

HIV TESTING

September 18, 2019

BREE A. WEAVER, MD

ASSISTANT PROFESSOR OF CLINICAL MEDICINE AND
CLINICAL PEDIATRICS
INDIANA UNIVERSITY SCHOOL OF MEDICINE



Disclosure Statement

- I have no disclosures.

Learning Objectives

1. Explain how the 4th generation HIV testing differs from prior available HIV screening tests
2. Describe available types of HIV testing
3. Interpret laboratory HIV test results

HIV Testing is Important for Prevention & Treatment of HIV

- An estimated 1.1 million people in the United States were living with HIV at the end of 2015
- Estimated 15%, or 1 in 7, did not know they were infected
- Approximately 40% of new HIV infections are transmitted by people who are living with undiagnosed HIV

HIV Testing is Important for Prevention & Treatment of HIV

- Those at high risk for HIV but who are HIV negative can:
 - Start PrEP
 - Be treated for other STIs that place them at higher risk for acquiring HIV
- When people become aware they are HIV+, they can:
 - Engage in care before they face significant challenges to their health
 - Start cART / HAART – resulting in viral suppression and markedly reduced transmission
 - Make safer decisions about sex, needle use

Source: Coates, et al JAMA 1987;258:1889. Doll et al. Health Psychol 1990;9:253-65. Fox, et al. AIDS 1987;1:241-6. Gibson, et al. AIDS and Behavior 1999;3:3-12. Rietmeijer, et al. AIDS 1996; 10:291-8. van Griensven et al. Am J Epidemiol 1989;129:596-603. Cohen MS, et al. NEJM 2011;365:493-505. Skarbinski J, et al. JAMA Intern Med 2015;175:588-96. Rodger AJ et al. JAMA 2016;316(2):1-11. Smith et al. JAIDS 2013; 63S2:S187-99. Kitahata MM, et al. NEJM 2009;360:1815-26.

HIV Screening Guidelines

CDC

- Test ***all*** pregnant women
- Test ***all*** pts 13-64 yo
- Test all pts with TB, STI
- Test high risk patients at least annually

Source: Branson BM, et al. MMWR 2006

USPSTF

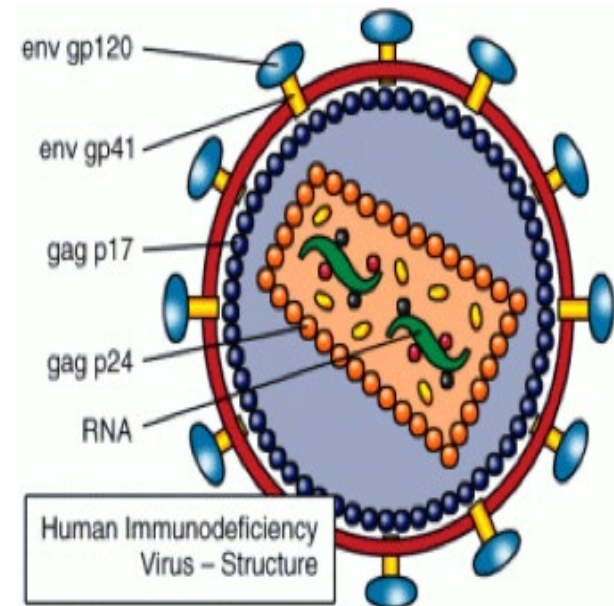
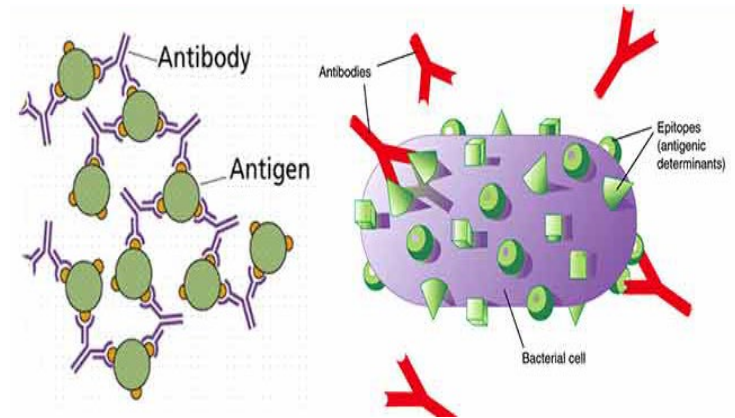
- Test ***all*** pregnant women
- Test ***all*** 15-65 yo
- Test <15 & >65 yo if at risk
- Grade A recommendation

