

HIV Testing – The Facts about the Fraud Reference Sheet

Part One: Knowing is Beautiful | Part Two: Sex Crimes

References to Part 1 – HIV Testing – The Facts about the Fraud

[1] "68% to 89% of all repeatedly reactive ELISA tests are likely to represent false positive results...each year we might expected to find 175 to 209 truly antibody-positive donors **[in Minnesota]** and between 371 and 1701 falsely positive donors among those who have repeatedly positive screening tests."

Osterholm MT et al. Screening donated blood and plasma for HTLV-III antibody: facing more than one crisis?. N Engl J Med. 1985;312:1185-8.

[2] "In 1990, of 20.2 million HIV tests done in Russia only 112 were confirmed and about 20,000 were false positives, 1991 saw some 30,000 false positives out of 29.4 million tests, with only 66 confirmations...in 1991 alone some 8000 false-positive results were reported in pregnant women, with only 6 confirmations **[presumably with the Western Blot test]**"

Voevodin A. HIV screening in Russia. Lancet. 1992;339:1548.

<http://www.omsj.org/wp-content/uploads/HIV-Screening-in-Russia.pdf>

[3] "As the number of women being screened has increased, the proportion of false-positive and ambiguous (indeterminate) test results has increased and the positive predictive value (PPV) of the standard HIV test has decreased "

"False-positive ELISA **[antibody]** test results can be caused by alloantibodies resulting from transfusions, transplantation, or pregnancy, autoimmune disorders, malignancies, alcoholic liver disease, or for reasons that are unclear...The WB **[Western Blot antibody test]** is not used as a screening tool because...it yields an unacceptably high percentage of indeterminate results. "

Doran TI, Parra E. False-Positive and Indeterminate Human Immunodeficiency Virus Test Results in Pregnant Women. Arch Fam Med. 2000 Sep/Oct;9:924-9.

<http://www.omsj.org/wp-content/uploads/Pregant-Women-Test-Positive.pdf>

[4] "**[H]**uman or technical errors, other viruses and vaccines" (Infectious Disease Clinician of North America 7; 1993) **[fix this - it is a paraphrase]**

"False-positive HIV ELISAs have been observed with serum from patients with a variety of medical conditions unrelated to HIV infection **[but claims that these can be eliminated by use of Western Blot test or synthetic peptides in the test kits]**...False-positive HIV ELISAs **[also]** occur because of human or technical errors associated with doing the tests or because of antibodies that coincidentally cross-react with HIV or nonviral components in the tests...Notable causes of false-positive reactions have been anti-HLA-DR antibodies that sometimes occur in multiparous women and in multiply transfused patients. Likewise, antibodies to proteins of other viruses have been reported to cross-react with HIV determinants. False-positive HIV ELISAs also have been observed recently in persons who received vaccines for influenza and hepatitis B virus **[but again claims that these can be eliminated by Western Blot tests or use of synthetic peptides in tests]**"

Proffitt MR, Yen-Lieberman B. Laboratory diagnosis of human immunodeficiency virus infection. Inf Dis Clin North Am. 1993;7:203-19.

[5] "**[conditions associated with false positive ELISA are]** autoimmune disease, renal failure, cystic fibrosis, multiple pregnancies, blood transfusions, liver diseases, parenteral substance abuse, hemodialysis, or vaccinations for hepatitis B, rabies, or influenza...Causes of indeterminate WB **[Western Blot]** results include...nonspecific antibody reactions (eg, due to lymphoma, multiple sclerosis, injection drug use, liver disease, or autoimmune disorders). Also, there appear to be healthy individuals with antibodies that cross-react with specific HIV-1 peptides or recombinant antigens...

The Association of Public Health Laboratories now recommends that patients who have minimal positive results on WB, eg, p24 and gp160 only, or gp41 and gp160 only, be told that these patterns have been seen in persons who are not infected with HIV and that follow-up testing is required to determine actual infective status. The clinician must judge the test results within the context of other epidemiological and clinical information **[i.e. gay men and IV drug users are likely to be defined as positive based on this prejudice in the presence of ambiguous test results]**.

In the appropriate clinical setting, positive ELISA and WB test results in patients with a normal CD4 + count and CD4/ CD8 ratio and undetectable HIV-1 RNA should be questioned, repeated, or confirmed with supplemented testing. A false-positive serological test result may be supported by normal CD4 + count and CD4/CD8 ratio and undetectable HIV-1 RNA, but is ultimately established by subsequent serological testing and, especially, close follow-up. **[i.e. there is no test that can be absolutely relied on]** "

Mylonakis E et al. Report of a False-Positive HIV Test Result and the Potential Use of Additional Tests in Establishing HIV Serostatus. Arch Intern Med. 2000 Aug 14;160:2386-8. <http://www.omsj.org/wp-content/uploads/1023-FalsePositiveHIVTest.pdf>

[6] "We selected the 20 most strongly **[indeterminate or atypical Western Blot]** reactive samples for further evaluation...Atypical WB **[Western Blot]** patterns in 19 of 20 of our donors remained substantially the same over time...our data show that the presence of p24 alone in WB should not be regarded as a false positive without subsequent testing of the individual...All study donors had normal immune status...[2] donors were multiparous females **[multiple children]**, and one other probably had received a blood transfusion...we observed a large proportion of individuals who had either lived or worked on dairy farms (6/16) and frequently drank unpasteurized cows' milk (7/16)..undefined

autoimmune phenomena [**such as multiple pregnancies**], bovine exposure, or cross-reactivity with other human retroviruses could be possible causes for consistently reactive HIV immunologic assays "

Dock NL et al. Evaluation of atypical human immunodeficiency immunoblot reactivity in blood donors. Transfusion. 1988;28:412.

[7] "Inhabitants of certain regions may have cross-reactive antibodies to locally prevalent non-HIV retroviruses"

Mortimer PP. The AIDS virus and the HIV test. Med Int. 1988;56:2334-9. <http://www.omsj.org/wp-content/uploads/AIDSvirus-HIVTest1.pdf>

[8] (same as [5])

Mylonakis E et al. Report of a False-Positive HIV Test Result and the Potential Use of Additional Tests in Establishing HIV Serostatus. Arch Intern Med. 2000 Aug 14/28;160:2386-8.

<http://www.omsj.org/wp-content/uploads/1023-FalsePositiveHIVTest.pdf>

[9] (same as [3]) "False-positive ELISA [**antibody**] test results can be caused by alloantibodies resulting from transfusions, transplantation, or pregnancy, autoimmune disorders, malignancies, alcoholic liver disease, or for reasons that are unclear...The WB [**Western Blot antibody test**] is not used as a screening tool because...it yields an unacceptably high percentage of indeterminate results. "

Doran TI, Parra E. False-Positive and Indeterminate Human Immunodeficiency Virus Test Results in Pregnant Women. Arch Fam Med. 2000 Sep/Oct;9:924-9. <http://www.omsj.org/wp-content/uploads/Pregant-Women-Test-Positive.pdf>

[10] Vironostika HIV Elisa Test (2003) <http://omsj.org/wp-content/uploads/Vironostika-HIV-Test.pdf>

SUMMARY AND EXPLANATION OF THE TEST

"Published data indicate a strong correlation between the acquired immunodeficiency syndrome (AIDS) and a retrovirus referred to as Human Immunodeficiency Virus (HIV)."

"Currently, two HIV serotypes, designated as HIV-1 and HIV-2, have been identified based on the results of serologic and molecular studies. Both HIV serotypes have been isolated from patients with AIDS and AIDS-related complex (ARC), as well as from apparently healthy individuals at high risk for AIDS."

"A majority of patients who exhibit symptoms of AIDS or ARC have HIV specific antibodies in their blood. In addition, a significant proportion of apparently healthy individuals at increased risk for AIDS also contain HIV specific antibodies in their blood specimens."

"The Vironostika HIV-1 Plus O Microelisa System assay was designed to be highly sensitive for a spectrum of HIV-1 serotypes, including group O virus. As a result, nonspecific reactions may occasionally be seen in specimens from people who have prior pregnancy, blood transfusion, or exposure to human cells or media containing cultured HIV antigen."

"Because of these and other potential nonspecific reactions, specimens reactive with the Vironostika HIV-1 Plus O Microelisa System assay should be confirmed with a confirmatory test ,e.g., Western Blot."

"Reactive specimens upon initial testing with the Vironostika HIV-1 Plus O Microelisa System assay should be re-tested in duplicate."

"Reactivity in either or both of the duplicate tests indicates a potential for the presence of HIV-specific antibody."

"In individuals at increased risk of infection, such as homosexual men, hemophiliacs, or intravenous drug users, repeatedly reactive specimens are usually found to contain antibodies to HIV by additional, more specific tests."

"However, when the ELISA is used to screen populations with a low prevalence of HIV infections, nonspecific reactions may be more common than specific reaction."

"Information about prevalence of HIV infections in persons in various categories of risk, as well as clinical and public health guidelines, are available in each CDC publication of Morbidity and Mortality Weekly Reports."

"Although information about the degree of risk for HIV-1 infection and the degree of reactivity of the serum are of value in interpreting the test, a diagnosis should not be based only on this information."

"Therefore, it is appropriate to investigate repeatedly reactive specimens by additional, more specific tests, such as Western Blot, immunofluorescence, radioimmunoprecipitation, viral antigen based immunoassays, peptide ELISAs, or nucleic acid amplification assays."

"High-risk populations:

To assess the performance of the test with specimens collected from high-risk populations, fifteen hundred and fourteen (1,514) specimens were collected from four high-risk populations, which included prison inmates, STD (sexually transmitted diseases) clinic patients, inner city hospital emergency room patients, and HIV-1 outreach clinic patients."

[11] "A dramatically lower number of Swazi teenage girls are being infected with HIV than was previously estimated...The findings in the report, 'A Baseline Study on HIV Risk Factors,' commissioned by the UN Children's fund (UNICEF) are derived from interviews and blood tests of over 1,000 Swazis in two rural areas and revealed only six percent of girls aged from 15 to 19 were found to be HIV-positive....The study was prompted by the results of the government's 2002 sero-surveillance study, which estimated that 32.5 [**were**] HIV-positive.

[Swaziland UNICEF representative, Dr. Alan Brody, said,] "We were baffled by the contradiction between the statistics and what we saw

happening on the ground.

