

Criteria used to define a positive HIV Western blot

HIV WESTERN BLOT STRIP*		AFR	AUS	FDA	RCX	CDC 1	CDC 2	CON	GER	UK	FRA	MAC									
	ENV	ANY 2	ANY 1	ANY 1	ANY 1	p160/ p120 AND p41	p160/ p120 OR p41	p160/ p120 OR p41	ANY 1	ANY 1	ALL 3	3 WEAK BANDS OR ANY STRONG BAND									
	POL												ANY 3 GAG OR POL	p32 AND p24	ANY 1 AND ANY 1	AND AND	AND AND	OR OR	ANY 1 GAG OR POL	p32 AND p24	ANY 1 OR ANY 1
	GAG																				
	p160																				
	p120																				
	p41																				
	p68																				
	p53																				
	p32																				
	p55																				
	p40																				
	p24																				
p18																					

AFR=AFRICA;¹ AUS=AUSTRALIA;² FDA=US FOOD AND DRUG ADMINISTRATION;³ RCX=US RED CROSS;³ CDC=US CENTER FOR DISEASE CONTROL;³ CON=US CONSORTIUM FOR RETROVIRUS SEROLOGY STANDARDIZATION;³ GER=GERMANY; UK=UNITED KINGDOM; FRA=FRANCE; MACS= US MULTICENTER AIDS COHORT STUDY 1983-1992. * Bands not in electrophoretic order

NOTE:

- I. "The Association of Public Health Laboratories now recommends that patients who have minimal positive results on the 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".⁴
 - II. In February 1993 the US Food and Drug Administration relaxed their criteria in order to "reduce the number of HIV-1 seroindeterminate Western blot interpretations", that is, to increase the number of HIV positive individuals.⁵
1. WHO. (1990). Acquired Immunodeficiency Syndrome (AIDS). Proposed criteria for interpreting results from Western blot assays for HIV-1, HIV-2 and HTLV-I/HTLV-II. *Weekly Epidemiological Record* 65:281-298.
 2. Healy DS, Maskill WJ, Howard TS, et al. (1992). HIV-1 Western blot: development and assessment of testing to resolve indeterminate reactivity. *AIDS* 6:629-633.
 3. Lundberg GD. (1988). Serological Diagnosis of Human Immunodeficiency Virus Infection by Western Blot Testing. *Journal of the American Medical Association* 260:674-679. (Data presented in this paper reveal that when the FDA criteria are used to interpret the HIV Western blot less than 50% of US AIDS patients are HIV positive whereas 10% of persons not at risk of AIDS are also positive).
 4. Mylonakis E, Paliou M, Greenbough TC, Flaningan TP, Letvin NL, Rich JD. Report of a false-positive HIV test result and the potential use of additional tests in establishing HIV serostatus. *Archives of Internal Medicine* 2000;160:2386-8.
 5. Kleinman S, Busch MP, Hall L, et al. (1998). False-positive HIV-1 test results in a low -risk screening setting of voluntary blood donation. *Journal of the American Medical Association* 280:1080-1083.

The criteria that define a positive test in Africa are different from those used in the rest of the world. An African who has antibodies which react with two of three proteins, p41, p120 and p160, is said to be HIV infected. However as far back as 1983,¹⁰ Montagnier accepted that p41 is a normal cellular protein, a view he has not subsequently altered.³⁵ By 1989 evidence accrued which showed that p120 and p160 in the WB

test are composed of subunits of p41.^{36,37} In other words, an African is deemed infected with HIV when he or she has antibodies which react with his or her own proteins. In one study “Of 201 laboratories that performed WB and responded, 44 (21.9%) indicated that they used more than one set of WB interpretive criteria; the remaining 157 (78.1%) laboratories indicated that they used only a single set of criteria to interpret WB results. However, discrepancies in WB interpretive practices occurred even among this latter group; when survey analysts compared the interpretive criteria that the laboratory reported using (e.g. ARC [American Red Cross], ASTPHLD/CDC [Association of State and Territorial Public Health Laboratory Directors/Centers for Disease Control], CRSS [Consortium for Retrovirus Serology Standardization] and Du Pont [FDA licensed]) with the band pattern that same laboratory used to classify a specimen as reactive, only 138 (87.9%) of 157 laboratories indicated a WB pattern that was representative of the interpretive criteria used in that laboratory”.³⁸ In the Genelabs Diagnostic HIV BLOT 2.2 Western Blot Assay Instruction Manual the laboratorian is advised, “Specific guidelines for interpretation may differ depending on the local policies, GENELABS recommends following the accepted policy to be in accordance with local regulations”.³⁷ This is followed by seven different criteria for defining a positive Western blot issued by “different international regulatory bodies”. However, GENELABS follow this advice with “We recommend the following guidelines for the interpretation of the Genelabs Diagnostic HIV BLOT 2.2” and list an eighth set of criteria for a positive Western blot. The manufacturer Bio-Rad advises “Each laboratory performing Western Blot testing should develop its own criteria for band interpretation. Alternatively, band interpretation may be left to the clinician” (Bio-Rad Laboratory Manual 1993). The fact that HIV experts do not agree as to which test, the ELISA or WB, should be used to prove HIV infection³⁹⁻⁴² indicates that neither test is conclusive. With two exceptions, nowhere in the world would a positive ELISA be considered proof for infection. The exceptions are Africa and England. According to Philip Mortimer, the “Western blot detection of HIV antibodies” which is used in most countries to prove HIV infection, “began as, and should have remained, a research tool”³⁹ and should not be used to prove infection with HIV.

10. Barré-Sinoussi F, Chermann JC, Rey F, et al. (1983). Isolation of a T-lymphotropic retrovirus from a patient at risk for acquired immune deficiency syndrome (AIDS). *Science* 220:868-71.

35. Chamaret S, Squinazi F, Courtois Y, Montagnier L. Presence of anti-HIV antibodies in used syringes left out in public places, beaches or collected through exchange programs. XIth International Conference on AIDS 1996, Vancouver.

36. Pinter A, Honnen WJ, Tilley SA, et al. (1989). Oligomeric structure of gp41, the transmembrane protein of human immunodeficiency virus type 1. *Journal of Virology* 63:2674-9.

37. Genelabs Diagnostics Pty Ltd (1999). HIV BLOT 2.2 Instruction Manual. Singapore, 1999.

38. CDC (1991). Interpretive criteria used to report western blot results for HIV-1- antibody testing--United States. *Morbidity and Mortality Weekly Reports* 40:692-5.

39. Mortimer P. (1991). The fallibility of HIV western blot. *Lancet* 337:286-287.

40. Mortimer P, Codd A, Connolly J, et al. (1992). Towards error free HIV diagnosis: notes on laboratory practice. *Public Health Laboratory Service Microbiology Digest* 9:61-64.

41. Turner VF, McIntyre A. (1999). The Yin and Yang of HIV. *NEXUS* 6:29-36.

www.peg.apc.org/~nexus/HIVnotAIDS1.html

42. Christie H. Interview with Dr. Robert Gallo July 1st Palexpo Conference Centre Geneva. [Betacam]. New York, 1998.