Source:

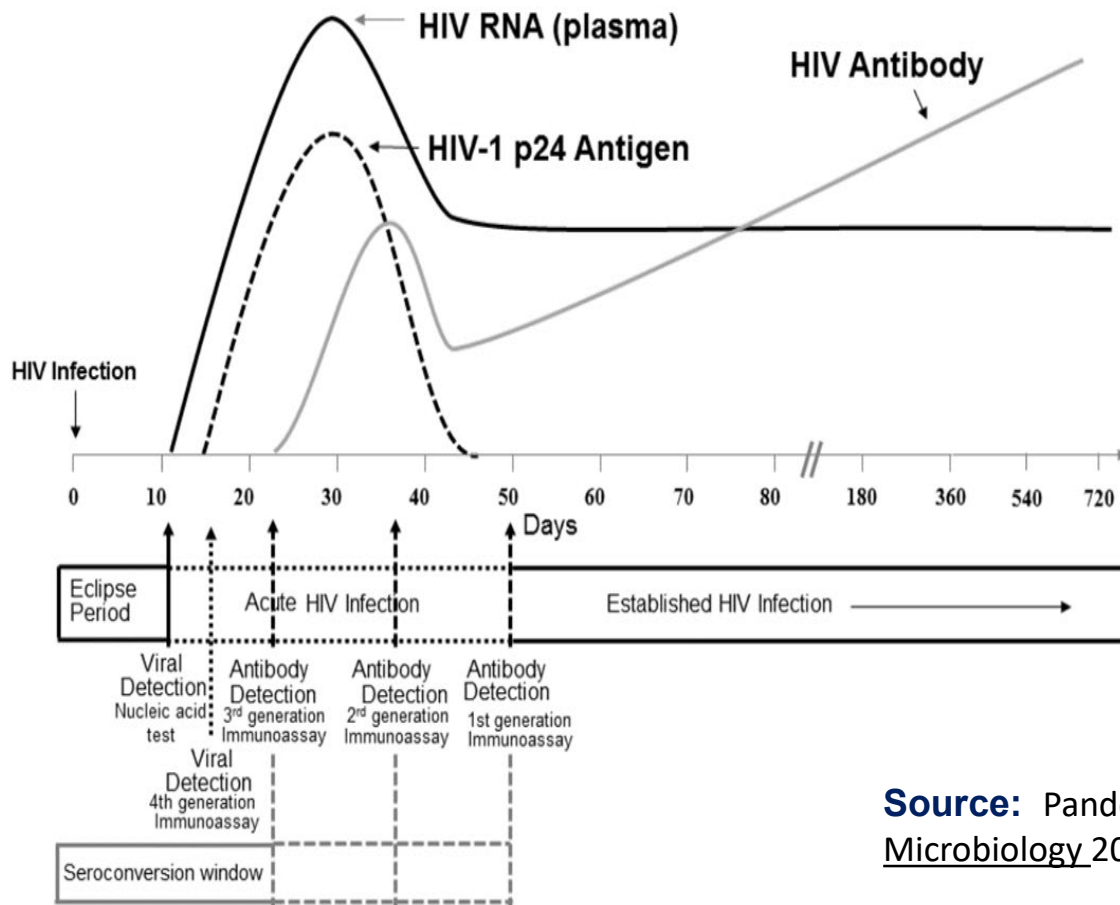
<https://www.uspreventiveservicestaskforce.org/Page/Document/draft-recommendation-statement/human-immunodeficiency-virus-hiv-infection-screening1>

