



Management of Donors and Units that Test Positive for Hepatitis B Virus (HBV) DNA by Nucleic Acid Tests (NAT)

**Blood Products Advisory Committee, July 21, 2005
Roger Y. Dodd, PhD**

**Chair, AABB Transfusion Transmitted Diseases Committee for
AABB, America's Blood Centers, American Red Cross**

AABB, America's Blood Centers (ABC), and the American Red Cross (ARC) appreciate the opportunity to address the Blood Products and Advisory Committee (BPAC) on the issue of management of donors and units that test positive for hepatitis B virus (HBV) DNA by nucleic acid tests (NAT).

AABB, ABC, and ARC support FDA's position on the desirability of an algorithm for reentering donors with false positive HBV DNA results and negative HBV serology (HBsAg and anti-HBc) results. We agree in general with the proposed reentry algorithm but request a clarification with regard to item 3.i.c. which reads: " c) If a negative individual sample HBV NAT result is obtained (at least 6 months after the original donation), together with a repeatedly reactive HBsAg result and/or a repeatedly reactive anti-HBc result, the donor should be further evaluated as described in the FDA recommendations. (Note: FDA's guidance documents do not yet address reentry of donors of blood and blood components intended for transfusion, who test anti-HBc repeatedly reactive on more than one occasion.)" We interpret this statement to mean that if such a donor tests anti-HBc reactive with no other HBV markers, then that donor is reentered and eligible to donate as per the HBV NAT reentry algorithm. We recognize that such a donor would be recorded as having a single hit for anti-HBc and that a subsequent reactive anti-HBc result would disqualify the donor.

With regard to anti-HBc reentry, AABB, ABC, and ARC urge FDA to issue a guidance document addressing anti-HBc reentry that supports the proposed algorithm endorsed by BPAC at its October 2004 meeting. We continue to encourage manufacturers of HBV DNA tests to qualify such algorithms in tandem with anti-HBc screening tests having improved specificity.

We agree with FDA that the major motivation for retesting an HBV NAT positive donor prior to the six-month reentry interval is to obtain information for accurate and

appropriate donor counseling. In addition, early retesting will provide important scientific information about early HBV infection and about HBV NAT performance. We encourage early retesting when it can assist with donor counseling.

In conclusion, accurate donor counseling messages along with reentry of donors testing falsely positive for any HBV marker whether HBV DNA, HBsAg or anti-HBc should be encouraged.

AABB is an international association dedicated to advancing transfusion and cellular therapies worldwide. Our members include more than 1,800 hospital and community blood centers and transfusion and transplantation services as well as approximately 8,000 individuals involved in activities related to transfusion, cellular therapies and transplantation medicine. For over 50 years, AABB has established voluntary standards for, and accredited institutions involved in, these activities. AABB is focused on improving health through the advancement of science and the practice of transfusion medicine and related biological therapies, developing and delivering programs and services to optimize patient and donor care and safety.

Founded in 1962, America's Blood Centers is North America's largest network of community-based blood programs. Seventy-seven blood centers operate more than 600 collection sites in 45 U.S. states and Canada, providing half of the United States, and all of Canada's volunteer donor blood supply. These blood centers serve more than 180 million people and provide blood products and services to more than 4,200 hospitals and health care facilities across North America.

The American Red Cross, through its 36 Blood Services Regions and nine National Testing Laboratories, supplies approximately half of the nation's blood supply. Over six million units of Whole Blood were collected from more than four million Red Cross volunteer donors, separated into 12 million components, and supplied to over 3000 hospitals to meet the transfusion needs of patients last year. Over one million liters of plasma from volunteer blood donations are recovered annually by the American Red Cross, further processed into numerous plasma derivatives, and distributed to healthcare providers.