

## Criteria defining a positive HIV Western blot

HIV WESTERN BLOT STRIP*		AFR	AUS	FDA	RCX	CDC 1	CDC 2	CON	GER	UK	FRA	MAC
ENV	p160	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
	p120											
	p41											
POL	p68	ANY 3 GAG OR POL	p32	AND	AND	AND	OR	ANY 1 GAG OR POL	p32	AND	OR	
	p53											
	p32											
GAG	p55	p24	ANY 1	AND	AND	p24	p24	ANY 1 GAG OR POL	p24	AND	OR	
	p39											
	p24											
	p18											

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

### NOTES:

- 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".<sup>4</sup>
  - 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.<sup>5</sup>
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. Keinman 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.

NOTE: Each horizontal band on the left represents a protein with which an antibody can react. Serum from a patient is added to a strip and the strip developed. Where there have been antibodies reacting a dark band occurs. The number and location determining a positive test, for the same virus, varies all over the world. Even today there are still no internationally agreed criteria as to what constitutes a positive WB. This gives rise to the bizarre situation where, for example, an individual positive in New York City on the CDC criteria would not be positive in Sydney, Australia. Or an Australian positive with p41, p32, p24 and p18 bands would not be positive in Africa. Or an African positive with a p41 and p120 band would not be positive in Australia, parts of the US or Europe. Confusion over antibody reactivity is confirmed in diagnostic laboratory manuals. The Genelabs Diagnostic HIV BLOT 2.2 Western blot Assay Instruction Manual advises, "Specific guidelines for interpretation may differ depending on the local policies, GENELABS recommends following the accepted policy to be in accordance with local regulations". This is followed by seven different criteria for defining a positive Western blot issued by "different international regulatory bodies". Genelabs also append, "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. This means that "different international regulatory bodies" or "local policies", and not the presumed pathogen determine patterns of antibody reactivity said to prove a retroviral infection. 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).