Definitions

- Antigen (Ag) - a toxin or other foreign substance which induces an immune response in the body, especially the production of antibodies
- Antibody (Ab) - a blood protein produced in response to and counteracting a specific antigen
- PCR or NAAT – virus amplification

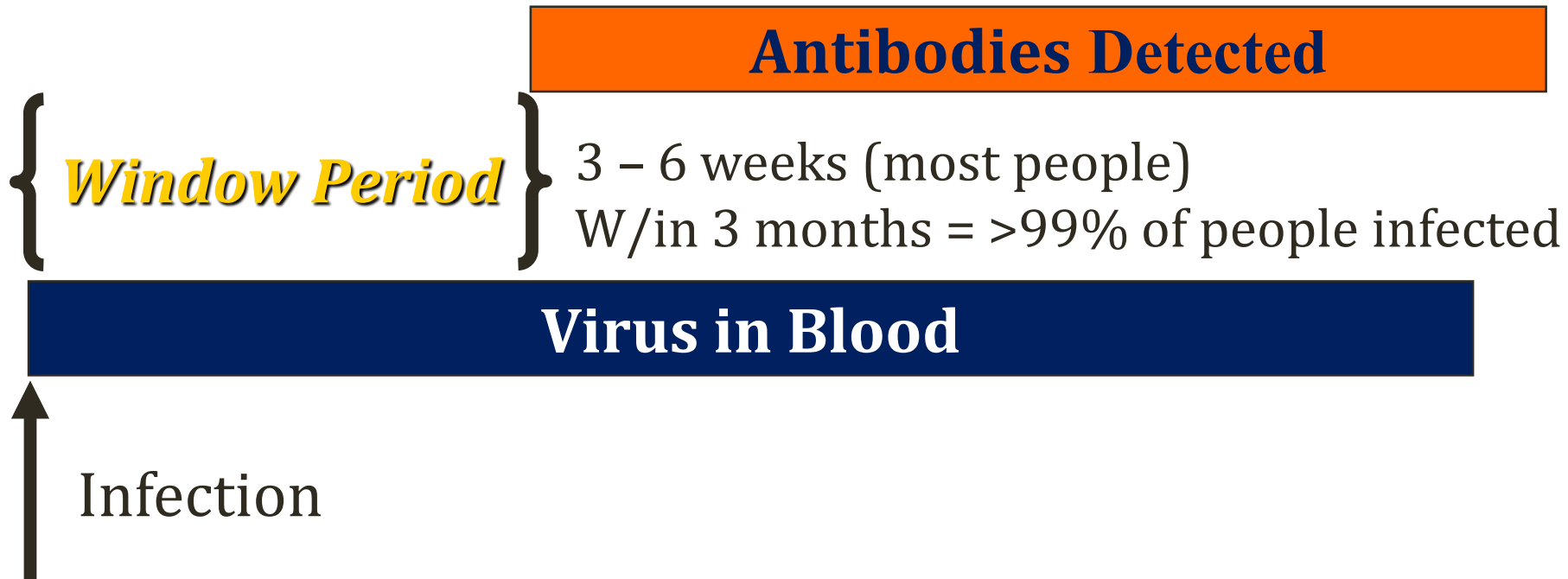


Sequence of Appearance of Laboratory Markers for HIV-1 Infection



Source: Pandori. Journal of Clinical Microbiology 2009.

Window Period



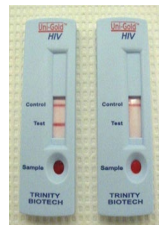
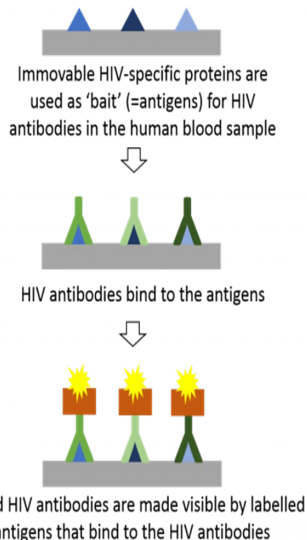
Diagnostic Tests for HIV Infection