"The problems is that all the sero-surveillance data came from pregnant women, and estimates for other demographics was based on that."
(PLUS News, August, 2004) <http://reducetheburden.org/?p=1362>

[12] 2004 Boston Globe reported that "the current estimate of 40 million people living with the AIDS virus worldwide is inflated by 25 percent to 50 percent."

<http://reducetheburden.org/?p=185>

Estimates on HIV called too high
New data cut rates for many nations
By John Donnelly, Globe Staff | June 20, 2004

PRETORIA — Estimates of the number of people with the AIDS virus have been dramatically overstated in many countries because of errors in statistical models and a possible undetected decline in the pandemic, according to new data and specialists on the disease.

In many nations, analysts are cutting the estimates of HIV prevalence by half or more.

Rwanda, for instance, a new United Nations estimate due out next month will put HIV prevalence at about 5 percent, according to Rwandan officials, down from more than 11 percent four years ago. In Haiti, a recent unpublished study by the Centers for Disease Control and Prevention has found HIV prevalence was less than 3 percent, compared with the UN's most recent estimate of 6 percent. And the numbers in India are coming under increasing scrutiny because surveys in AIDS hot spots are indicating a prevalence rate that is much lower than the national average.

Even with lower estimates, health specialists agree that AIDS remains the most dangerous pandemic in the developing world. In particular, it threatens to ravage societies in southern Africa, and throughout the continent the disease has killed millions in the prime of their lives.

Several AIDS specialists said they think the current estimate of 40 million people living with the AIDS virus worldwide is inflated by 25 percent to 50 percent, based on a wide spectrum of household surveys in nearly a dozen countries. That would go against the grain of years of assertions by UNAIDS that the disease is relentlessly on the rise.

A significant downward revision in AIDS and HIV numbers calls into question many of the lessons on fighting AIDS that are based on prior estimates. It also is likely to affect future budgets and cause many countries to consider revising strategies on how to prevent and treat the disease.

"It is fundamental that we have accurate information of what we're up against," said Robert R. Redfield, cofounder of the University of Maryland's Institute of Human Virology and a leading AIDS specialist. "If you are overestimating the epidemic, you may attribute positive impacts to things that have nothing to do with it."

[...]

The tools today are much more refined but still based on a long list of assumptions.

More than a decade ago, AIDS researchers in sub-Saharan Africa found that HIV tests on blood samples from pregnant women at prenatal clinics provided a good indicator of HIV prevalence among adults aged 15 to 49 in countries with high rates; early household surveys confirmed the finding.

But the surveys were limited at first to a few sites in countries. "We were talking about four or five urban sites and one or two rural sites, and extrapolating that to the whole country. You can see what potential inaccuracies there can be with this crude methodology," said Chin, who now is an independent AIDS analyst and criticizes UN estimates as overstated.

Other unknowns contribute to potential errors. One is estimating a country's population; the estimates for Nigeria, for instance, range from 120 million to 160 million people, but a census of the country has not been completed in more than half a century. Another is that most countries do not collect data on deaths.

[...]

In the late 1980s and early 1990s, HIV prevalence in adults aged 15 to 49 in Uganda was estimated as high as 30 percent; now HIV prevalence is estimated at 5 percent. But now many no longer believe the 30 percent figure, raising questions about the true impact of Uganda's much-touted prevention program. Said Ghys: "If we recast our estimates, it wasn't 30 percent, it was maybe 22 or something."

Earlier this year, the US government announced its first substantial grants in President Bush's multibillion-dollar plan to fight AIDS. The news release cited a 15 percent HIV prevalence rate in Kenya and a 6 percent rate in Haiti, even though US-funded surveys in both countries had recently concluded that the rate was at least half those figures. http://www.boston.com/news/world/articles/2004/06/20/estimates_on_hiv_called_too_high/

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[13] "A common misperception is that, if a serological [**antibody**] assay is based on recombinant antigens, then results obtained by that assay must, by definition, be completely accurate. In fact, however, certain types of sera...known to generate false-positive results in conventional serological assays can still give false-positive reactions in recombinant antigen-based assays...false-positive reactions have been observed with every single HIV-1 protein, recombinant or authentic. "

Ng V. Serological diagnosis with recombinant peptides/proteins. Clin Chem. 1991;37(10):1667-8. <http://www.omsj.org/wp-content/uploads/469-SerologicalDiagnosisRecombinantPolypeptides1.pdf>

[14] "Diagnosis of HIV infection is based almost entirely on detection of antibodies to HIV, but there can be misleading cross-reactions between HIV-1 antigens and antibodies formed against other antigens, and these may lead to false-positive reactions. Thus, it may be impossible to relate an antibody response specifically to HIV-1 infection. "

Mortimer PP. The AIDS virus and the HIV test. Med Int. 1988;56:2334-9. <http://www.omsj.org/wp-content/uploads/AIDSVirus-HIVTest1.pdf>

[15] "A confirmed positive test [i.e. one or two ELISA tests, followed by a Western Blot] indicates that a person has been exposed to the virus and has mounted an immunologic response (serum antibodies). However, this test does not indicate whether the person currently harbors the virus "

Zhang Z-Q et al. Sexual Transmission and Propagation of SIV and HIV in Resting and Activated CD4+ T Cells. Science. 1999 Nov 12;286 (5443):1353-7.

[16] "Establishing the cutoff value to define a positive test result from a negative one is somewhat arbitrary." (CDC-EIS, "Screening For HIV," 2003)

CDC instruction/quiz for HIV test interpretation

<http://www.omsj.org/wp-content/uploads/CDC-Instruction-for-Test-Interpretation.pdf>

"Establishing the cutoff value to define a positive test result from a negative one is somewhat arbitrary. Suppose that the test manufacturer initially considered that optical density ratios greater than "A" on the above figure would be called positive.

Where might the blood bank director and the head of drug treatment want the cutoff point to be for each program? Who would probably want a lower cutoff value?"

[17] The University of Vermont Medical School agrees: "Where a cutoff is drawn to determine a diagnostic test result may be somewhat arbitrary...Where would the director of the Blood Bank who is screening donated blood for HIV antibody want to put the cut-off?...Where would an investigator enrolling high-risk patients in a clinical trial for an experimental, potentially toxic antiretroviral draw the cutoff?" (University of Vermont School of Medicine teaching module: Diagnostic Testing for HIV Infection) **[Find Page and Link]**

University of Vermont School of Medicine – Department of Genetics, Epidemiology, Ethics and Public Health –

"[I]f one examines the ODs for a large group of samples from patients with and without HIV infection you can see that there is some overlap in their IEA results if a value of A is used for the cutoff: Where a cutoff is drawn to determine a diagnostic test result may be somewhat arbitrary."

"Where would the director of the Blood Bank who is screening donated blood for HIV antibody want to put the cut-off? Where would an investigator enrolling high-risk patients in a clinical trial for an experimental, potentially toxic antiretroviral draw the cutoff?"

http://cats.med.uvm.edu/cats_teachingmod/gee/modules/

[18] "A 1995 study comparing four major brands of HIV tests found that they all had different cut-off points, and as a result, gave different test results for the same sample: "[C]ut-off ratios do not correlate for any of the investigated ELISA pairs," and one test's cut-off point had "no predictive value" for any other. (INCQS-DSH, Brazil 1995). <http://omsj.org/wp-content/uploads/Testing-and-Confirmation-Brasil.pdf>

Results

The signal/cut-off ratio in any assay has no predictive value for the signal/cut-off ratio in any other assay, since the signal/cut-off ratios do not correlate for any of the investigated ELISA pairs (Figure 1). On the other hand, all sera with a signal/cut-off ratio greater than 2.0 for all ELISA pairs were also positive in Western blot. This fact was used to develop a simplified confirmation strategy for HIV testing (Figure 2).

[19] "Most patients (68 to 89%) from low risk groups (prevalence of 0.1% or less) who show reactivity on screening tests will have false-positive results...The predictive value of a positive ELISA varies from 2% to 99%...One notable association with false positive ELISA reactivity in some commercial preparations has been patients with anti-HLA-DR4 antibodies, most often multiparous **[having experienced one or more births]** or multiply transfused patients...the Western blot method lacks standardization, is cumbersome, and is subjective in interpretation of banding patterns. "

Steckelberg JM, Cockerill F. Serologic testing for human immunodeficiency virus antibodies. Mayo Clin Proc. 1988;63:373-9.

[20] A 1988 study in the Journal of the American Medical Association reported that 19 different labs, testing one blood sample, got 19 different Western Blot results. Serological Diagnosis of Human Immunodeficiency Virus Infection by Western Blot Testing, The Consortium for Retrovirus Serology Standardization; (JAMA. 1988;260(5):674-679).

<http://www.omsj.org/wp-content/uploads/Consortium-Western-Blot-19-labs.pdf>

<http://www.omsj.org/wp-content/uploads/Western-Blot-19-labs-19-results-1988.jpg>

[21] A 1993 review in Bio/Technology reported that the FDA, the CDC/Department of Defense and the Red Cross all interpret WB's differently, and further noted, "All the other major USA laboratories for HIV testing have their own criteria." (Bio/Technology, June 1993) <http://www.virusmyth.com/aids/hiv/epwbtest.htm>

All the other major USA laboratories for HIV testing have their own criteria. For all laboratories, a negative result requires the absence of any and all bands including bands which do not represent "HIV proteins". All other patterns which do not satisfy a given laboratory's criteria for a positive or negative test are regarded as WBI by that laboratory.

Thus, in the scientific literature, no strips have been published of a standard positive WB. Fig.0 is reproduced from the instruction manual of a WB kit manufacturer, Bio-Rad. Although given as "Examples of a typical reactive patient serum sample and reaction with a strong, weak and non-reactive control" it is also stated, "This example shows typical reactive patterns only, and is not to be used as a reference for comparisons with results from unknown serum samples... Patient samples may show varying degrees of reactivity with different proteins, thus showing different band development patterns... Each laboratory performing Western Blot testing should develop its own criteria for band interpretation. Alternatively, band interpretation may be left to the clinician".

