

**STATEMENT OF THE AMERICAN ASSOCIATION OF BLOOD BANKS
BEFORE THE BLOOD PRODUCTS ADVISORY COMMITTEE**

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Interpretation of HIV-1 Western Immunoblots

**Presented by Louis Katz, MD
Chair, AABB Transfusion Transmitted Disease Committee**

The American Association of Blood Banks (AABB) is the professional society for over 9,000 individuals involved in blood banking and transfusion medicine and represents roughly 2,200 institutional members, including community and Red Cross blood collection centers, hospital based blood banks, and transfusion services as they collect, process, distribute, and transfuse blood and blood components and hematopoietic stem cells. Our members are responsible for virtually all of the blood collected and more than 80 percent of the blood transfused in this country. For over 50 years, the AABB's highest priority has been to maintain and enhance the safety and availability of the nation's blood supply.

AABB Statement Regarding Interpretation of HIV-1 Western Immunoblots

The AABB is grateful for the attention of the FDA and the Blood Products Advisory Committee on this issue.

You have heard data today drawn from large numbers of blood donors that are a testament to the ability of our donor historical screening methods, in concert with high sensitivity screening assays, to protect the blood supply from HIV infectious donors.

The consequence of the extraordinary sensitivity of these in vitro diagnostics when applied to a population of blood donors with a very low incidence and prevalence of HIV infection is the identification of a substantial pool of false positive test results. False positive results must be reconciled if blood donors are to receive accurate and reassuring messages when they are notified of repeatedly reactive screening test results. Unfortunately, the western blot supplemental assays in use for this purpose are quite nonspecific, generating many indeterminate test results when applied to EIA repeat reactive blood donors.

Place yourselves in the position of an altruistic volunteer blood donor who hears the classic mixed message we give for indeterminate blot results. "We are very certain that you are not infected with HIV, but please don't come back to the Blood Center in the future." This confuses our donors, provokes enormous anxiety and gives them the strong impression that we know less than we really do.

The FDA makes an excellent beginning, we think, by allowing a negative western blot interpretation when only non-viral bands are identified. Volunteer blood donors with these patterns should be counseled that they are not infected. They should be re-enterable according to already accepted re-entry algorithms when subsequent testing at appropriate intervals is negative. No decrement in blood safety will result, and our effort to reassure these donors will be reinforced by our acceptance of their badly needed gift. While the impact on the total blood supply may not be operationally significant, our credibility with this subset of our donors will improve. It is important that similar advantages will accrue to the many clinically oriented HIV testing services around the country.

The excellent beginning that discounting non-viral bands will represent should be a preface to consideration of a similar approach to other clearly non-specific western blot patterns -- for example, isolated p24 reactivity. Seroconverting donors with indeterminate blots, as we have heard from Drs. Busch and Stramer, universally have positive NAT testing, even in minipools. An enormous amount of historical experience, and now almost 12 months of NAT data obtained under IND, informs us that indeterminate immunoblot patterns, in the absence of full seroconversion, do not represent HIV or other pathogenic retroviral infections.

If the data we have heard from Dr. Stramer at ARC are generalizable, there may be as many as 5000 volunteer blood donors annually in the United States with indeterminate tests being stigmatized by our inability to state plainly that their results are medically irrelevant. The FDA needs to start considering the use of nucleic acid testing and repeat serological testing to address the distressing mixed messages we are currently compelled to deliver.