	Assay Type	Indicated Uses
Antibody/ Antigen	ELISA / Western Blot P24-Ag/HIV-Ab Rapid HIV-Ab Rapid HIV-Ab/Ag	Screening and Diagnosis of acute and chronic HIV infection
Virus	PCR – DNA	Diagnosis of HIV exposed infants
	PCR – RNA	Baseline assessment and follow-up of viral load and/or Diagnosis of acute HIV infection

HIV Testing

3rd Generation

- Antigens bind HIV antibodies from patient sample



4th Generation

- Antigens bind HIV antibodies from patient sample and monoclonal antibodies detect p24 antigen
- Allows detection prior to seroconversion (Ab formation)



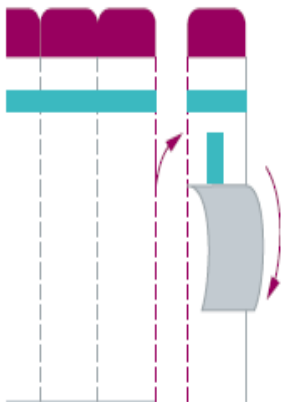
Alere Determine™ HIV-1/2 Ag/Ab Combo Fourth-Generation Rapid Test

Test in just 3 easy steps

1

Prepare Test

Tear one strip from the right and remove cover.

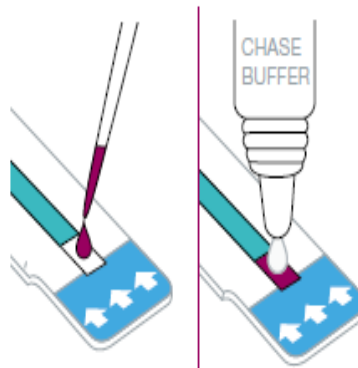


2

Add Sample

Add sample of whole blood, wait 1 minute and add chase buffer.

Also compatible with serum and plasma. Read full instructions prior to running test.



1 min

3

Read Results

Read the results – for both the HIV-1 p24 antigen (Ag) and HIV-1/2 antibodies (Ab) – in just 20 minutes.

The control line should appear for all results. If it does not appear, the results are invalid.