[22] An early review of the technology in the 1991 Journal of AIDS reported that "a true positive PCR test cannot be distinguished from a false positive." (J.AIDS, 1991)

"... there is no "gold standard" laboratory test that defines the true infection status, and a true positive PCR test cannot be distinguished from a false positive.... 8.6% of the [seronegative] specimens showed weak reactivity.... in a previous study of seronegative regularly repeating blood donors ... we observed a ... somewhat higher rate of nonnegative [positive] PCRs (38 of 246, or 15%)."

(Sheppard, HW, et al. JAIDS 1991; 4:819-23.)

[23] "This proficiency study of PCR detection of HIV-1 DNA in serum identified a disturbingly high rate of nonspecific positivity with a widely employed gag primer pair system. In fact, the overall rate of positivity was not significantly different for serum specimens from seropositive patients and seronegative control donors (26% versus 18%) "

Busch MP et al. Poor sensitivity, specificity, and reproducibility of detection of HIV-1 DNA in serum by polymerase chain reaction (PCR). J Acquir Immune Defic Syndr. 1992;5(9):872-879.

[24] "[Table 2 shows that the results for identical material sent to multiple laboratories provided viral load results varying from 3,849 to 1,291,635 (Roche Amplicor HIV-1 Monitor), from 63,750 to 205,500 (Bayer HIV-1 3.0 RNA) and from 89,000 to 360,000 (Organon Teknika NucliSens)] "

Guidelines for Laboratory Test Result Reporting of Human Immunodeficiency Virus Type 1 Ribonucleic Acid Determination. MMWR. 2001 Nov 16;50(RR20):1-12. <http://www.omsj.org/wp-content/uploads/CDC-PCR-Review.pdf>

[25] "56 clinically asymptomatic HIV-1-infected individuals [from Ethiopia], 31 (55%) of whom were also infected with helminths [intestinal worms], were studied... At baseline, HIV plasma VL [viral load] was strongly correlated to the number of eggs excreted and was higher in individuals infected with more than one helminth. After treatment of helminths, the 6-month change in HIV plasma VL was significantly different between the successfully treated group and the persistently helminth-positive group. "

Wolday D et al. Treatment of Intestinal Worms Is Associated With Decreased HIV Plasma Viral Load. J Acquir Immune Defic Syndr. 2002 Sep 1;31:56-62.

<http://journals.lww.com/jaids/> | <http://www.omsj.org/>

[26] "The AMPLICOR HIV-1 MONITOR Test is an in vitro nucleic acid amplification test for the quantitation of Human Immunodeficiency Virus Type 1 (HIV-1) RNA in human plasma... [It] is not intended to be used as a screening test for HIV or as a diagnostic test to confirm the presence of HIV infection... Quantitative culture has limited utility for monitoring virus levels in infected individuals since only a small fraction of virus particles is infectious in vitro. Infectious virus is often undetectable in asymptomatic individuals... The clinical specificity of the... test was determined by analysis of 495 anti-HIV-1 negative blood donors. None of these specimens was reactive... Assuming [!] a zero prevalence of HIV-1 infection in the seronegative blood donors, the specificity of the test was 100% "

Amplicor HIV-1 Monitor Test. Roche. 1996. <http://www.omsj.org/wp-content/uploads/Roche-Amplicor-PCR.pdf>

[27] "Evaluation of a new test requires an established or known standard for comparison. At this point, however, no established standard exists for identifying HTLV-III [HIV] infection in asymptomatic people. Current culture methods for [HIV] identify virus in only 36% to 85% of persons with AIDS or related conditions and cannot be used as an absolute standard for HTLV-III/LAV [HIV] infection. For this reason, we defined [note: not 'proved'] specimens positive on Western blot or culture as positive for infection with [HIV]."

Ward JW et al. Laboratory and epidemiologic evaluation of an enzyme immunoassay for antibodies to HTLV-III. JAMA. 1986 Jul 18;256(3):357-61.

[28] "The meaning of positive tests will depend on the joint [ELISA/WB] false positive rate. Because we lack a gold standard, we do not know what that rate is now. We cannot know what it will be in a large-scale screening program."

Meyer KB, Pauker SG. Screening for HIV: can we afford the false positive rate?. N Engl J Med. 1987;317(4):238-41.

[29] "The evaluation of the sensitivity and specificity of PCR for the diagnosis of HIV infection in infants is particularly difficult because there is

no reference or 'gold standard' test that determines unequivocally the true infection status of the patient [**but antibody tests, generally agreed to be inapplicable to infants, hardly qualify as a 'gold standard', so the same problem occurs with all people being tested for HIV**]...a single positive PCR test result does not provide definitive evidence of HIV infection in infants...This finding holds even for more recent studies published after PCR technology had matured "

Owens DK et al. *A Meta-analytic Evaluation of the Polymerase Chain Reaction for the Diagnosis of HIV Infection in Infants*. JAMA. 1996 May 1;275(17):1342-1348. <http://omsj.org/wp-content/uploads/1500-PCR-Infants-Analysis.pdf>

[30] "At present there is no recognized standard for establishing the presence or absence of HIV antibody in human blood." (Abbot Laboratories HIV Elisa Test 1997)

Abbott Laboratories 1997 HIVABtm HIV-1 EIA

"At present there is no recognized standard for establishing the presence or absence of HIV-1 antibody in human blood."

"A person who has antibodies to HIV-1 is presumed to be infected with the virus ..."

"... non-specific reactions may be seen in samples from some people,"

"... the degree of risk for HIV-1 infection of the person studied ... may be of value in interpreting the test ..."

"The risk of an asymptomatic person with a repeatedly reactive serum sample developing AIDS or an AIDS-related condition is not known."

Abbot Labs 2006 HIV Test <http://www.omsj.org/wp-content/uploads/Abbott-Labs.pdf>

"At present there is no recognized standard for establishing the presence or absence of antibodies to HIV-1 and HIV-2 in human blood."

"The risk of an asymptomatic [**not chronically ill**] person with a repeatedly reactive [**positive**] serum sample developing AIDS or an AIDS-related condition is not known"

"Clinical studies continue to clarify and refine the interpretation and medical significance of the presence of antibodies to HIV."

"AIDS and AIDS-related conditions are clinical syndromes and their diagnosis can only be established clinically. EIA testing [**that's this test**] cannot be used to diagnose AIDS, even if the recommended investigation of reactive specimens suggest that the antibodies to HIV are present."

"Sensitivity for HIV-1 antibodies was computed based on the clinical diagnosis of Aids."

[31] "Antibodies directed to the env-encoded surface glyco-protein gp160 [**of HIV**] were detected in the cervicovaginal secretions of a small proportion of HIV-seronegative sex workers in Abidjan. In 2.9 to 12.3% of these women, depending on the test used, the anti-HIV antibodies were present in vaginal fluids that were free of contaminating semen. Since there is no established gold standard test, it is unclear which of these two proportions is the best estimate of the real prevalence rate of cervicovaginal anti-HIV antibodies in the absence of contaminating semen in HIV seronegative sex workers..."

The 25 HIV-1-seronegative sex workers with anti- HIV antibodies in their semen-free cervicovaginal secretions by both in-house ELISA and Seradyn Sentinel HIV-1 Urine EIA [**ELISA**] had no evidence of HIV-1 RNA in plasma. It is therefore unlikely that these antibodies are part of a primary HIV infection, although these women were not followed up...In the present study, increased sexual exposure was not associated with the presence of HIV-antibodies in cervicovaginal secretions, as measured by either of the two tests. "

Ghys PD et al. *Cervicovaginal anti-HIV antibodies in HIV-seronegative female sex workers in Abidjan, Cote d'Ivoire*. AIDS. 2000;14:2603-8. <http://www.omsj.org/wp-content/uploads/1128-CervicovaginalAntibodies.pdf>

[32] In 1993, the CDC added "Idiopathic CD4 Lymphocytopenia" to the AIDS category. What does it mean? Non-HIV AIDS.

<http://www.autoimmune.com/Non-HIVAIDSGen.html>

<http://content.nejm.org/cgi/content/full/328/6/373>

<http://content.nejm.org/cgi/content/full/328/6/393>

<http://nejm.highwire.org/cgi/content/full/328/6/380>

[33] In 1993, the CDC also made "no-illness AIDS" a category. If you tested positive, but weren't sick, you could be given an AIDS diagnosis. By 1997, the healthy AIDS group accounted for 2/3rds of all U.S. AIDS patients. (That's also the last year they reported those numbers, CDC Year End Addition, 1997).

<http://www.cdc.gov/mmwr/preview/mmwrhtml/00018871.htm>

<http://www.thebody.com/content/art14002.html>

<http://www.virusmyth.com/aids/hiv/gkaid.htm>

Centers for Disease Control and Prevention. 1993 revised classification system for HIV infection and expanded surveillance case definition for AIDS among adolescents and adults. Morb Mort Weekly Rep 1992,41(No. RR17):1-19.

Centers for Disease Control and Prevention. U.S. HIV and AIDS cases reported through December 1997, Year-end edition. HIV AIDS Surveillance Report 1997

<http://www.omsj.org/wp-content/uploads/CDC-19971.pdf>

<http://www.omsj.org/wp-content/uploads/Figure-3-CDC-graph.jpg>

<http://www.omsj.org/wp-content/uploads/61-percent-of-cases-by-new-definition-1997.png>

[34] "Our attention is now focused on the considerably large number of the seronegative group (135/227, 59%) who were clinically diagnosed as having AIDS. All the patients had three major signs [from the WHO's so-called 'Bangui' definition of AIDS]: weight loss, prolonged diarrhoea, and chronic fever. Many of them also had other AIDS-associated signs, such as lymphadenopathy, tuberculosis, dermatological diseases, and neurological disorders."

Hishida O et al. Clinically diagnosed AIDS cases without evident association with HIV type 1 and 2 infections in Ghana . Lancet. 1992 Oct 17;340(8825):971-2.

[35] 2215 out of 4383 (50.0%) African AIDS patients from Abidjan, Ivory Coast, Lusaka, Zambia, and Kinshasa, Zaire, were HIV-antibody negative.

Br. Med. J. 302, 1206, 1991 1991

For debate. AIDS surveillance in Africa: a reappraisal of case definitions

End Part 1

Part 2

[1] As the CDC Says, "HIV tests look for the presence of HIV antibodies; they do not test for the virus itself."

