AIDS Testing Quotes

From: David Crowe (RA President) [mailto:David.Crowe@RethinkingAIDS.com]
Sent: Tuesday, November 16, 2010 2:08 PM
To: Gary Null
Subject: Testing quotes...

Gary;

Here are some of the most important questions:

- Why is an antibody test used for HIV/AIDS when antibodies indicate past exposure to a virus not current infection?
- If Western Blot is used to verify the initial ELISA tests how could we recognize a false positive on a Western Blot?
- No single protein on a western blot by itself is accepted as a positive meaning that all proteins can occur without HIV. If one protein can occur without HIV surely multiple proteins can occur. Why should these be accepted as positive?
- What other method than purification of the virus and comparing the ability to purify from people versus the results of antibody and other tests could be used to validate tests?
- If purification is necessary for validation and purification has never occurred does this not mean that no HIV tests are validated?
- If a test is 99% accurate testing 1000 people with a prevalence of HIV of 1/1000 then 10 false positive and 1 true positive result will be obtained. Based on this how is it possible to recommend HIV testing of low risk populations?

Here is my archive of quotes: http://aras.ab.ca/test.html

Here are some articles I've written:

- http://aras.ab.ca/articles/popular/pregnant.html
- http://www.questionsquestions.net/docs04/0725_hiv_sars_test.html
- http://aras.ab.ca/articles/popular/hivtestingimmigrants.html
- ftp://aras.ab.ca:@aras.ab.ca/public/articles/correspondence/20070516-LetterToRichardCodey-NJSenate.pdf

Here are some of the better quotes all from 2000 or later:

"[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 14/28; 160(15): 2386-8. http://davidcrowe.ca/SciHealthEnv/papers/1023-FalsePositiveHIVTest.pdf

"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."

"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 et al. False-Positive and Indeterminate Human Immunodeficiency Virus Test Results in Pregnant Women. Arch Fam Med. 2000 Sep/Oct; 9: 924-9. http://davidcrowe.ca/SciHealthEnv/papers/1060-FalsePos-Indeter-PregnantWomen.pdf
"We report the case of a sexually active woman with symptoms suggestive of ARS [Acute Retroviral Syndrome] who had a false-positive HIV-1 RNA assay result...Laboratory evaluation revealed negative results on HIV-1 ELISA and Western blot [antibody tests]. However, an HIV-1 RT-PCR [viral load] assay...revealed a viral load of 623 copies/ml, through p24, gp120, and gp160 antigens were not present. The HIV-1 RT-PCR assay was repeated and revealed a similar measurement...Subsequent studies 2 weeks later revealed an undetectable HIV-1 RNA viral load, as well as negative results on HIV-1 ELISA and Western blot serologies. Two months later, the patient's symptoms [headaches, swollen glands etc.] had completely resolved...Four months after the onset of symptoms, the patient remained seronegative for HIV-1 infection"

"Because of the RNA assay's 1.9% to 3.0% false-positive rate, results must be carefully interpreted and compared to HIV-1 viral load levels seen during proven HIV-1 seroconversion. We report the case of a sexually active woman with symptoms suggestive of ARS who had a false-positive HIV-1 RNA assay result."
More D et al. Utility of an HIV-1 RNA assay in the diagnosis of acute retroviral syndrome. S Med J. 2000 Oct; 93(10): 1004-6. http://davidcrowe.ca/SciHealthEnv/papers/1105-HIV-RNA-Assay-ARS.pdf

"Primary infection was defined as a confirmed positive virologic test result with either a negative HIV antibody assay result or an indeterminate Western blot. Because there is no virologic gold standard, we assumed that levels of plasma HIV RNA had a sensitivity of 100% for diagnosing primary infection [bonus marks for detecting the flaw in this logic]. False-positive HIV RNA measurements were defined as those that were negative on repeated testing and those obtained in patients who did not undergo seroconversion [note the contradiction with the previous sentence]...Eight of 303 uninfected patients (2.6%) had false-positive results on HIV RNA testing [note that in a population that is mostly uninfected, this could result in several times more false positives than true positives]"
Daar ES et al. Diagnosis of primary HIV-1 infection. Ann Intern Med. 2001 Jan 2; 134(1): 25-9. http://davidcrowe.ca/SciHealthEnv/papers/1139-Early%20HIV%20tests.pdf

"The controversy currently revolves around one key question: at what CD4+ cell count can the greatest benefit of therapy be achieved with the lowest possible risk of disease progression, drug toxicity, and drug resistance?...[a little later]...if the goal of therapy is to halt further immune deterioration, starting treatment when the CD4+ cell count is between 200 and 350 cells/mm3 may be sufficient. However, if the goal is more complete CD4+ cell restoration, early initiation of therapy may be more effective. [where was all that talk about drug toxicity and disease progression? That seems to have vanished from consideration.]"

