Criteria defining a positive HIV Western blot

AFR=AFRICA; AUS=AUSTRALIA; FDA=US FOOD AND DRUG ADMINISTRATION; RCX=US RED CROSS; CDC=US CENTER FOR DISEASE CONTROL; CON=US CONSORTIUM FOR RETROVIRUS SEROLOGY STANDARDIZATION; 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”.
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.

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).


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).