



# e-Network Forum

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- Corporate Support →
- Jobs & Sale Listings →
- Useful Links →
- Site Help/Info →
- Member Area Login

### *Frustration of a repeat blood donor who was permanently deferred due to a false positive HIV antibody-screening test*

**An individual located in an Atlantic state** reports that until 1996 he was a frequent blood donor until being informed that he was permanently deferred due to what he refers to as an unconfirmed (false positive) HIV screening test. **Until being deferred he reports being a regular donor and having donated about thirty times.** He is frustrated that he **cannot find a donor center that will consider employing a donor re-entry protocol.** He is aware of the [1992 FDA document](#) [page 10 at that permits some (but not all) HIV screening test false positive donors to be re-entered]. He is aware of the [FDA draft Guidance concerning deferrals and re-entry proposed in 2005](#). He is also aware that it is **up to each individual blood bank** if they want to take advantage of FDA guidance to reenter donors. He is **concerned that many 'good' donors have been disqualified** and asks "How many lives could have been saved if these donors could have been safely requalified?" He also **wonders if the FDA will be finalizing the reentry protocol** so that it is more likely to be followed by a greater number of blood collection centers.

The following comments have been received.

1. **A knowledgeable individual affiliated with the American Red Cross** reports that the **FDA does not permit blood facilities to use the draft Guidance** for HIV and HCV re-entry in association with **blanket variance requests**, but **does permit** use of the draft guidance's algorithms on a **case by case** basis with the submission of a variance request (21 CFR 640.120). The Red Cross has submitted variance requests for dozens of donors who have had false positive HIV antibody screening tests, when the donor requests re-entry, and FDA has turned around these requests promptly. Although it does involve an increased amount of work to prepare the variance requests, the re-entry process itself is the same as described in the draft Guidance so the lack of final Guidance does not impact the major part of the Red Cross process.
2. **A knowledgeable individual affiliated with Blood Systems** reports that the individual (repeat blood donor) who initiated this discussion is well informed of the current regulatory status of re-entry protocols (in effect and in draft form) for donors with unconfirmed HIV screening tests. Briefly, with most blood centers (since 1992) utilizing an EIA anti-HIV-1/2 combination screening test, to be considered for reentry a donor must have a negative confirmatory test (Western Blot or IFA) and a non-reactive result on a second (different) licensed EIA anti-HIV-2 test. **Donors with an indeterminate result on a licensed Western blot, including those due to non-viral bands, are ineligible for re-entry.** The current approved protocol, which was issued prior to the introduction of NAT testing, requires a reentry sample to be collected six months (or later) after the index donation with non-reactive/negative result on a minimum of 4 anti-HIV tests, including a licensed whole virus lysate based HIV-1 EIA. Unsuccessful completion of donor reentry may place a donor in a predicament with future eligibility for a second reentry attempt. With **relatively high rates of indeterminate and unreadable Western blots, the likelihood of successful re-entry is suboptimal.** In addition, if the donor's false reactivity in a screening test is due to a "stable" factor, the prospect for successful reentry remains low until the primary screening test is replaced with a different, more specific test. When this occurs, the reentry algorithm gets more complicated because it introduces a requirement for a substitute sample. The substitute and reentry samples (separated by 180 days or more) must be non-reactive/negative in the four anti-HIV tests mentioned above. **Because of the operational and regulatory complexity,** the current HIV reentry algorithm is not widely used by blood collection centers as noted by the deferred donor. One

blood center cannot re-enter a donor that has been deferred by another blood center. Blood Systems does not routinely offer re-entry for HIV but would consider its application on a case-by-case basis. Like the deferred donor, Blood Systems **awaits the FDA to finalize its guidance document**. The changes included in the draft may be considered as a superior approach since it takes into consideration the NAT results and the detection of HIV-1 group O variant. It is more user friendly from the blood center and the deferred donor perspectives: most donors with indeterminate confirmatory tests would be eligible for re-entry, the interval between the donation and the reentry follow up sample collection is reduced to 8 weeks, and the test algorithm is simpler.

**ADDENDA** March 17, 2008

3. **The 'frustrated donor' who initiated this discussion** comments that after reading the replies from individuals affiliated with the American Red Cross and with Blood Systems, he now appreciates why he is essentially 'persona non grata' at his local blood banks. Yet, he believes that "the challenge remains to increase the available blood supply with safe units as does the need for a executable re-entry procedure." He believes that "the possibility of accomplishing both is at hand if the FDA would finalize the guidance drafted in 2005 using NAT technology."

The **donor asks the following questions**:

1. Are there **any statistics of the number of donors with false positive or likely false positive donations that result in permanent deferral?** He guesses that the number is not trivial since the draft guidance itself states; "Each year, thousands of donors are deferred from donating blood for an indefinite period, because of a false positive test result on a serological test, followed by a Negative or Indeterminate supplemental test for antibodies to HIV-1 or HCV".
2. **How many blood bank sites are attempting to apply the existing re-entry guidance?**
3. He **asks the FDA, "Why the wait?"** He points out that it has been nearly three years since the draft guidance was proposed, the studies are done, and the technology is available.

Please submit comments to the [e-Network Forum](#).

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**Addenda:** March 17, 2008

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