"The 2 articles recently published in JAMA are probably among the most important HIV-related papers of the year and have tremendous implications for decision-making. They question the rather arbitrary viral load threshold used in current antiretroviral guidelines and suggest that the main factor that should influence when to start therapy -- and maybe the only one to consider -- should be the CD4+ cell count. The only contributions that viral load can make to this decision are (a) to determine how quickly a given individual is likely to reach the CD4+ cell count threshold at which therapy is indicated, and (b) perhaps to determine the frequency of CD4+ cell-count monitoring. Monitoring viral load only becomes critical when therapy is started."
Tebas P. When should antiretroviral therapy be initiated? Medscape HIV/AIDS. 2002; 8(1).
http://davidcrowe.ca/SciHealthEnv/papers/1580-start%20late.html

"If the French intended to use the CDC to prove they had found the cause of AIDS, Gallo would do the same...[after blinded testing of a number of samples] only 48 percent of Gallo's AIDS patients' samples were positive, compared to the Pasteur [Institute]'s 72 percent...Almost all Sarngadharan's [a member of Gallo's lab] equivocal blood-testing scores, recorded as 'plus/minus', had come from AIDS patients'...Gallo thought the CDC should allow him to change his borderline results to positive. Pasteur hadn't asked to change any of its results after the fact and Don Francis [of the CDC] was against allowing Gallo that extra advantage. [However] Jim Curran agreed to Gallo's request...now Gallo and the French each scored 92 percent of the pre-AIDS patients positive. Among AIDS patients, the French had gotten 80 percent right to Gallo's 78."
Crewdson J. Science fictions: A scientific mystery, a massive cover-up, and the dark legacy of Robert Gallo. Little, Brown. 2002. http://www.sciencefictions.net

"The p24 antigen test had specificity of 99.5%...[but] a lower sensitivity than HIV-1 RNA testing: 79%"

"The third-generation EIA HIV-1 antibody test had a sensitivity of 77% [false negative rate of 23%] and a false-positive rate of 3%. All of the patients with a false-negative third-generation EIA antibody test had a positive p24 antigen test."

"The three tests for HIV-1 RNA were 100% sensitive [in this sample of 40] for preseroconversion PHI [i.e. no people diagnosed with Primary HIV Infection symptoms by other methods did not have detectable RNA]. However, bDNA [branched DNA] testing for PHI had a 5% false-positive rate, PCR testing had a 3% false-positive rate and the transcription-mediated amplification assay had a 2% false-positive rate. The false-positive results on the bDNA test ranged from 584 to 2058 copies/ml. False-positive PCR tests ranged from 58 to 103 copies/ml."
Hecht FM et al. Use of laboratory tests and clinical symptoms for identification of primary HIV infection. AIDS. 2002 May 24; 16(8): 1119-29.
http://davidcrowe.ca/SciHealthEnv/papers/1926-IdentifyPrimaryHIV.pdf

"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://davidcrowe.ca/SciHealthEnv/papers/1995-Worms-VL.pdf

""In my case, I will never go for an HIV test no matter what. I have seen so many people who went [for] that test dying just months after testing positive because knowing you have the virus will psychologically kill you just like that," said Alfred Chanza of Kawale in Lilongwe [Malawi]..."The other problem is the trauma you go through once you know you are positive. I have seen people being discriminated against because they are suffering from Aids. It is so painful and I would not want to be treated like that," the journalist [for the Malawi Broadcasting Corporation] added."
Ligomeka B. Many Malawians are reluctant to go for HIV tests. Malawi Insider. 2002 Sep 26.

