women at increased risk for HIV acquisition.

What types of HIV tests are available for my patients?

HIV tests identify virus antibodies in a person to determine if the individual is infected. Virus antibody production begins between 2 and 12 weeks after the initial infection. There are 2 options for screening test settings: medical/clinic settings and at-home testing.

Medical/Clinical Settings:

There are 2 screening test mechanisms for use in a medical setting like a doctor's office, health clinic, or emergency department: the *Rapid* HIV test and the *ELISA* test, which can also be referred to as standard testing.

- **Rapid HIV tests** produce results in 15-25 minutes. Rapid tests use either blood or oral fluid (not saliva). There are currently 10 FDA-approved rapid tests.
- The **ELISA** (enzyme-linked immunosorbent assay or "EIA" enzyme immunoassay) test is administered to blood, oral fluid, or urine. Test results are generally available from a lab within a few days to one week.
- Of note, **4th generation tests** have greater sensitivity, because they detect both HIV antibodies and the p24 antigen. Previous generation tests tested only for HIV antibodies.

Is the rapid HIV ELISA test as good as the standard HIV ELISA test?

Both tests are highly sensitive and specific. The rapid test may have slightly higher specificity than the standard ELISA test. There is no need to perform both a rapid and a standard HIV ELISA test.

HIV Screening Testing at Home:

There are 2 FDA-approved HIV tests for **home use***:

- The *OraQuick In-home HIV* test uses results from a mouth swab to produce screening test results in about 20 minutes.
- The *Home Access HIV-1 Test System* allows users to collect a small blood sample via a finger prick, send the sample to a licensed laboratory, and to call for their test results a few days later.

*Note: Patients who complete an HIV screening test at home should follow up with their healthcare provider, and all home-use tests should be followed up with a clinical lab test.

What is the 'window period' and how does it impact screening test results?

This is the time between a person's exposure incident and when HIV antibodies can be detected. Average window period length is 2-8 weeks, although some people take longer to develop antibodies. During the window period, the person has HIV infection but a screening test may not indicate infection.

The window period is signficant because:

- HIV viral load is usually high during the first several weeks and months of infection, and there is an increased risk for transmitting HIV.
- Patients who receive a positive HIV diagnosis during the window period should be quickly referred to follow-up care and treatment, which can improve health outcomes.

What does a positive HIV screening test result mean?

A positive screening test result does not necessarily mean that the patient is HIV+. ***Any positive screening test result must be followed up with a confirmatory lab test***. Accurate results (sensitivity and specificity >99.5%) are generally available in 1-2 days from a commercial laboratory.

4th Generation Tests:

Positive **4th generation** HIV screening test results can be followed-up with the *Multispot HIV-1/HIV-2 Rapid Test*. The Multispot is a qualitative immunoassay used to detect and differentiate circulating antibodies to HIV Types 1 and 2. This rapid HIV-1/HIV-2 test kit is intended as an aid in the diagnosis of infection with HIV-1 and/or HIV-2 in blood samples.

1st-3rd Generation Tests:

For 1st, 2nd, and 3rd generation tests, there are currently 2 confirmatory tests available:

- Western Blot
  - Tests for HIV antibodies via proteins from known HIV-infected cells.
- Indirect Immunofluorescent Antibody Assay (IFA)
  - Serum containing HIV antibodies reacts with intracellular HIV, then with antiimmunoglobulin antibodies. Reaction is observed via fluorescent microscope.
  - IFA results may be considered a more definitive diagnosis of samples that produced indeterminate Western Blot results.

What causes a false positive ELISA test result?

The ELISA is a highly sensitive test, and can sometimes generate false positives by mistaking other antibodies for those of HIV.

- Standard HIV ELISA test specificity is >95%. Specificity for the rapid ELISA HIV test is >98.9%.
- Common causes of a false positive ELISA include: administration of flu vaccine, presence of HLA-DR antibodies in multigravada women, presence of rheumatoid factor, positive RPR test, hypergammaglobulinemia (e.g. multiple myeloma) and autoimmune hepatitis.

Any positive ELISA test must be followed by a confirmatory test (WB or IFA).

What are the causes of an indeterminate Western Blot?

The CDC defines a positive HIV Western Blot (WB) test as having at least 2 of the following bands: p24, gp41, gp120/160.

- Indeterminate results occur when there are 1 or more positive bands that do not fulfill the criteria above.
- Common causes of an indeterminate WB include early HIV-1 seroconversion, malignancy, cross reaction to other antibidies (e.g., rheumatoid factor), infection by HIV-2 or O Group, infection by a related retrovirus (e.g. HTLV), hypergammaglobulinernia (e.g. multiple myeloma), autoimmune disease (e.g. SLE), collagen vascular diseases, participation in HIV trial vaccines, and cross contamination.

What is the follow-up to an indeterminate Western Blot?

Significance of an indeterminate Western Blot (WB) depends on which bands are positive and the patient's clincial status and risk factor(s).

- In a high-risk individual, an ELISA antibody test should be repeated at about 2-4 weeks, 2-3 months (if needed), and at 6 months (if needed). An HIV viral load can be run on a high-risk person, with the caveat that there can be a false positive

rate of <1%, especially if the viral load is <5,000-10,000 copies/mL. For low-risk individuals who receive indeterminate WB results, an ELISA repeat test is recommended at 3-6 months. If the ELISA is positive and a confirmatory WB remains indeterminate, it is unlikely the person is infected with HIV.

What is the initial work-up for a newly diagnosed HIV positive person?

Initial work-up of a newly diagnosed person should include:

- Complete medical history including approximate date and source of HIV infection, sexual and/or drug using contacts, history of sexually transmitted infections (STIs)
- Current sexual activity
- Substance use and depression history
- Symptoms (e.g. fever, night sweats, weight loss) that may indicate progressive HIV disease and/or opportunistic infection (OI)

Basic lab tests should include:

- CD4 count, HIV viral load, HIV resistance test (genotype), CBC with differential, complete metabolic panel, fasting lipid panel, VDRL or RPR, urinalysis, Hepatitis B serologies (HBsAg, HBsAb, HBcore total antibody), Hepatitis C antibodies, Hepatitis A total antibodies, toxoplasmosis IGG
- G6PD (for high risk populations) and CMV IGG (except in men who have sex with men)
- HLA B*5701

Health care maintanence should include:

- PPD skin test and/or interferon gamma release assay (IGRA)
- pneumovax (repeat in 5 years)
- influenza vaccine
- Hepatitis A vaccine (if indicated) and Hepatitis B vaccine (if indicated)

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This material is intended for educational purposes for healthcare providers only.

It is not intended as a substitute for professional medical care or advice, nor to replace a healthcare professionals' clinical judgment regarding their individual patient care.

Resources

Centers for Disease Control and Prevention. *HIV/AIDS*. Retrieved from http://www.cdc.gov/hiv/testing/index.html.

Department of Health and Human Services. *AIDSinfo*. Retrieved from http://www.cdc.gov/hiv/basics/index.html.

US Preventive Services Task Force. *Screening for HIV*. Retrieved from http://www.uspreventiveservicestaskforce.org/uspstf/uspshivi.htm