But, they add: "The HIV-antibody test is the only way to tell if you are infected. You cannot tell by looking at someone if he or she carries HIV." (CDC: National HIV Testing Resources; "HIV Test FAQ" 2005)

What is an HIV antibody test?

When HIV enters the body, it begins to attack certain white blood cells called T4 lymphocyte cells (helper cells). Your doctor may also call them CD4 cells. The immune system then produces antibodies to fight off the infection. Although these antibodies are ineffective in destroying HIV, their presence is used to confirm HIV infection. Therefore, the presence of antibodies to HIV result from HIV infection. HIV tests look for the presence of HIV antibodies; they do not test for the virus itself.

What blood tests detect the presence of HIV?

HIV testing consists of an initial screening with two types of tests commonly used to detect HIV infection. The most commonly used initial test is an enzyme immune assay (EIA) or the enzyme-linked immunosorbent assay (ELISA). If EIA test results show a reaction, the test is repeated on the same blood sample. If the sample is repeatedly the same result or either duplicate test is reactive, the results are "confirmed" using a second test such as the Western blot. This more specific (and more expensive) test can tell the difference between HIV antibodies and other antibodies that can react to the EIA and cause false positive results. False positive EIA results are uncommon, but can occur. A person is considered infected following a repeatedly reactive result from the EIA, confirmed by the Western blot test.

[...]

How do I know if I am infected?

The HIV-antibody test is the only way to tell if you are infected. You cannot tell by looking at someone if he or she carries HIV. Someone can look and feel perfectly healthy and still be infected. In fact, an estimated one-third of those who are HIV positive do not know it. Neither do their sex partners.

When HIV enters the bloodstream, it begins to attack certain white blood cells called T4 lymphocyte cells (helper cells). The immune system then produces antibodies to fight off the infection. Therefore, the presence of antibodies to HIV result from HIV infection. Testing can tell you whether or not you have developed antibodies to HIV.

[2] From the University of Michigan Health Service:

"Although the HIV tests are very precise, sometimes the test result can be positive even though you do not have HIV infection (this is called a false-positive test)." ("HIV Antibody Tests" McKesson Health Solutions LLC. 2004)

This information is not a tool for self-diagnosis or a substitute for medical treatment. You should speak to your physician or make an appointment to be seen if you have questions or concerns about this information or your medical condition.

HIV-1 Antibody Test (ELISA and Western Blot)

What is the HIV-1 antibody test?

The HIV-1 antibody test checks your blood for antibodies to the most common type of the human immunodeficiency virus (HIV-1). HIV is the virus that causes AIDS (acquired immunodeficiency syndrome), a life-threatening disease. If you are infected with HIV, your immune system makes a type of protein called an antibody to try to destroy or get rid of the virus.

There are different HIV antibody tests. One test is the ELISA (enzyme-linked immunosorbent assay). If the ELISA test is positive, a second test called a Western blot is done to confirm the result. The Western blot takes longer to perform and is more expensive than the ELISA test, but it is more precise.

There is no way to know, without testing, if you are infected with HIV. Learning whether you are HIV-positive will help you protect yourself and your loved ones.

Why is this test done?

This test is done to see if you are infected with the virus that causes AIDS. This test is also used to screen donated blood for HIV.

How do I prepare for this test?

It is important to get counseling before you have the HIV test. This can help to identify things you do that may increase your risk for HIV infection.

How is the test done?

Usually a small amount of blood is taken from your finger or your arm. Blood from a finger prick is put in a vial of solution and tested with a dipstick. Blood taken from your arm with a needle will be sent to a lab for testing. In some hospitals and facilities a new, faster test is now available. A sample for testing is obtained by swabbing your gums with a cotton swab rather than drawing blood.

Having the test takes just a few minutes of your time. There is no risk of getting AIDS, hepatitis, or any other blood-borne disease from this test.

Home test kits have become available through the Internet. However, some of these tests have been shown to be inaccurate. The only HIV test approved by the FDA is the Home Access HIV testing kit. When you do this home test, first you register by phone. Then you collect a sample of blood and mail the sample to the lab for testing. Toll-free telephone support is available 24 hours a day for test and result questions. You should see a doctor to confirm any positive results from a home test.

How will I get the test result?

Ask your health care provider when and how you will get the result of your test. Results from the quick HIV test may be available in 30 minutes or less. You may get results from other HIV tests in 2 to 10 days.

The test results are confidential. Confidential testing ensures that your results will be guarded with care. Positive results are reported by name to the health department for 2 reasons. The first reason is to provide help with partner notification and referral to care. The second is to provide reports to the federal government so there can be a count of how many people have HIV. The count helps determine how much money each state needs for HIV care.

Some centers offer anonymous testing. Anonymous testing does not use your name at all. Positive results are reported without any personal identifiers. Some people feel this better protects the civil rights of people who test positive for HIV.

What do the test results mean?

In general, a positive HIV test means that you are infected with HIV, and a negative test means that you are not infected with HIV. The test does not directly measure or identify the HIV virus in the blood, however. Instead it measures antibodies that the body makes in response to the viral infection. Because it takes at least a few weeks for the antibodies to appear in the blood after infection by the virus, it is possible to have a negative test if you have been recently infected (this is called a false-negative test). In this case, the test will become positive if it is repeated several weeks or months later. If you have a negative test result but you are in a high-risk group, you may need to have another test 3 to 6 months later.

Although the HIV tests are very precise, sometimes the test result can be positive even though you do not have HIV infection (this is called a false-positive test). For this reason, when a positive result occurs, labs automatically perform a second HIV test (Western blot) to check the result.

What if my test result is positive?

If your first test for HIV is positive, you should have more blood tests to confirm the results. If repeat tests are positive, you should seek medical care, even if you have no symptoms. In some cases you may need to start taking medicine to try to stop the HIV infection from developing into AIDS. You need to discuss the test results with your health care provider or an HIV counselor as soon as possible to protect your health and the health of people you love.

Written by Jonathon Evans, MD.

Published by McKesson Health Solutions LLC.

This content is reviewed periodically and is subject to change as new health information becomes available. The information is intended to inform and educate and is not a replacement for medical evaluation, advice, diagnosis or treatment by a healthcare professional.

Adult Health Advisor 2004.1 Index

Adult Health Advisor 2004.1 Credits

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University of Michigan

HYPERLINK "http://www.med.umich.edu/1libr/aha/aha_hivantib_crs.htm" http://www.med.umich.edu/1libr/aha/aha_hivantib_crs.htm

[3] "In 1990, of 20.2 million HIV tests done in Russia only 112 were confirmed and about 20,000 were false positives, 1991 saw some 30,000 false positives out of 29.4 million tests, with only 66 confirmations...in 1991 alone some 8000 false-positive results were reported in pregnant women, with only 6 confirmations [**presumably with the Western Blot test**]"

Voevodin A. HIV screening in Russia. Lancet. 1992;339:1548.

<http://www.omsj.org/wp-content/uploads/HIV-Screening-in-Russia.pdf>

[4] "At present there is no recognized standard for establishing the presence or absence of HIV antibody in human blood."- (Abbott Laboratories HIV Elisa Test. 1997). [**see Abbott reference top**]

[5] "[W]hat constitutes a positive Western blot test has not been standardized (various agencies use different reagents, testing methods, and test-interpretation criteria)." ("AIDS Counseling for Low-Risk Clients"; Max Plank Institute/Aids Care, 10, 1998)
<http://omsj.org/wp-content/uploads/Max-Planck-Institute-HIV-Counseling-for-Low-Risk-Clients.pdf>
From the Max Planck Institute, Germany, 1998.

HIV Testing for Low-Risk Clients

Sensitivity and Specificity

In Germany, as in most Western countries, HIV testing typically involves the following sequence. If the first test, ELISA, is negative, the client is notified that he or she is HIV-negative. If positive, at least one more ELISA (preferably from a different manufacturer) is conducted. If the result is again positive, then the more expensive and time-consuming Western blot test is performed. If the Western blot is also positive, then the client is notified of being HIV-positive, and sometimes a second blood sample is also tested. Thus, two errors can occur. First, a client who is infected is notified that he is HIV-negative. The probability of this error (false negative) is the complement of the sensitivity of the ELISA test. The estimates for the sensitivity typically range between 98% and 99.8% (Eberle et al., 1988; George & Schochetman, 1994; Schwartz et al., 1990; Spielberg et al., 1989; Tu et al., 1992; Wilber, 1991).

Second, a client who is not infected is notified of being HIV-positive. The probability of this second error (false positive) is the complement of the combined specificity of the ELISA and Western blot tests. Although all surveys agree that false positives do occur, the quantitative estimates vary widely.[3] This is in part due to the fact that what constitutes a positive Western blot test has not been standardized (various agencies use different reagents, testing methods, and test-interpretation criteria [Stine, 1996, p. 335]), that the ELISAs and the Western blot tests are not independent (that is, one cannot simply multiply the individual false positive rates of the tests to calculate the combined false positive rate, Spielberg et al., 1989), and that the higher the prevalence in a group is, the lower the specificity seems to be for this group (Wittkowski, 1989).

For instance, 20 samples – half with HIV antibodies and half without (the laboratories were not informed which samples were which) – were sent in 1990 to each of 103 laboratories in six WHO regions (Snell et al., 1992). About 70 different combinations of tests were applied. Of the samples without HIV antibodies, 1.3% were incorrectly classified as positive. A combined specificity of only 98.7%, as in this blind proficiency testing, however, is an unusually low estimate. Most of the estimates in the literature are considerably higher, usually higher than 99.9% (Burke et al., 1988; Eberle et al., 1988; Peichl-Hoffman, 1991; Tu et al., 1992). For instance, the German Red Cross achieved for first-time blood donors a combined specificity of 99.98% (Wittkowski, 1989). From the figures published, a reasonable estimate for the combined specificity seems to be about 99.99%. That is, the false positive rate is about 1 in 10,000. This is an estimate, and more accurate numbers may be available from future research.

Abstract. This study addresses the counselling of heterosexual men with low-risk behaviour who, voluntarily or involuntarily, take a HIV test. If such a man tests positive, the chance that he is infected can be as low as 50%. We study what information counsellors communicate to clients concerning the meaning of a positive test and whether they communicate this information in a way the client can understand.