"At the present time, if a newborn tests positive at birth, the baby may only be showing passive antibodies, passed along by the mother. As notted earlier, only a small percentage of infants born to HIV positive women will turn out to be infected. Infants who test positive will have their blood retested using a more sophisticated technique called PCR. The State recommends that newborns with a positive HIV test should have the first of two or three PCR tests beginning at one month of age. PCR detects small amounts of genetic material in the blood and produces a definitive HIV diagnosis by the time the infant is two months old...One potential drawback to voluntary testing [why would involuntary testing be any different?] is the unknown toxicity affect AZT use can have on infants who are born without HIV [and what about the toxicity on children who will later be found to be HIV-positive?] and the pregnant women who take it. There are no long-term studies on the efficacy of AZT use on healthy children [how could AZT be effective in HIV-negative children?]. Most clinical studies have excluded women. Moreover, a report prepared by the Institute of Medicine indicated that PCP prophylaxis or antiviral therapy for those who were HIV positive but asymptomatic had serious ramifications, especially regarding toxicity...Convincing pregnant women, especially African Americans, to use AZT or other anti-viral drugs may be difficult. One study showed that African American women hold disturbing views towards AZT use. For instance, some respondents said that AZT could harm them [shocking!], others said the drug was indiscriminately prescribed, while others were unwilling to use it because AZT had not been tested on women of color. A number of respondents indicated that AZT use was a way for pharmaceutical companies to make money"
Cameron T. Mandatory HIV testing of newborns in New York State: what are the implications? J Health Soc Policy. 2002; 14(3): 59-78.
http://davidcrowe.ca/SciHealthEnv/papers/2369-MandatoryTestingNewbornsNY.pdf

"Further legislative measures to support HIV prevention, identified in this review, address requirements for, or offers of, prenatal testing of pregnant women, (9 of 121 [7%], 6% of the world's population)...The observation that 25% of the world's population still lives with laws requiring quarantine, isolation, or coercive hospitalization, measures that heavily infringe on human rights without any documented public health justification, compared with a very much lower percentage that require screening for pregnant women and encouraging the use of condoms, measures the preventive capability of which has been well documented, is a further dismal confirmation of the scarce impact of the international institutions on the legislative activity of member states...Public health is recognized as a

societal good that may at times call for measures that restrict human rights to some extent (16). Nonetheless, any such restrictions are considered acceptable only if they are: 1. "Provided for and carried out in accordance with the law; 2. Based on a legitimate interest, as defined in the provisions guaranteeing the rights; 3. Proportional to that interest and constituting the least intrusive and least restrictive measure available and actually achieving that interest in a democratic society. Public health is most often cited by states as a basis for restricting human rights in the context of HIV/AIDS. Many such restrictions, however, infringe on the principle of non-discrimination". Moreover, "coercive [public health] interventions can be justified in only 3 cases: to avert a risk of serious harm to other persons, to protect the welfare of incompetent persons, and, most controversially, to prevent a risk to the person himself/herself" ."
D'Amelio R et al. A global review of legislation on HIV/AIDS: the issue of HIV testing. J Acquir Immune Defic Syndr. 2001 Oct 1; 28(2): 173-9.
http://davidcrowe.ca/SciHealthEnv/papers/2378-HIVTestLegislation.pdf

"For eight years, Hayward resident Jim Malone attended biweekly counseling sessions for men living with HIV...He had been told in 1996 that he was HIV-positive. Earlier this month, Malone, 59, was summoned to his doctor's office. He listened as the doctor delivered the stunning news: He is HIV negative...Malone had arrived at the clinic in 1996 with lab results from an outside testing firm in Southern California. Those results showed he was HIV positive. The VA did its own confirmatory HIV test on Malone and found he was negative [but due to a list of mixups did not inform him for another 8 years]"
Guthrie J. False diagnosis of HIV discovered after 8 years: Veteran's life severely affected after VA doctor made mistake. San Francisco Chronicle. 2004 Aug 28.

