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ANALYSIS OF DONORS ELIGIBLE FOR A MODIFIED HBSAG RE-ENTRY PROTOCOL

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Background:

At the end of July, 2003, a large regional blood donor testing laboratory implemented a new HBsAg EIA for routine donor screening and confirmatory testing. This new assay demonstrated improved sensitivity in clinical trials with specificity approximately equivalent to other currently available HBsAg assays. Since that time, several testing facilities implementing this new assay have identified a dramatic increase in repeatedly reactive (RR) donations. The confirmed positive rate did not increase in conjunction with the increased RR rate but a large proportion of the confirmed positive donations were nonreactive for anti-HBc. Data presented at a recent Blood Products Advisory Committee (BPAC) meeting led to a recommendation that blood centers submit a variance request to the FDA to allow evaluation of these HBsAg confirmed positive, anti-HBc nonreactive donors for re-entry.

Analysis:

An analysis of test data generated since implementation of the HBsAg System 3 test was performed to identify the number of donors that would be eligible for re-entry evaluation using a modified HBsAg re-entry protocol. From the end of July 2003 through March 2004, a total of 1,649,000 donations were screened for HBsAg using the System 3 assay. A total of 2,079 (0.126%) donations were repeatedly reactive. Of these 2,079 RR donations, a total of 1,995 were tested by the confirmatory neutralization assay, which resulted in 702 (35%) confirmed positive samples. The remaining 65% of the RR donations were not neutralized in the confirmatory assay. Of the 702 confirmed positive donations, 175 (25%) were also nonreactive for anti-HBc. These 175 donors would be eligible for re-entry evaluation using the modified re-entry protocol described at the BPAC meeting in March.

Conclusion:

With the current RR rate for the new HBsAg assay, a total of 175 donors (9% of the RR donors) could be evaluated for re-entry. Each blood center facility with an FDA-approved variance would be allowed to test these index donations using an alternate, licensed 3.0 HBsAg EIA. Donors with an index donation found RR by the alternate EIA would remain permanently deferred. However, donors with a nonreactive index donation using the alternate EIA could be contacted to submit an 8-week follow-up sample. This follow-up sample would then be tested for HBsAg, anti-HBc and

anti-HBs. Donors with nonreactive results for all three follow-up tests could be re-entered as regular donors. This modified HBsAg re-entry protocol would allow blood centers an opportunity to re-enter donors that might have been deferred inappropriately using the HBsAg System 3 assay.