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CENTER

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Vice President & Chief Medical Officer

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Assistant Clinical Professor
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August 15, 2005

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

Re: Docket No. 2005D-02

To Whom It May Concern:

I write regarding the draft guidance, "Nucleic Acid Testing (NAT) for Human Immunodeficiency Virus (HIV-1) and Hepatitis C Virus (HCV): Testing, Product Disposition and Donor Deferral and Reentry".

I am very pleased that the FDA has issued updated guidance regarding reentry of falsely reactive HIV-1 and HCV donors.

I think that the FDA should clarify that the sample for re-entry should be tested as a singlet NAT. However, when the donor returns to donate, the donation sample would be acceptable to test in a pool as licensed for screening blood donors (both HIV-1 and HCV NAT).

Regarding Table 7-

I think that the HIV-1 P24 Antigen may have false reactive results with a false reactive anti-HIV 1/2 EIA, so the criteria for reentry eligibility could be based on a non-reactive NAT and a Western Blot or IFA indeterminate or negative, which would have to be done to qualify.

Thank you for your time and effort on this guidance. I really appreciate not having to request variances on an individual case by case basis since your work covers so many circumstances.

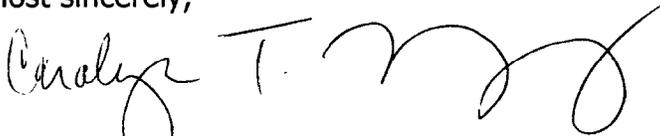
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I'm especially happy to see that there is an additional "second chance" pathway for NAT non-reactive, EIA reactive tests on donors.

I hope you finalize this guidance soon!

Most sincerely,

A handwritten signature in black ink, appearing to read "Carolyn T. Young". The signature is fluid and cursive, with a large loop at the end.

Carolyn T. Young, M.D.
Vice President and Chief Medical Officer
Rhode Island Blood Center

CTY/Imp