"After testing positive five different times, Nakalembe recently tested negative after two confirmatory tests at Mbuya Parish Outreach Clinic. Two initial tests were done at Mulago Hospital and the third at Mbuya Parish Outreach Clinic...Nakalembe tested positive in January 2003 at the age of 12. Her confirmatory test in July 2003, also posted positive...She suffered depression and stigma, failed to get antiretroviral drugs [luckily!] and her mother resorted to buying local herbs for her...when you test positive to a rapid test kit and the confirmatory test posts negative, a third test has to be done. It is called a tie-breaker kit - it resolves the uncertainty. If it turns out negative, then we know that person is negative...Betty Tibaleka, a journalist who hosted Nakalembe on her Untold Story programme on UBC Television recently, says she has had many stories like Nakalembe's"
Basudde E. HIV negative after five positive results. The New Vision (Uganda). 2007 Apr 3.

"The [new] Genscreen Plus HIV Antigen-Antibody is an EIA [Enzyme Immuno-Assay or ELISA] for the detection of HIV infection based on the detection (sandwich technique) of antibodies to HIV-1 and HIV-2, as well as the HIV-1 p24 antigen in human serum or plasma. These assays become valuable in diagnosing early HIV infection, reducing the window period by 4-5 days compared with third-generation assays [5]. Genscreen Plus is an assay with enhanced sensitivity for HIV antibody detection that does not differentiate between the antigen and antibody signal...In the first 6 months of its introduction we detected three acute HIV seroconversions in adults who tested antibody negative by the third-generation (antibody only) assays...Using this assay in 18 infants with three consecutive negative HIV-DNA PCR we found that eight were antibody negative (age range 18-24 months), and 10 were positive (age range 19-20 months). Of the 10 infants positive by the fourth generation assay, nine were negative by our previous third-generation HIV assay (performed simultaneously). Repeat fourth-generation EIA testing was negative for nine infants within a few months, confirming waning levels of maternal antibody and not emerging infection. In one infant it was not possible to obtain a repeat sample but it shows no clinical evidence of HIV infection [although a positive HIV test with no symptoms is usually accepted as a genuine infection]."

"The [new] Genscreen Plus HIV Antigen-Antibody is an EIA [Enzyme Immuno-Assay or ELISA] for the detection of HIV infection based on the detection (sandwich technique) of antibodies to HIV-1 and HIV-2, as well as the HIV-1 p24 antigen in human serum or plasma...Using this assay in 18 infants with three consecutive negative HIV-DNA PCR we found that eight were antibody negative (age range 18-24 months), and 10 were positive (age range 19-20 months). Of the 10 infants positive by the fourth generation assay, nine were negative by our previous third-generation HIV assay (performed simultaneously). Repeat fourth-generation EIA testing was negative for nine infants within a few months, confirming waning levels of maternal antibody and not emerging infection. In one infant it was not possible to obtain a repeat sample but it shows no clinical evidence of HIV infection [although a positive HIV test with no symptoms is usually accepted as a genuine infection]." Nastouli E et al. False-positive HIV antibody results with ultrasensitive serological assays in uninfected infants born to mothers with HIV. AIDS. 2007 May 31; 21(9): 1222-1223. http://davidcrowe.ca/SciHealthEnv/papers/6161-FalsePositiveHIVTestsInfants.pdf

"Tommy Morrison had a seemingly boundless future in 1996. A former heavyweight boxing champion, he had had a starring role in "Rocky V" and was in line for his biggest payday, a showdown against Mike Tyson. All that came to an abrupt end, though, when he tested positive for H.I.V...In 1996, he tested positive for H.I.V. These days, he is back in the ring. He fought in West Virginia in February, and his return has raised questions of just how a fighter whose blood tested positive for H.I.V. in 1996 could test clean today.
This year, Morrison took two separate blood tests to support his assertion that he was not infected with H.I.V., West Virginia officials said last week. The test results provide new details on why they licensed him to return to the ring 11 years after he tested positive. Two nationally renowned H.I.V. experts reviewed those and a third blood test for The New York Times, and said they suggested Morrison had been knocked out of the ring by false positive tests - if, indeed, the new tests are his blood...Morrison, 38, who has often derided conventional views on H.I.V. and AIDS, said he was pleased to hear some experts supported his assertion of a false positive.

"People are starting to wake up," he said last week in a telephone interview. "There's been a lot of careers destroyed along the way for no reason. Mine's certainly been one of them." The Times obtained copies of three documents, not previously made public, that purport to be tests of Morrison's blood this year.