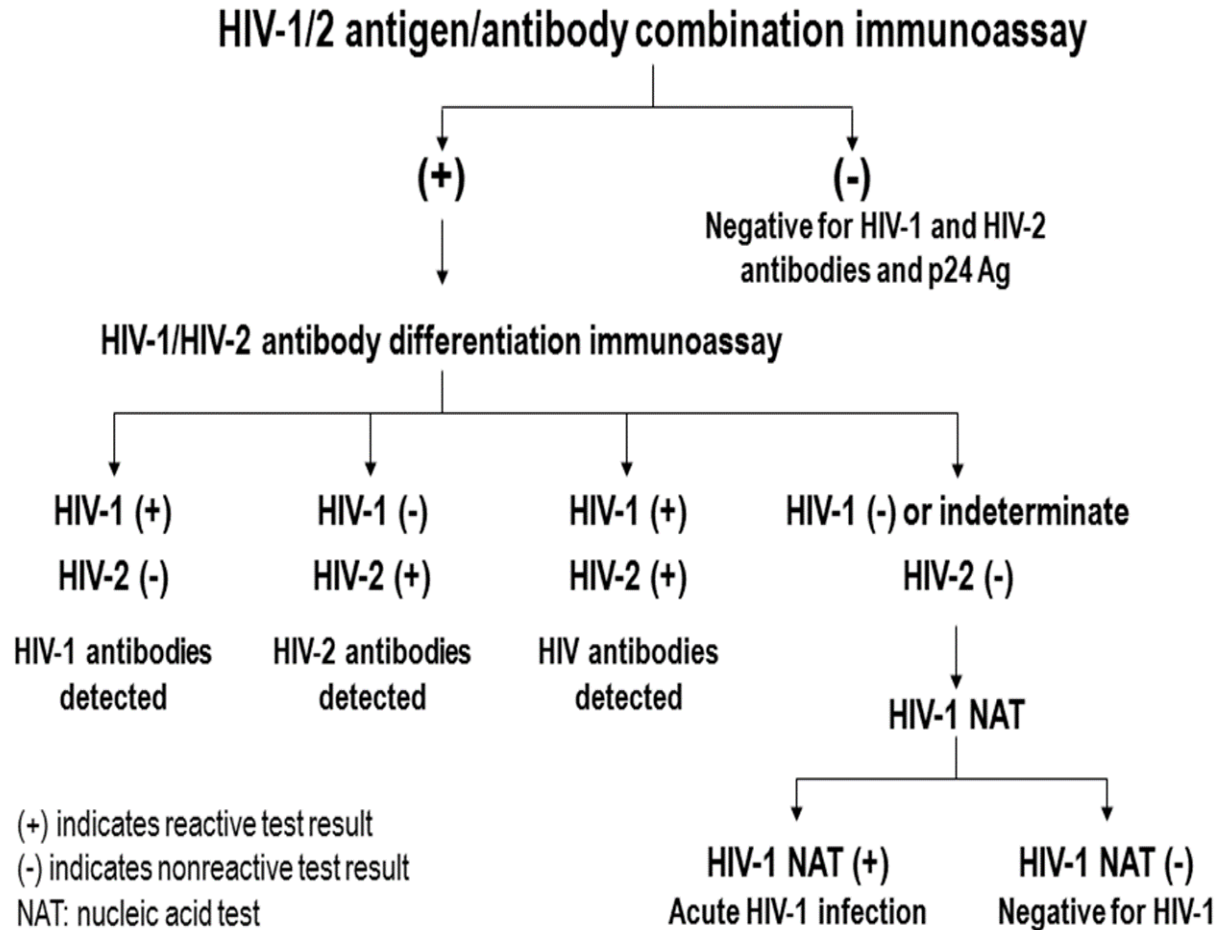
Line	Positive	Negative	Invalid
Control	Present	Present	Absent
Ag	Present	Absent	Present
Ab	Present	Absent	Present

