

**American
Red Cross**

March 11, 2002

Dockets Management Branch (HFA-305)
Docket No. 01D-0584
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Draft Guidance for Industry: Use of Nucleic Acid Tests on Pooled Samples from Source Plasma Donors to Adequately and Appropriately Reduce the Risk of Transmission of HIV-1 and HCV [67 FR 4719, Jan. 31, 2002; Docket No. 01D-0584]

Dear Docket Officer:

This letter is to provide public comments on behalf of the American Red Cross (ARC or Red Cross) concerning the Food and Drug Administration's (FDA or Agency) draft guidance: *Use of Nucleic Acid Tests on Pooled Samples from Source Plasma Donors to Adequately and Appropriately Reduce the Risk of Transmission of HIV-1 and HCV*.

The Red Cross, through its 36 Blood Services regions and 9 testing laboratories, supplies approximately half of the nation's blood for transfusion needs. Blood donated by Red Cross volunteers is also processed or fractionated into plasma derivatives, and the Red Cross is also a large supplier of human allograft tissue.

The Red Cross is committed to the safety of our donors, our patients, and the public we serve. Thus, the Red Cross fully supports the intent behind this guidance, which is to require the use of Nucleic Acid Tests (NAT) on samples associated with Source Plasma collections and promote the use of licensed NAT kits. However, the Red Cross believes that the guidance does not include allowances for blood manufacturers that are not sole collectors of Source Plasma but who collect and manufacture Source Plasma as a small part of their other blood and blood component collections.

The Red Cross wishes to raise the following issues and questions concerning the draft guidance:

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Background - ARC Source Plasma and NAT Testing

Although the Red Cross manufactures and ships Source Plasma (Infrequent Voluntary Source Plasma (IVSP)), the vast majority of the ARC's collections are cellular products for transfusion, frozen products for transfusion, and recovered plasma for further manufacture. At this time, plasmapheresis collections (which include both Fresh Frozen Plasma (FFP) for transfusion and IVSP) equal only 1.07% of total Red Cross Whole Blood and blood component collections out of more than 6 million collections per year. Red Cross regional blood centers are seeking an increase in plasmapheresis collections to reach a total of 2.34% of collections. Even with such an increase, the ratio of Source Plasma to other collections would still be minimal.

The Red Cross currently uses the Gen-Probe HIV-1/HCV Assay (under Red Cross' IND: BB-IND 8121), which cross references the test kit manufacturer's IND (BB-IND 8090), to perform real-time Nucleic Acid testing in-house under our control in five NAT laboratories. This test is performed on pools of 16 donor samples, and all samples from allogeneic donors are tested using the Gen-Probe NAT kit. The Gen-Probe NAT kit was licensed on February 27, 2002, for the detection of HIV-1 and/or HCV RNA in plasma from donors of whole blood and blood components for transfusion. The Red Cross will be making the necessary changes to use the licensed Gen-Probe assay under IND in the near future. The approved package insert does not address screening of samples from plasmapheresis donors.

The plasmapheresis samples used for NAT are inseparable from those from Whole Blood and plateletpheresis collections. This holds true for non-Red Cross blood manufacturers, as well.

Based on this, an exemption from the draft guidance's requirement to use only a licensed NAT assay specifically approved for Source Plasma after June 1, 2002, should be granted to manufacturers who collect Whole Blood and blood components.

Impact of the Draft Guidance on NAT

In order to comply with the guidance document without an exemption, ARC would need to develop a system to segregate the plasmapheresis samples from the whole blood samples. The plasmapheresis samples would have to be shipped to the test manufacturer currently licensed to screen Source Plasma, National Genetics Institute (NGI). To use the NGI system, the Red Cross would have to implement systems for pooling (pools of 512), ship pools and samples to NGI, and implement systems for the receipt and distribution of test results. This would require setting up a duplicate system for NAT for less than 1% of Red Cross' total collections. This would not only be unduly cumbersome, it would have significant potential for error as samples were inadvertently shipped and subsequently tested by the wrong licensed test.

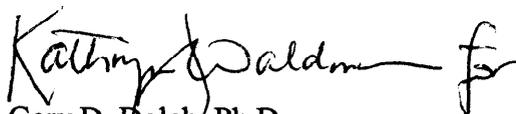
The ARC only uses one system for NAT and would like to continue to do so. The Red Cross has been testing plasmapheresis samples by the Gen-Probe assay and will collect the data and submit it to the FDA in an IND amendment. The Red Cross will also provide the data to Gen-Probe so that they may modify their package insert and submit it to the FDA for approval.

Use of Licensed Tests vs. Approved IND Tests

The Red Cross requests clarification of Section IV, Implementation, Sentence 6, of the draft guidance which states, "After we approve the supplement for use of a licensed HIV-1 and HCV, the establishment may continue use of alternative NAT testing under an approved IND provided that the manufacturer implements the approved test at the same time." The Red Cross does not understand how a blood manufacturer can use a licensed test and alternative NAT under an approved IND unless, as stated previously, the manufacturer is performing NAT twice on samples associated with one donor. We believe FDA intended to indicate that blood centers may use an unlicensed test under an IND until a test is licensed for samples from all whole blood and blood components.

The Red Cross appreciates the Agency's efforts to clarify and communicate their expectations and requirements for Nucleic Acid testing and this opportunity to provide public comments on the draft guidance. If you have any further questions or require follow-up, please contact Anita Ducca, Director, Regulatory Affairs at 703-312-5601 (phone), or DuccaA@usa.redcross.org (e-mail) or Sharon Leiser, Manager, Licensing, 703-312-5809 (phone), or Leiser@usa.redcross.org (e-mail).

Sincerely,



Gary D. Dolch, Ph.D.
Senior Vice President
Quality and Regulatory Affairs
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cc: Indira Hewlett, Ph.D.

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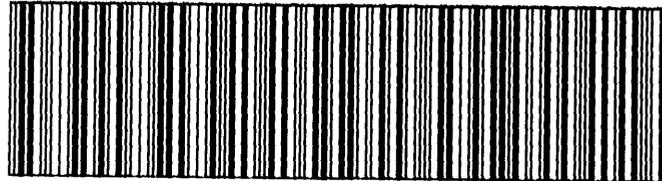
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