To get realistic data, one of us visited as a client 20 public health centres in Germany to take 20 counselling sessions and HIV tests. A majority of the counsellors explained that false positives do not occur, and half of the counsellors told the client that if he tests positive, it is 100% certain that he is infected with the virus. Counsellors communicated numerical information in terms of probabilities rather than absolute frequencies, became confused, and were inconsistent.

Recall that under the currently available estimates, only some 50% of heterosexual German men with low-risk behaviour actually have HIV if they test positive. The information provided by the counsellors was quite different. Half of the counsellors (ten of 18; two repeatedly ignored this question) told the client that if he tested positive it was absolutely certain (100%) that he has HIV (Table 1 and Session 1). Five told him that the probability is 99.9% or higher (e.g., Session 3). Thus, if the client had tested positive and trusted the information provided by these 15 counsellors, (Stine, 1996).

Counseling people at low risk requires paying particular attention to false positives, that is, to the possibility that the client has a positive HIV test even though he or she is not infected with the virus....If clients are not informed about this fact, they tend to believe that a positive test means that they are infected with absolute certainty....Emotional pain and lives can be saved if counselors inform the clients about the possibility of false positives..."

[6] "for HIV infection, there is no independent, unequivocal way of identifying a group of individuals who are all assuredly infected or uninfected "

Clery PD et al. Compulsory premarital screening for the human immunodeficiency virus: Technical and public health considerations. JAMA. 1987;258:1757-62.

[7] "The evaluation of the sensitivity and specificity of PCR for the diagnosis of HIV infection in infants is particularly difficult because there is no reference or 'gold standard' test that determines unequivocally the true infection status of the patient [**but antibody tests, generally agreed to be inapplicable to infants, hardly qualify as a 'gold standard', so the same problem occurs with all people being tested for HIV**]...a single positive PCR test result does not provide definitive evidence of HIV infection in infants...This finding holds even for more recent studies published after PCR technology had matured "

Owens DK et al. A Meta-analytic Evaluation of the Polymerase Chain Reaction for the Diagnosis of HIV Infection in Infants. JAMA. 1996 May 1;275(17):1342-1348. <http://omsj.org/wp-content/uploads/1500-PCR-Infants-Analysis.pdf>

[8] "Diagnosis of HIV infection is based almost entirely on detection of antibodies to HIV, but there can be misleading cross-reactions between HIV-1 antigens and antibodies formed against other antigens, and these may lead to false-positive reactions. Thus, it may be impossible to relate an antibody response specifically to HIV-1 infection. "

Mortimer PP. The AIDS virus and the HIV test. Med Int. 1988;56:2334-9. <http://www.omsj.org/wp-content/uploads/AIDSvirus-HIVTest1.pdf>

[9] "Serologic [blood] tests for HIV antibodies appear to be characterized by extra-ordinarily high false – positive results...Furthermore, any increase in false positive rate could turn a screening program into a social catastrophe. A false positive result may label an infant, born to HIV positive mother, as HIV positive where as the same infant may actually be HIV negative." ("High Frequency of False Positive Results in HIV Screening in Blood Banks" Ayub Medical College, Pakistan. 1999)

<http://www.ayubmed.edu.pk/JAMC/PAST/16-1/Aqleem.htm>

[10] "The likelihood that a positive screening test truly indicates the presence of HIV infection decreases as HIV prevalence in the tested population becomes lower. Therefore, false-positive HIV test results are more likely in settings where the tested population prevalence is lower than in settings where the tested population prevalence is higher."

(CDC: "Revised Guidelines for HIV Counseling, Testing, and Referral" November 9, 2001)

Recommendations and Reports

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Individual risk can be ascertained through risk screening.

Because of the availability of antiretroviral therapy to reduce the risk for perinatal HIV transmission, all pregnant women should be recommended HIV testing regardless of setting prevalence or behavioral or clinical risk (see Revised Recommendations for HIV Screening of Pregnant Women).

Low Prevalence Settings

Prevention counseling and referral are recommended for persons at increased risk even if HIV testing is declined.

High Prevalence Settings

In high prevalence settings (e.g., >1%), all clients should be routinely recommended HIV testing (Figure 3

In these settings, clients with ongoing risk behaviors identified during risk screening

Regardless of population risk, setting prevalence, or individual behavioral or clinical risk, voluntary HIV testing should be routinely recommended to a) all pregnant women, b) clients with acute occupational exposure, and c) clients with acute nonoccupational (e.g., high-risk sexual or needle-sharing) exposure.

Regardless of whether a client receives an HIV test, HIV prevention counseling and referral should target pregnant women based on risk screening and be routinely recommended to clients with either acute occupational or nonoccupational exposures.

The likelihood that a positive screening test truly indicates the presence of HIV infection decreases as HIV prevalence in the tested population becomes lower. Therefore, false-positive HIV test results are more likely in settings where the tested population prevalence is lower than in settings where the tested population prevalence is higher. When a preliminary, positive rapid test is explained to clients, phrases like "a good chance of being infected" or "very likely infected" can be used to indicate the likelihood of HIV infection and qualified based on the HIV prevalence in the setting and the client's individual risk (120). Further testing is always required to confirm a reactive screening test result.

Testing is more likely to be accepted when clients perceive their own HIV risk and acknowledge behaviors placing them at increased risk (135); testing is voluntary and routinely offered to clients rather than clients having to request it (113,136); alternate HIV test technologies are offered to clients (26); providers recommend testing as part of appropriate medical care (139,140); and providers (141) and clients (113) perceive HIV counseling and testing to be beneficial for early diagnosis and prevention purposes.

Expanding CTR into nontraditional settings can be accomplished through partnership with community-based service providers and use of new, FDA-approved HIV test technologies that offer portability, less-invasive sample collection, less-complex sample collection and processing, and reduced biohazard.

Counseling

Staff members working in community-based and other nontraditional settings should know and use risk-screening strategies to determine whether HIV prevention counseling should be recommended.

[11] As Dr. Dan Cohen, medical director of Boston's Fenway HIV test center told me in a 2003 interview:

"The majority of people who are going to be infected [in the Boston area] are in their teens and twenties.

<http://liamscheff.com/daily/2010/04/05/aids-in-boston-the-other-aids-debate-interview/>

Interview by Liam Scheff, with Dr. Dan Cohen, M.D. at Boston's Fenway HIV/AIDS Clinic, 2003.

Liam Scheff: What's the process at the Fenway when someone tests positive for HIV?

Dr. Cohen: When someone is tested positive, they get counseling before and after, regarding the test process, they're counseled regarding the possibility of getting a false negative when they're really HIV infected.

Liam Scheff: How do they get a false negative?

Dr. Cohen: The HIV test is testing for antibodies, not for the presence of the HIV virus itself.

Liam Scheff: How does that equal a false negative?

Dr. Cohen: If a person has become infected recently their body might not be making antibodies yet. This a problem if someone has become infected in last several weeks.

Liam Scheff: Do they get counseling regarding false positives?

Dr. Cohen: Well, this is less of a problem than it used to be because of the way the test is conducted. The first test is a regular screening test, called the ELISA, which is looking for antibodies against HIV, it is fairly specific, but not 100 percent, none are 100 percent.

Liam Scheff: I've read that ELISA tests are as much as 80 percent nonspecific.[1]

Dr. Cohen: Well, new tests seem to better. If the ELISA is positive, then they're retested again with the ELISA. If they test positive a second time, they move to a more specific test called Western Blot, which more specifically tests against certain antibodies against the HIV virus.

Liam Scheff: You're diagnosing HIV based on two tests, the ELISA repeated twice and the Western Blot. If it's a faulty test, what's the purpose of repeating it?

Dr. Cohen: Sometimes it might turn up positive for reasons that don't have to do with the test, such as human error.

Liam Scheff: But if the test itself is faulty – I've read that the ELISA test reads blood only after it's been diluted 400 percent. But if it tests undiluted blood, then everybody's blood tests as HIV-positive.

Dr. Cohen: Yeah, that's the way the test works.

Liam Scheff: I've read that the Western Blot is faulty, and that it picks up many nonspecific antibodies.

Dr. Cohen: If it's conducted by a lab that knows what it's doing, it's not likely to be a false positive.

Liam Scheff: What if the lab doesn't know what it's doing?

Dr. Cohen: Then anything is possible. If you don't have confidence in your lab, then you can't have confidence in your test results.

Liam Scheff: The Massachusetts Department of Public Health records the number of HIV-infections in the State last year [2001-2002] at 3,184. Their report states that "327 people reported with AIDS in Massachusetts died." [ed - **The report adds that this number includes deaths from motor vehicle crashes, drug overdoses, and suicides.**] [2]

Dr. Cohen: That's absolutely correct. I think a lot of people have an inflated idea of the impact AIDS is still causing today. But that doesn't mean we should dismiss it.

Liam Scheff: No, we shouldn't dismiss it. But we're constantly told that it's an epidemic. Why do we call it an epidemic?

Dr. Cohen: We shouldn't be focusing our view on the U.S. because worldwide, AIDS is killing millions.

Liam Scheff: What do you think of the amfAR ads on buses which say "1 million treated – 40 million to go." Is this part of the reason people have an 'inflated idea of the impact AIDS is still causing today?' [3]

Dr. Cohen: Just because people have an inflated idea of AIDS today, doesn't mean it's not a huge problem.

Liam Scheff: You said it's not.

Dr. Cohen: But AIDS disproportionately affects young people.

Liam Scheff: The majority of people infected in Boston are in their 30's in 40's.

Dr. Cohen: But the majority of people who are going to be infected are in their teens and twenties.

Liam Scheff: How do you know that?

Dr. Cohen: Because we're seeing increasing number of other STDs in this young population, and it's only a matter of time before HIV appears. That's especially true among people of color. That's the reason it's an emergency. The most important thing, just because we're not seeing the numbers, doesn't mean that we shouldn't pay attention. It's lurking beneath the surface; we must continue with the prevention message and strategies.

Liam Scheff: What are good prevention strategies?

Dr. Cohen: Condoms are the most important strategy. There are many people at risk who won't use condoms. Avoiding anal sex without a condom would be another. Limiting the number of partners. Getting tested regularly for other std's and getting tested for those will reduce the incidence.

Liam Scheff: What do you say to scientists who question the validity of the HIV=AIDS hypothesis?