Result key

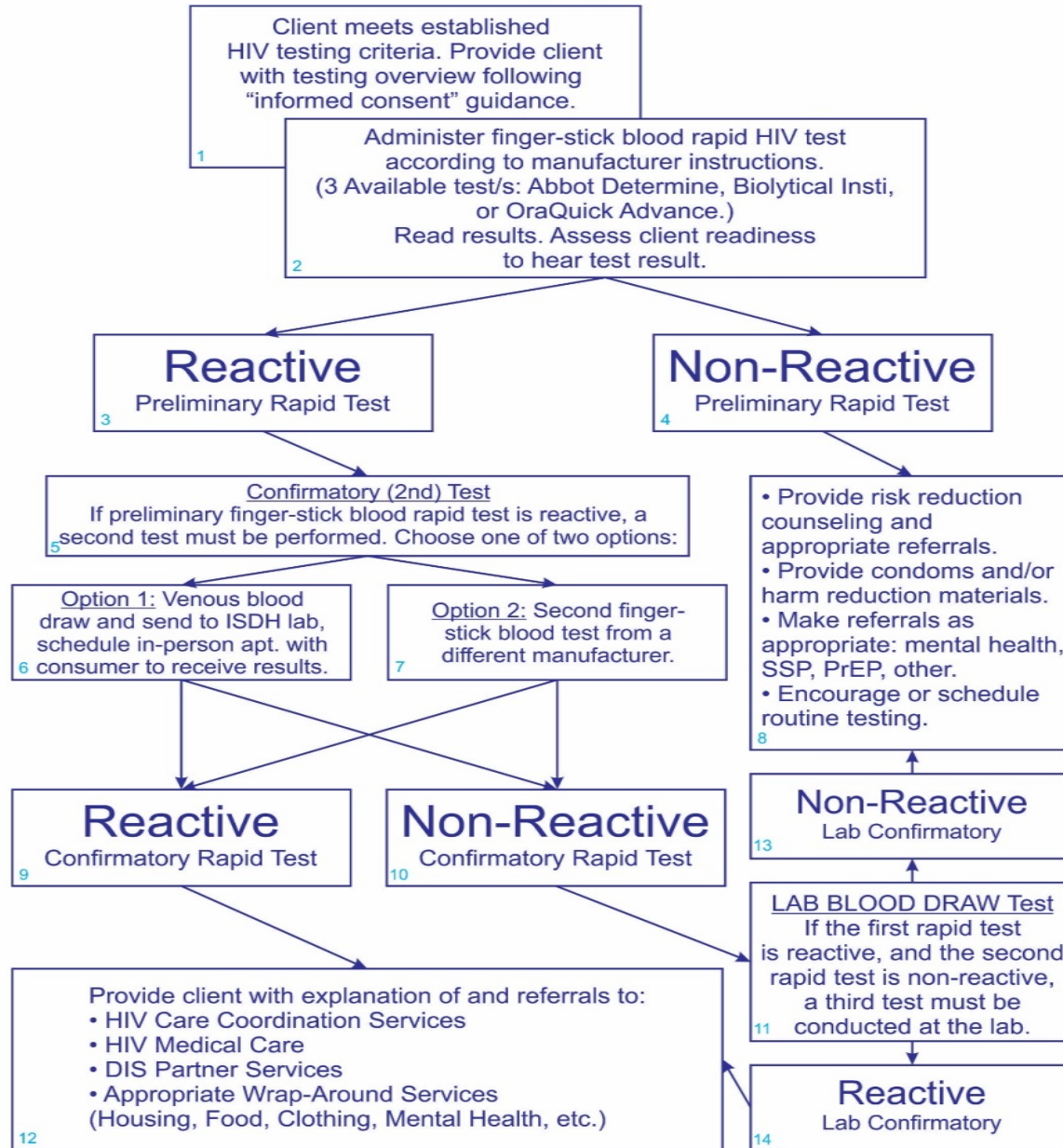


20 min

Algorithm for HIV Testing



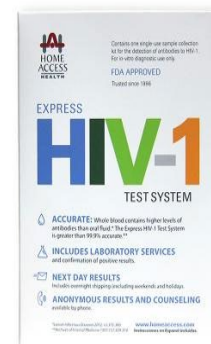
HIV Testing Algorithm



Home HIV Testing

- Home Access® HIV-1 Test System
 - Anonymous finger prick sample mailed to lab
 - Reactive tests reflexed to confirmatory test
 - Call for results next business day

- OraQuick® In-Home HIV Test
 - Oral fluid sample tested with home kit
 - Results available in 20 minutes
 - Reactive tests need confirmation
 - 1 in 5,000 - false positive
 - 1 in 12 - false negative



Source: FDA Approved 7/1996. http://www.homeaccess.com/HIV_Test.asp

FDA Approved 7/2012. <http://www.oraquick.com/what-is-oraquick/oraquick-in-home-hiv-test>

Communicating the Negative HIV Test Result

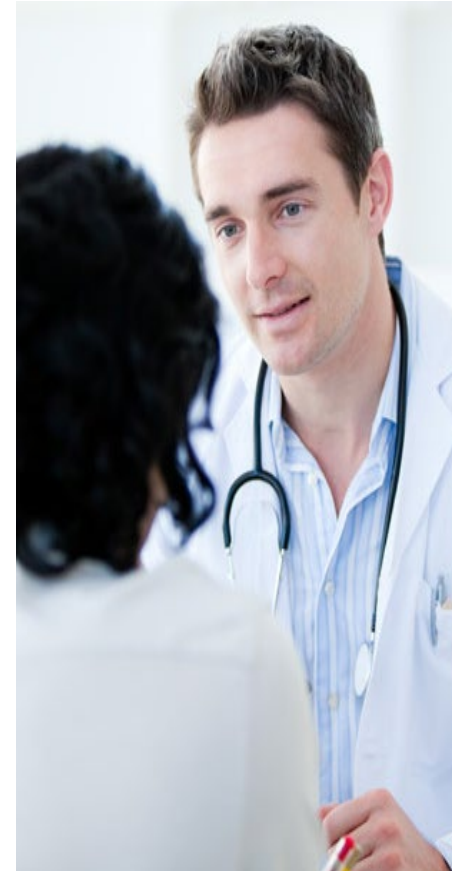
- Does not require direct personal contact
- Discuss how high-risk negative patients can remain HIV-negative
 - Periodic retesting for persons at high risk
 - Prevention measures



