

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

Implementation of NAT for HCV and HIV: Donor and Product Management

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

The American Association of Blood Banks (AABB) is the professional society for over 8,000 individuals involved in blood banking and transfusion medicine and represents roughly 2,000 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.

The AABB compliments the FDA and blood community for the timely and efficient implementation of routine blood donor screening by nucleic acid amplification under IND. The encouragement and flexibility shown by the agency in this effort helped overcome the critical hurdles such a project faces, and the result is a quantifiable decrease in potential window period transmissions of HCV and HIV.

The IND holders, manufacturers and FDA need to cooperate now for timely submission of the voluminous data from these unprecedented clinical trials, leading to expedited licensure of both platforms in use in this county. Licensure will be our member's best assurance of continued research and development to improve current assays and develop more robust tests. A pressing need is application of the levels of automation required for the tight process control we are now demanding in blood collection facilities.

Data presented in public forums and to this committee from the ongoing INDs, as well as the historically low yield of the HIV-1 p24 antigen test, strongly support the feasibility of discontinuing the requirement for testing of volunteer whole blood donors. We encourage the IND holders to submit their data as quickly as possible and the FDA to consider discontinuation of p24 testing as soon as they have adequately evaluated the information.

You have seen draft donor management algorithms to be applied to NAT screened populations. We encourage the agency to adopt such common sense approaches, and not unnecessarily complicate donor requalification algorithms in the event of false positive testing with NAT.

There is, based on the data we have seen, no reason for FDA to continue requirements for supplemental, more specific, serological assays such as RIBA, western blot and immunofluorescence, in EIA reactive/NAT reactive volunteer whole blood donors. FDA rules requiring these tests should be revised as soon as possible to reflect the additional information we are routinely and rapidly receiving on our donors, so that it can be used in our counseling, deferral and medical referral messages.