Dr. Cohen: I've heard this HIV not equal AIDS message for years. I'm satisfied that the virus Montagnier's and Gallo's virus causes AIDS.

Liam Scheff: Montagnier disagreed. He's stated that HIV, on its own cannot cause AIDS.

Dr. Cohen: I respectfully disagree; I'm satisfied that every who gets AIDS is infected with HIV but not everyone who has HIV will get AIDS.

[12] I pointed out that in 2002, all of Massachusetts recorded 327 AIDS deaths – that included auto-accidents, overdoses and suicides (the state counts all HIV positive deaths as AIDS deaths).

Massachusetts Department of Public Health HIV/AIDS Statistics 2002:

"In 2001, 327 people reported with AIDS in Massachusetts died. Seventy-two percent of these deaths were among men, 47% were among people of color, and 55% were among people who had injected drugs. By comparison, the profile of people recently diagnosed with HIV infection (1999-2001) is comprised of 70% men, 58% people of color, 24% among injection drug users.

One should note that the death data presented in this analysis include all deaths among people reported with AIDS in Massachusetts. This includes deaths from non-HIV related causes such as motor vehicle crashes, drug overdoses, and suicides. Therefore, the total number of annual deaths reported here will vary slightly from the number of HIV-related deaths reported in Massachusetts Deaths by the MDPH Bureau of Health Statistics, Research and Evaluation."

There were 14,499 AIDS-related deaths in the US in 2001. In 2000 it was 16,765. AIDS is not in the top 15 causes of death in the US. Total AIDS-related deaths since 1981 [as of 2002/2003] were 467,910.] By comparison, in 2001 alone, 699,697 people died of heart disease, 553,091 of cancer, 71,252 of diabetes and 97,902 of unintentional injuries. [\[LINK\] MASS Gov. Link](#)

[13] "[P]atients who test positive, but who live in a low-prevalence [low-risk] part of the country and engage in no activities that put them at risk for HIV infection, might be told a positive reaction means they "probably" or "very likely" don't have HIV.

On the other hand, "In higher-risk settings, patients might be told that a positive test means they "probably are" infected." ("Coming to Your Clinic: Candidates for Rapid Tests." Aids Alert; March 1998)

<http://reducetheburden.org/?p=149>

"[The test's] error rate won't matter much in areas with a high prevalence of HIV, because in all probability the people testing false-positive will have the disease. But if the same test was performed on 1,000 white, affluent suburban housewives – a low-prevalence population – in all likelihood all positive results will be false, and positive predictive values plummet to zero."

Aids Alert – March 1998

With the shift in U.S. Public Health Service policy on rapid HIV screening tests, new manufacturers are expected to begin entering the U.S. market in the next year, experts say. Here's a look at what's here, on the way, or possibly arriving soon.

Murex, a Norcross, GA-based firm [(800) 334-9332], makes an enzyme immunoassay that uses serum or plasma, called SUDS HIV-1. The test is already approved for U.S. use (although current FDA regulations prohibit the immediate report of reactive tests). List price, \$10; sensitivity, 99.9%; specificity, 99.6%. It is used in the United States in instances of occupational exposure, with mothers presenting in labor with no history of prenatal care, or in emergency-room situations.

Trinity Biotech [(716) 483-3851], based in Dublin, Ireland, with U.S. headquarters in Jamestown, NY, expects its Uni-Gold HIV test to win FDA approval in the next year. List price, \$50 for 20 tests. Now sold abroad, a combination test for HIV 1 and 2; uses plasma, serum, or whole blood. Ten-minute incubation. Also from Trinity, Rapid Saliva Card, which tests for HIV 1 and 2 with saliva; Trinity has no plans at present to bring that test to U.S. markets, spokesmen say.

Sanofi Diagnostics, Pasteur (based in Paris), along with its U.S. subsidiary, Genetic Systems [(206) 728-4900], based in Redmond, WA, makes the MultiSpot test, formerly known as Genie. In widespread use abroad, and the CDC's choice for "tiebreaker" in two-test rapid studies. Costly, in part because it distinguishes between HIV 1 and 2, MultiSpot might list here for \$10 to \$15, says Patrick Coleman, MD, test developer and spokesman. MultiSpot's makers are wary of getting burned again by the U.S. marketplace, where 10 years ago they gambled (and lost) on an OTC niche that turned out to be nailed shut.

Meanwhile, half a dozen U.S. states are trying to get hold of the test by importing it as an "investigational device," a plan experts doubt will work.

Saliva Diagnostics Systems [(360) 696-4800], in Vancouver, WA, is about to bring three tests to market in Canada this year, each of them well-liked by U.S. experts. Paul Slowey, PhD, Saliva Diagnostics' chief operating officer and vice president of marketing, dreams of finding a U.S. backer as well. Sero.Strip, a serum test for HIV 1 and 2, might list here for \$4 to \$5, Slowey says; it features 99.6% sensitivity and 99.8% specificity. Hema.Strip, a fingerstick test that can use whole blood, might sell here for about \$10; it has 99.6% sensitivity, 99.9% specificity, and 20-minute incubation time. Saliva.Strip, which could cost \$10 to \$12, has 99.4% sensitivity and specificity, and uses a pad on a stick to collect plain saliva, which is filtered, buffered, and incubated for 20 minutes.

Abbott Laboratories [(847) 937-3357], in Abbott Park, IL, is tight-lipped about two whole-blood, fingerstick-type tests now in clinical trials, but is said to be eager to bring the tests to market.

CDC launching new era in testing by giving OK to rapid screening tests New fingerstick tests will bring access to the streets In a move that is likely to have profound and far-reaching consequences, the Centers for Disease Control and Prevention has made an about-face on rapid HIV screening tests.

In the Feb. 27, 1998, issue of Mortality and Morbidity Weekly Report, the CDC will recommend a change in U.S. Public Health Service policy. It will urge that under at least some circumstances, health care providers should be able to disclose provisional results of HIV tests, instead of making patients wait two weeks while a confirmatory test is performed.

The new recommendations are expected to be incorporated into regulations by the U.S. Food and Drug Administration (FDA). When that happens, the effect will be the opening of a vast new market in the United States for rapid HIV screening tests, CDC experts say.

Though dozens of rapid tests are already in widespread use abroad, scant incentive exists for test manufacturers to mount the expensive clinical trials needed for approval in the United States, because the FDA at present prohibits the disclosure of provisional rapid-test results, says Bernard M. Branson, MD, MPH, medical epidemiologist at the National Center for HIV, STD and TB Prevention at the CDC, and chief architect of the new CDC recommendations.

With a new policy in place, many new rapid tests for HIV will be submitted for FDA approval, experts say. Most of the new tests are

simple fingerstick tests that incorporate a new technology perfected within the last year, and which – in theory – could be used by anyone, from outreach workers to consumers of home-test kits.

Two new tests are in clinical trials, a third is already available, and another is expected to become available within the next year or so, CDC experts say. (For details, see story, p. 26.)

The anticipated influx of new rapid tests promises to have a dramatic impact in two different ways. First, the new tests will greatly increase access, making it much easier for people to learn their HIV status, says Branson.

"By cutting down on the cost and the technological requirements of rapid tests, and by getting rid of the waiting time, HIV testing doesn't have to be clinic-based anymore," he says. "Now it can be done as street outreach."

Indeed, one reason driving the CDC's turnaround on rapid tests was researchers' frustration over the effects of a two-week waiting period. As it stands now, almost 30% of U.S. patients who get HIV testing never come back for their results, says Charles A. Schable, chief of the National Center for Infectious Disease at the CDC. Studies have found that the waiting period is too burdensome for clients who have a hard time taking off from work or finding child care, Branson says.

But when clients in a Dallas study were given the chance to learn their test results right away, they understood the provisional nature of positive results, and they also came back to get confirmation and more counseling, Branson says.

The second arena in which new tests will make an impact relates to accuracy. Studies in Honduras and other sites abroad have shown that using two different rapid tests side by side provides far greater accuracy than using a single rapid test alone, Branson says. Rapid tests could be used in the same fashion in the United States if there were more than one on the market; but without a new policy on the disclosure of results, that would never happen, researchers realized.

Ethical concerns are raised by the prospect of outreach workers offering injecting drug users an on-the-spot HIV test, or home-test consumers being able to perform an instant test on themselves, say Branson and Schable. How will clients decide whether or not they are ready to get on-the-spot information about their HIV status? How will counselors help clients understand a provisionally positive result? As this issue of AIDS Alert went to press, the new CDC recommendations called for disclosure of provisional results by clinicians only in certain circumstances, says Schable. Tests were to be offered to the following kinds of clients:

- . those in high-risk populations (such as those presenting at TB and STD clinics);
- . mothers presenting in labor, with no history of prenatal care and with unknown HIV status;
- . health care workers who are victims of a needlestick, and possibly other high-risk situations.

Ways to convey provisional positive results were also still being worked out at press time. For example, patients who test positive, but who live in a low-prevalence part of the country and engage in no activities that put them at risk for HIV infection, might be told a positive reaction means they "probably" or "very likely" don't have HIV. In higher-risk settings, patients might be told that a positive test means they "probably are" infected.

Whether the tests will perform as well in the United States as they have abroad is still unknown, experts add. For one thing, using a single rapid test in a low-prevalence population will give a lower positive predictive value, says Branson.

Suppose, for example, a single rapid test that has 99.4% specificity is administered to 1,000 people, meaning six will test false-positive. That error rate won't matter much in areas with a high prevalence of HIV, because in all probability the people testing false-positive will have the disease. But if the same test was performed on 1,000 white, affluent suburban housewives – a low-prevalence population – in all likelihood all positive results will be false, and positive predictive values plummet to zero.

Two rapid tests used together abroad seem to overcome that difficulty by ensuring virtually 100% accuracy. However, no one knows for sure if paired tests will perform the same way here as they do abroad. "I have confidence in these tests, but until we have more data, we can't extrapolate and say for sure how they will work here," says Mark Rayfill, PhD, assistant chief for International Laboratory Activities of the HIV Retrovirus Disease Branch of the Division for AIDS, STDs, TB and Laboratory Research at the National Center for Infectious Diseases. To get those data, researchers need more rapid tests, Rayfill adds.

But two other roadblocks may keep the tests from reaching the market as fast as researchers would like.