One of them, negative for H.I.V. antibodies, was a report from LabCorp in Phoenix on blood drawn Feb. 6 and was released by Peter McKinn, Morrison's promoter. The second, which did not detect H.I.V. in DNA, was a LabCorp report on blood drawn Feb. 14 and was released by West Virginia. The state used those tests to license Morrison to box, said Michele Duncan Bishop, general counsel for the West Virginia Department of Revenue, which oversees the athletics commission. A third test, from Specialty Laboratories of Valencia, Calif., on blood drawn Jan. 5, indicates Morrison tested positive for H.I.V. antibodies but negative for H.I.V. in RNA. That report was released by Randy D. Lang, Morrison's former legal adviser, who said the antibody result showed Morrison was still infected. But the experts said the RNA result in the same report raised the possibility that the antibody result was a false positive...The mixed result in the Jan. 5 test makes it "likely that the antibody result is a false positive," according to Dr. Daniel R. Kuritzkes, a Harvard professor who directs AIDS research at Brigham and Women's Hospital in Boston and is chairman of the board of the H.I.V. Medicine Association. Kuritzkes reviewed the test for The Times. Without additional blood work, he added in an e-mail message, "it's hard to know for sure what's going on, but I suspect he was never H.I.V.-infected."

Dr. Michael P. Busch, director of the Blood Systems Research Institute and a professor of laboratory medicine at the University of California, San Francisco, said H.I.V. antibody screening was misinterpreted a small percentage of the time. He said the RNA and DNA

tests, which measure the virus directly rather than through antibodies, would virtually prove that the person was not harboring even a latent infection. "If those results are really all from this person, I would tell you there is no way this person is infected, so something is wrong with those earlier results," Busch said. Busch said there was a biological basis for some false positives on H.I.V. antibody tests, which makes some people repeatedly test false positive, although the reasons are not well understood."
Eligon J et al. Morrison says error in H.I.V. test hurt career. NY Times. 2007 Jul 22.
http://www.nytimes.com/2007/07/22/sports/othersports/22boxing.html?ex=1189915200&en=7595f5062ca56ffb&ei=5070

"In many countries laboratories employ a two-test algorithm that examines repeatedly EIA screen reactive specimens by Western blot, but in England and Wales the prevailing approach has been, and remains, to employ at least two different tests following the initial reactive screening test, as recommended by the World Health Organisation3, or an additional screening test with a line immunoassay (LIA). This approach has been called the 'alternative confirmatory strategy'"

"All screening tests [usually ELISA/EIA] are prone to producing occasional weakly-reactive results that very often do not prove to be consistent with HIV infection...Any screening tests may give rise to some weak reactions. In low-risk populations many of these will not be true HIV-positive results...apply a cautious interpretation to specimens that give weak reactions in some or all assays employed, including weak, or few, bands on Western blot...The golden rules are: 1) caution with weak reactions in some or all assays...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."

"Experience has shown that HIV culture and 'standalone' tests for p24 antigen are of limited diagnostic value. They may be insensitive and/or non-specific, and they are expensive compared with the standard serological screening tests...When testing for p24 Ag it must be remembered that it, too, is prone to false positivity, which must be ruled out by a neutralisation test."

"Experience has shown that HIV culture and 'standalone' tests for p24 antigen are of limited diagnostic value. They may be insensitive and/or non-specific, and they are expensive compared with the standard serological screening tests"

"the not infrequent occurrence of borderline quantitative HIV RNA results can confuse the diagnostic status of the child."

"Any screening tests may give rise to some weak reactions. In low-risk populations many of these will not be true HIV-positive results."

"the not infrequent occurrence of borderline quantitative HIV RNA results can confuse the diagnostic status of the child."

"In many countries laboratories employ a two-test algorithm that examines repeatedly EIA screen reactive specimens by Western blot, but in England and Wales the prevailing approach has been, and remains, to employ at least two different tests following the initial reactive screening test, as recommended by the World Health Organisation3, or an additional screening test with a line immunoassay (LIA). This approach has been called the 'alternative confirmatory strategy'"
Parry JV et al. Towards error-free HIV diagnosis: guidelines on laboratory practice. Commun Dis Public Health. 2003 Dec; 6(4): 334-50.
http://www.hpa.org.uk/cdph/issues/CDPHvol6/No4/6_4guideline1.pdf