



Blood Systems, Inc.

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October 25, 2005

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 2005D-0261: Draft "Guidance for Industry-Nucleic Acid Testing (NAT) for Human Immunodeficiency Virus Type 1 (HIV-1) and Hepatitis C Virus (HCV): Testing, Product Disposition, and Donor Deferral and Reentry" 27 July 2005

Dear Docket Officer:

Blood Systems Inc (BSI) is the parent company for United Blood Services, which operates 18 blood centers situated in 12 states west of the Mississippi, collecting 1.1 million units of red blood cells and about 120,000 apheresis platelet concentrates. We operate two centralized donor testing labs and 1 transfusion medicine research institute in San Francisco, California.

BSI acknowledges and supports the comments made by the American Association of Blood Banks (AABB) and America's Blood Centers (ABC) and wishes to provide FDA with data in support of allowing donors with unreadable anti-HIV-1 Western Blots (WB) to be considered for re-entry.

Enclosed with these comments is an abstract presented at the AABB annual meeting in Seattle (October 2005). Data showed that Donor F/U samples from 45% of unreadable (UNR) cases were available for repeat HIV-1 WB. The majority of F/U samples yielded UNR results on repeat WB. 89% of these repeat WB UNR samples were negative by HIV-1 IFA, 11% were inconclusive, and none were positive.

IV. RECOMMENDATIONS - 7. Reentry for Donors Deferred Because of HIV-1 Test Results, page 20, "...Donors who were NAT-Non-Reactive (or NAT was not performed) and who were Repeatedly Reactive on a screening test for HIV-1 antibody, with an HIV-1 Western Blot or IFA that was Negative (or was not performed), or an HIV-1 Western Blot result that was Indeterminate (viral bands may be present). This includes donors previously deferred because of Repeatedly Reactive serologic test results prior to the initiation of testing by NAT."

CLARIFICATION REQUEST – This section should clarify that this statement also applies to a Western Blot that is classified as unreadable as follows: "Donors who were NAT-Non-Reactive (or NAT was not performed) and who were Repeatedly Reactive on a screening test for HIV-1 antibody, with an HIV-1 Western Blot or IFA that was NOT positive. This includes donors previously deferred because of Repeatedly Reactive serologic test results prior to the initiation of testing by NAT."

Questions concerning these comments may be directed to Nancy Lynch, Senior Regulatory Associate at nlynch@bloodsystems.org or (480) 675- 5606.

Sincerely,

Hany Kamel, M.D.
Corporate Medical Director