Source: Branson B, et al. Centers for Disease Control and Prevention. *Morbidity and Mortality Weekly Report. (MMWR)*. 2006;55(RR-14):1-17.

Communicating Positive HIV Test Result

- Provide result by direct personal contact
- Provide result confidentially
- Ensure patient understands test result
- Connect to services



Source: Branson B, et al. Centers for Disease Control and Prevention. *Morbidity and Mortality Weekly Report. (MMWR)*. 2006;55(RR-14):1-17

Current Indiana Testing Sites

Howard County Health Department

Hamilton County Health Department

Boone County Health Department

Madison County Health Department

Aspire Indiana

Eskenazi Health Centers

Open Door Health Services

**Planned Parenthood of Indiana and
Kentucky Incorporated**

Brothers United Incorporated

Damien Center Incorporated

**Marion County Public Health
Department**

Indianapolis Urban League

Step Up Incorporated

Indiana University Health LifeCare

Tippecanoe County Health Department

Henry County Health Department

Centerstone

NIMCHN Family Planning

Clarity Testing Clinic

Crisis Pregnancy Center

Damien Center

Source: <https://aidsvu.org/>

References

- Centers for Disease Control and Prevention and Association of Public Health Laboratories. *Laboratory Testing for the Diagnosis of HIV Infection: Updated Recommendations*. 6/2014. <http://stacks.cdc.gov/view/cdc/23447>
- Clinical and Laboratory Standards Institute. *Criteria for laboratory testing and diagnosis of human immunodeficiency virus infection*. Clinical and Laboratory Standards Institute 2011.
- Centers for Disease Control and Prevention and Association of Public Health Laboratories. *Planning and Implementing HIV Testing and Linkage Programs in Non-Clinical Settings: A Guide for Program Managers*. https://www.effectiveinterventions.org/Libraries/Public_Health_Strategies_Docs/HIVTestingImplementationGuide_Final.sflb.ashx
- Branson BM, et al. *Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings*. MMWR Recommendations and Reports. 2006;55(RR-14):1-17.
- American College of Emergency Physicians Board of Directors. HIV testing and screening in the emergency department. Ann Emerg Med. 2007;50:209.
- American College of Obstetrics and Gynecologists Committee Opinion Number 411. *Routine HIV screening*. Obstet Gynecol. 2008;114:401-403.
- www.uspreventiveservicestaskforce.org
- Geren et al. *Identification of Acute HIV Infection Using Fourth-Generation Testing in an Opt-Out Emergency Department Screening Program*. Annals of Emergency Medicine 2014.
- Myers JE, et al. *Rapid HIV self-testing: long in coming but opportunities beckon*. AIDS 2013;27(11):1687-1695.

References [2]

- CDC. [Prevalence of diagnosed and undiagnosed HIV Infection — United States, 2008–2012](#). *MMWR* 2015;64:657-662
- Centers for Disease Control and Prevention. *HIV Surveillance Report, 2014; vol. 26*. <http://www.cdc.gov/hiv/library/reports/surveillance/>. Published November 2015.
- Cohen MS, Chen YQ, McCauley M, et al. [Prevention of HIV-1 infection with early antiretroviral therapy](#). *N Engl J Med* 2011;365:493-505.
- Rodger AJ et al for the PARTNER study group. *Sexual activity without condoms and risk of HIV transmission in serodifferent couples when the HIV-positive partner is using suppressive antiretroviral therapy*. *JAMA* 2016;316(2):1-11. <http://jama.jamanetwork.com/article.aspx?doi=10.1001/jama.2016.5148>