For one thing, Paris-based Sanofi Diagnostics, Pasteur, holds patent rights in the United States to the HIV-2 antigen, which the FDA says new HIV tests must be able to detect to be approved. Thus, it's possible other companies submitting products for licensure could face a court challenge.

The bigger hurdle, at least for some pharmaceutical firms, is simply cost. Saliva Diagnostics Systems (SDS), a small firm based in Vancouver, WA, has three rapid tests it would like to launch in the United States. But without a backer, that will prove tough, says Paul Slowey, PhD, chief operating officer and vice president of SDS.

"People want these kinds of tests very badly right now," says Slowey. That's why the new rapid HIV tests will eventually find their way not only into the U.S. market, but into home-test kits as well, Slowey adds. "It's simple:

Consumers want to know."

[14] When a preliminary, positive rapid test is explained to clients, phrases like "a good chance of being infected" or "very likely infected" can be used to indicate the likelihood of HIV infection and qualified based on the HIV prevalence in the setting and the client's individual risk." (CDC: "Revised Guidelines for HIV Counseling, Testing, and Referral" November 9, 2001) [see CDC reference Above part 2, #10] [Link Paper]

[15] [R]apid HIV testing should routinely be made available for the mother or her newborn" (CDC: National HIV Testing Resources: "HIV Test FAQ" 2005)

Why is the Centers for Disease Control and Prevention (CDC) recommending that pregnant women be tested for HIV?

Highly effective interventions exist that can prevent HIV-infected women from transmitting the virus to their infants. The timely administration of antiretroviral drugs during pregnancy can reduce the risk of mother-to-child HIV transmission to 1-2 percent, and also improve the health of the mother.

When preventive anti-retroviral treatment is not initiated until labor and delivery or given solely to the newborn, the risk of transmission is estimated at about 9 percent to 13 percent. Without any intervention, the chance of transmission is approximately 25 percent in the United States.

To reduce HIV transmission in the United States, CDC recommends that all pregnant women:

Receive prenatal care;

Be offered screening for HIV;

If the woman is HIV infected, be offered combination antiretrovirals prenatally and intrapartum; as well as obstetrical interventions at delivery and antiretroviral prophylaxis to their newborn;

Be offered routine voluntary rapid screening at labor and delivery with right of refusal; and

For women not tested prenatally or at labor/delivery, rapid HIV testing should routinely be made available for the mother or her newborn in order to offer HIV prophylaxis as soon as possible to HIV exposed neonate.

[16] "As the number of women being screened has increased, the proportion of false-positive and ambiguous (indeterminate) test results has increased and the positive predictive value (PPV) of the standard HIV test has decreased"

Doran TI, Parra E. False-Positive and Indeterminate Human Immunodeficiency Virus Test Results in Pregnant Women. Arch Fam Med. 2000 Sep/Oct;9:924-9. <http://www.omsj.org/wp-content/uploads/Pregant-Women-Test-Positive.pdf>

[17] "In 1990, of 20.2 million HIV tests done in Russia only 112 were confirmed and about 20,000 were false positives, 1991 saw some 30,000 false positives out of 29.4 million tests, with only 66 confirmations...in 1991 alone some 8000 false-positive results were reported in pregnant women, with only 6 confirmations [**presumably with the Western Blot test**] "

Voevodin A. HIV screening in Russia. Lancet. 1992;339:1548. <http://www.omsj.org/wp-content/uploads/HIV-Screening-in-Russia.pdf>

[18] "One might expect that women found to be seropositive would opt for an elective abortion." (Screening for HIV antibody. Health Canada, 1994)

"Screening of pregnant women is a special situation because the risk of vertical transmission to the fetus is about 30%. One might expect that women found to be seropositive would opt for an elective abortion. However, two studies involving injection drug users showed that seropositive women had the same rate of pregnancy and therapeutic abortion as seronegative women. Nevertheless, knowledge of seropositivity may result in: 1) avoidance of certain obstetric maneuvers (e.g., amniocentesis, chorionic villus sampling and fetal monitoring) that may increase the risk of HIV transmission; 2) earlier diagnosis of associated illnesses that might otherwise be attributed to pregnancy; 3) avoidance of breast feeding, which may be a vehicle for HIV transmission; and 4) earlier treatment of infected infants."

[19] "For pregnant women who do not know their HIV status at the time of delivery, rapid HIV testing permits [**drug**] therapy to be initiated for these mothers during labor, and to their infants post partum." (OraQuick Rapid HIV Test, 2003) <http://www.omsj.org/wp-content/uploads/Oraquick-Rapid-Test.pdf>

"Using a rapid HIV test increases the number of HIV-infected persons who may be diagnosed. The Centers for Disease Control and Prevention (CDC) estimates that nearly one fourth of the estimated 900,000 HIV-infected persons in the United States do not know their HIV status. As a result, they cannot benefit from early intervention with effective antiviral therapy. Rapid HIV testing addresses this issue by providing results during the initial visit and enabling immediate counseling.

Additionally, for pregnant women who do not know their HIV status at the time of delivery, rapid HIV testing permits therapy to be initiated for these mothers during labor, and to their infants post partum, substantially reducing the chance that the infants will become infected with HIV. Likewise, rapid HIV testing is instrumental in the decision to initiate treatment for health care workers after accidental exposures to body fluids from infected individuals. In the U.S., it is estimated that 600,000 to 1,000,000 "needlestick injuries" occur each year. Critical decisions about treatment depend on the availability of accurate, rapid HIV test results."

[20] "Newborns of HIV infected mothers may carry maternal antibodies for up to eighteen months, which may not necessarily indicate the true infection status of the new born." (MedMira Reveal HIV test. 2003) <http://www.omsj.org/wp-content/uploads/Reveal-Rapid.pdf>

"Infection with HIV-1 and/or HIV-2 elicits an immune response resulting in the production of corresponding anti-HIV antibodies. Antibody detection tests for HIV-1/HIV-2 antibodies provide a means to aid in the diagnosis of HIV-infected individuals 1,2. However, when utilizing HIV antibodies to diagnose HIV infection, corresponding clinical factors must also be considered. Following a recent exposure to HIV, it may take several months for the antibody response to reach detectable levels, during which time testing for antibodies to HIV will not be indicative of true infection status. On the other hand, newborns of HIV -infected mothers may carry maternal antibodies to HIV for up to eighteen months, which may not necessarily indicate the true infection status of the new born."

[21] HIGH FREQUENCY OF FALSE POSITIVE RESULTS IN HIV SCREENING IN BLOOD BANKS

Ayub Medical College Pakistan

<http://www.ayubmed.edu.pk/JAMC/PAST/16-1/Aqleem.htm>

"[B]efore we screen low-risk groups for antibody to the human immunodeficiency virus (HIV), we should consider what the results would mean. Serologic tests for HIV antibodies appear to be characterized by extra-ordinarily high false-positive results in a low risk screening setting of voluntary blood donation.

"Furthermore, any increase in false positive rate could turn a screening program into a social catastrophe. A false positive result may label an infant, born to HIV positive mother, as HIV positive where as the same infant may actually be HIV negative.² The false positive result regarding HIV in a neonate can lead to very serious problems."

"If we want to test each other, we should make a deliberate choice of the threshold probability of infection above which we will screen. We should make explicit the trade-offs implicit in any testing program. How many engagements should end to prevent one infection? How many jobs should be lost? How many insurance policies should be cancelled or denied? How many fetuses should be aborted and how many couples should remain childless to avert the birth of one child with AIDS?"

[22] Emotional pain and lives can be saved if counselors inform the clients about the possibility of false positives... ("AIDS Counseling for Low-Risk Clients"; Max Planck Institute/Aids Care, 10, 1998)

<http://omsj.org/wp-content/uploads/Max-Planck-Institute-HIV-Counseling-for-Low-Risk-Clients.pdf>

[23] "Lesbians have been excluded from epidemiological risk groups." ("A lesbian at very low risk for HIV infection" HIV InSite/UCSF Center for HIV Information, 2004)

University of California, San Francisco | UCSF Medical Center

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A lesbian at very low risk for HIV infection insists on getting tested twice a year. Should she get tested so often?

Answered by Nicolas Sheon, HIV InSite Prevention Editor

Question

I am an HIV test counselor. Every so often, I see clients who are very low risk that want to get tested every few months.

For example, I saw a woman recently who reported that 5 or 6 years ago she performed oral sex on an HIV+ woman without a latex barrier. She has been tested twice a year since then, except for the past three years – she has been tested 8 times since 1996: all negative. Her only other partner since this encounter has been an uninfected female she has been mutually monogamous with for three years. In my experience I find many people confuse the HIV antibody test window period with progression to an AIDS diagnosis in an HIV+ person; so I made sure that this client understood this – that she did not have to wait years and years to find out whether or not she was infected.

This was her ninth test in three years and it seemed to me she was very low risk: she had been monogamous with someone for 3 years and reported using latex barriers all of the time. There was nothing I could say or do to let her know coming in for all these tests was not necessary, from a clinical standpoint – once a year would be fine if she and her partner maintained monogamy.

At the same time, I did not want to deny her a test, and she was so emphatic about having a risk I wasn't sure of an appropriate way to address this. There is, of course, the possibility that this patient had some kind of risk activity that she did not report to me, although my "gut feeling" tells me she was being honest.

Any advice for test counselors on how to handle low risk patients who seem too paranoid or obsessive compulsive?

Answer

This is an intriguing question that I asked myself when I first started counseling. Soon after the HIV test was licensed in 1985, certain patterns emerged in the way people used the test. First of all, counselors told clients to get tested every six months, ostensibly because of the uncertainties around the window period. For a number of reasons, clients heard this as an injunction to test every six months. Magic Johnson's announcement that he was HIV positive late in 1991 initiated an enormous increase in testing volume among low-risk people. That increase in testing volume has largely remained steady over the years, clearly suggesting that HIV testing for low risk people has become routinized. After Magic, it was no longer possible to claim "innocent victim" status because it was your responsibility to know your status and test regularly.

