

Puget Sound Blood Center

OCT 28 A9:17

October 21, 2005

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Re: Docket No. 2005D-0261

Draft Guidance for Industry on Nucleic Acid Testing for Human Immunodeficiency Virus Type 1 and Hepatitis C Virus: Testing, Product Disposition, and Donor Deferral and Reentry

To Whom It May Concern:

Please accept the following comments.

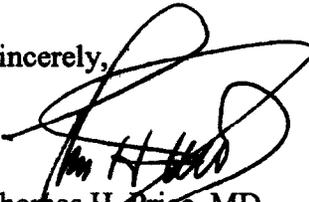
1. The title of this guidance does not reflect that recommendations are for combined NAT and serologic test results for HIV and HCV.
2. Regarding the recommendation to consider for reentry two classes of donors deferred because of HCV test results [page 8 of the draft guidance document]: Please clarify whether a donor who had previously failed HCV reentry because of a second Repeatedly Reactive screening test for HCV antibody could be considered for reentry.
3. Regarding Recommendation IV.7, Reentry for Donors Deferred Because of HIV-1 Test Results [page 20 of the draft guidance document]: Recommendation 7.a.i.(1) specifies using: "a licensed HIV-1 NAT that is the same as the NAT (i.e., the Discriminatory NAT for HIV-1) that was run on the original donor sample..." The phrase in parentheses should be deleted; it does not accurately clarify that samples previously tested using the Roche test should use the Roche test again.
4. Regarding Recommendation IV.7, Reentry for Donors Deferred Because of HIV-1 Test Results [page 21 of the draft guidance document]: Please clarify whether a donor who was deferred for reactive a-HIV-1 test only (i.e., prior to a-HIV-1/2 assay) is eligible to be evaluated for reentry according to this guidance.

2005D-0261

C3

5. Regarding Recommendation IV.7, Reentry for Donors Deferred Because of HIV-1 Test Results and IV.8, Reentry for Donors Deferred Because of HCV Test Results: For both HCV and HIV, this guidance states that if a donor is repeatedly EIA reactive on a sample drawn PRIOR TO the reentry sample, they must be permanently deferred. If a donor is repeatedly reactive ON the reentry sample, an additional follow up sample can be drawn after 8 weeks (6 months for HCV), and the reentry process can proceed. Why isn't this also true for a sample drawn PRIOR TO the reentry sample?
6. Regarding Recommendation IV.7, Reentry for Donors Deferred Because of HIV-1 Test Results and IV.8, Reentry for Donors Deferred Because of HCV Test Results: If the results of follow-up testing on the donor's new sample is NAT Non-Reactive and EIA Repeatedly Reactive, the donor may be reconsidered for reentry by additional follow-up testing after a second waiting period (8 weeks for HIV, 6 months for HCV). Please clarify whether NAT NR, EIA RR results on subsequent follow-up testing would again allow the donor to be reconsidered for reentry; i.e., can this cycle be repeated indefinitely?
7. Regarding Figure 7. Reentry for donors deferred because of HIV-1 Test Results, Footnote #9:
Please clarify the phrase "or if an Indeterminate blot pattern has not progressed."
Does "not progressed" mean no more bands? No different bands? No more viral bands? No different viral bands?
8. Regarding lookback for HCV.
Is HCV lookback to be continued to be performed dating back 5 years prior to the anti-HCV repeatedly reactive donation, or to the date 12 months prior to the donor's most recent negative licensed multiantigen screening test for anti-HCV per the July 19, 1996 Blood Memorandum?

Sincerely,



Thomas H. Price, MD
Medical Director