Another perspective on this comes from my research on confession rituals. I find that testing begets more testing because people find it convenient to get a "clean slate" every six or twelve months. Testing has become a routine part of dating and courtship rituals as well as a way for individuals to cope with the growing anxieties around sex and intimacy during the conservative period that followed the sexual revolution. The test and the intense scrutiny imposed by the test counselor's risk assessment represents a modern version of the ancient rite of confession. A negative test is therefore sought, not so much in response to a particular risk incident, so much as in response to a sense of moral or sexual pollution that is often expressed as a nagging doubt about one's HIV status. In this way, a negative test result represents a kind of absolution. However, because the epidemiological (and ethical or even theological) significance of HIV risk behaviors remain shrouded in uncertainty, a negative test result offers only a fleeting sense of reassurance and absolution must be sought again and again. Note that this parallels Western discourses on sin and confession. For centuries, priests and theologians debated the issue of scrupulosity and recidivism, or how to deal with the spiritually worried well and those recalcitrant sinners who regularly confessed but refused to change their ways. I think HIV counselors can learn a lot from the history of confession rituals, something I explored in my dissertation.

The problem with assessing Obsessive Compulsive Disorder (OCD) is that I believe AIDS really challenges traditional criteria for diagnosing and treating this disorder. While you can incorporate behavioral therapy into a treatment for a fear of heights or agoraphobia,

it's difficult to imagine behavioral therapy for someone obsessed with the idea that they were infected with HIV from a blow job or lap dance they received from a sex worker three years ago. Is repeat testing a ritual response to an obsession (akin to washing one's hands or checking the stove) or is this person merely being "responsible?" There are screening tools for OCD, but it's really difficult to draw the line between paranoia and prudence when talking about safer sex.

I think there are particular contradictions that lesbians face around safer sex. The dominant society associates lesbians with exclusively same sex behavior which is, in turn, associated with AIDS. However, the actual risk of transmission between women is unknown, largely due to the fact that lesbians have been excluded from epidemiological risk groups. At the same time, many lesbians — up to 70%, according to one study — have had sex with men, a fact which challenges many of the assumptions made by and about lesbians with regard to HIV risk.

There is also the possibility that this woman's need to test regularly is related to power issues in the relationship. Maybe she is worried about her partner's fidelity or the other way around. Rather than discuss this issue with her partner, she may be using the test to avoid the issue. In this case I would try to discuss with her how she talks with her partner about testing, and whether her partner gets tested as well. Hope this helps.

[24] [A]cceptable prevalence rates to justify screening [the general population] have not been defined. (Screening for HIV antibody. Health Canada, 1994)

"The contents of such a history are described in guidelines from the Canadian Medical Association and other groups. Once a decision is made to screen, informed consent must be obtained, and counselling must be provided before the test and after receipt of the results – an important component of the testing procedure. Maintaining confidentiality is likely to increase the acceptance of testing, although it has not been studied. Screening for HIV infection currently involves detection of antibodies. The first step requires one of a number of commercially available enzyme-linked immunosorbent assay (ELISA) kits. These are highly sensitive but their specificity is reduced by cross-reactions with components other than HIV antigens. ELISA is easy to perform and inexpensive. If the results are repeatedly positive, the second step involves a more specific confirmatory test, such as the Western blot, radioimmunoprecipitation or immunofluorescence assay. These confirmatory tests are labour intensive and costly. The combined sensitivity of the two tests approaches 100%. However, the trauma to a single individual falsely identified as seropositive may offset the advantage to those who are truly seropositive. The higher the prevalence, the more true positives are identified for every false positive; acceptable prevalence rates to justify screening have not been defined.

False negative results after combined testing with ELISA and the Western blot technique may occur because of the delay in antibody development after HIV exposure. This period is usually less than 6 months. A false negative result may falsely reassure people in whom antibody has not yet developed. Testing should be repeated after 6 months in seronegative people whose behaviour put them at risk. In neonates inaccurate results may occur if only the antibody but not the virus is passed to the neonate or because of poor antibody response. The screening test is not accurate for detecting infection in neonates. Thus, viral DNA detection through a polymerase chain reaction or virus isolation is required for diagnosis. False-positives may also result from errors in specimen identification or contamination in the laboratory."

[25] "[T]here was no information about [HIV] prevalence in men and women with no risky behaviour." ("AIDS Counseling for Low-Risk Clients"; Max Planck Institute/Aids Care, 10, 1998) [see Max Planck ref # XXX] <http://omsj.org/wp-content/uploads/Max-Planck-Institute-HIV-Counseling-for-Low-Risk-Clients.pdf>

[26] "Most patients (68 to 89%) from low risk groups (prevalence of 0.1% or less) who show reactivity on screening tests will have false-positive results...The predictive value of a positive ELISA varies from 2% to 99%...One notable association with false positive ELISA reactivity in some commercial preparations has been patients with anti-HLA-DR4 antibodies, most often multiparous [having experienced one or more births] or multiply transfused patients...the Western blot method lacks standardization, is cumbersome, and is subjective in interpretation of banding patterns."

Steckelberg JM, Cockerill F. Serologic testing for human immunodeficiency virus antibodies. Mayo Clin Proc. 1988;63:373-9.

[27] "The predictive value of a positive test is strongly influenced by the prevalence of HIV-1 infection in the population tested. For example, in low prevalence populations the predictive value was 11.1% (1/9) while in populations with known HIV-1 infection, the predictive value was 97.1% (395/407)."

Antibody to Human Immunodeficiency Virus type 1; HIVAG-1 Monoclonal. Abbott Laboratories. 1996 Apr.

[28] In a high risk group, "The Positive Predictive Value of a home screening test would be 67%; 33 of 100 would be false positives. With a lower prevalence [low risk group] the PPV drops to 17%, and 83 out of 100 positive tests would be false. – Advances in HIV Testing Technology and their Potential Impact on Prevention – William Kassler, AIDS Education and Prevention – 1997. [Find Paper]

[29] The test manufacturers list the following as their high risk group: "Prison inmates, STD clinic patients, inner city hospital emergency room patients... homosexual men [and] intravenous drug users." (Vironostika HIV Antibody Test. 2003)

[see Vironostika test above References Part 1, #10]
<http://omsj.org/wp-content/uploads/Vironostika-HIV-Test.pdf>

[30] "Whether the tests will perform as well in the United States as they have abroad is still unknown, experts add. For one thing, using a single rapid test in a low-prevalence population will give a lower positive predictive value....That error rate won't matter much in areas with a high prevalence of HIV because in all probability the people testing false-positive will have the disease. But if the same test was performed on 1,000 white, affluent suburban housewives – a low-prevalence population – in all likelihood all positive results will be false, and positive predictive values plummet to zero."

(Coming to your clinic: Candidates for Rapid Tests. Aids Alert, March 1998)

<http://reducetheburden.org/?p=149>

[see references Part 2, #13]

[31] "If you have a negative test result but you are in a high-risk group, you may need to have another test 3 to 6 months later. ("HIV Antibody Tests" McKesson Health Solutions LLC.)

[see references Part 2, #2]

University of Michigan

HYPERLINK "http://www.med.umich.edu/llibr/aha/aha_hivantib_crs.htm" http://www.med.umich.edu/llibr/aha/aha_hivantib_crs.htm

[32] "Testing should be repeated after 6 months in seronegative people whose behaviour put them at risk." (Screening for HIV Antibody, Health Canada, 1994) [see references part 2, #18, #24]

"Screening for HIV infection currently involves detection of antibodies. The first step requires one of a number of commercially available enzyme-linked immunosorbent assay (ELISA) kits. These are highly sensitive but their specificity is reduced by cross-reactions with components other than HIV antigens. ELISA is easy to perform and inexpensive. If the results are repeatedly positive, the second step involves a more specific confirmatory test, such as the Western blot, radioimmunoprecipitation or immunofluorescence assay. These confirmatory tests are labour intensive and costly. The combined sensitivity of the two tests approaches 100%. However, the trauma to a single individual falsely identified as seropositive may offset the advantage to those who are truly seropositive. The higher the prevalence, the more true positives are identified for every false positive; acceptable prevalence rates to justify screening have not been defined.

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[33] UK test Guidelines ("Towards error-free HIV diagnosis: guidelines on laboratory practice" Communicable Disease and Public Health 2003)

<http://omsj.org/wp-content/uploads/UK-Interpretation-Guidelines.pdf>

The official interpretation guidelines for the UK. [with notes in brackets]

"Specimens from HIV-infected individuals typically give rise to strong, and often maximum, signals in most commercial screening assays whereas falsely reactive specimens infrequently do."

–[What makes it a false reaction? The strength of the reaction? ...Nope]

"However, this is not a reliable basis on which to make a diagnosis of HIV infection, and further testing is essential, employing several different tests carefully selected to minimise the possibility of each additional test being prone to the same false-positive effect as gave rise to the false reaction in the initial screening test."

–[So, how do they know which is a false reaction and which is a true reaction? — "Expectation"]

"Other pitfalls arise from the use of fourth generation tests (where, as noted above, both components need to be checked) and the application of screening tests to populations where the strong expectation is of a negative result. Reactivity on these specimens needs very careful scrutiny, unhurried by inappropriate 'turn-around' targets."

–[But – if they think you've got it, then, well, you've got it.]

"Clearly, waiting for six months to test is untenable, and an approach should be adopted that strikes a balance between certainty that transmission has not happened and the need to be able to reassure the patient as soon as possible."

"A nucleic acid test (see below) may hasten a positive finding after exposure to HIV, but it is not a substitute for anti-HIV testing after a 'safe' interval."

–[Here the ELISA test is considered more accurate than the PCR. This is the opposite of the standard line (That PCR is more accurate than the ELISA).] –[But the ELISA antibody tests (what they delightfully call "anti-HIV") are not virologic tests, they're non-specific antibody tests, hence the call for PCR ("nucleic acid test", which they'll say, is more specific than ELISA (except that it's actually not)... Clear?] "We would suggest testing using a sensitive fourth (or third) generation screening test immediately after the exposure and then: at one to two months, at three to four months, and six months."

"Should suspicious clinical signs and symptoms develop, ie almost anything occurring in persons in the pre-designated "risk groups" – cold, allergy, fever, etc an immediate test, including for HIV RNA, is indicated."

"Some time and care will be needed to explain the reasons underlying the need for follow-up testing and to communicate without undue alarm an appropriate level of residual risk of infection, despite negative results, prior to completing the six-months follow up."

<http://omsj.org/wp-content/uploads/UK-Interpretation-Guidelines.pdf>