recommendations in section IV.8. (See **Figure 8** and **Table 8**). If the original donor sample that was NAT-Reactive was Positive or Negative on both the Discriminatory NAT for HIV-1 and on the Discriminatory NAT for HCV, you may attempt to reenter the donor according to the recommendations in both sections IV.7 and IV.8 (See **Figures 7** and **8,** and **Tables 7** and **8**).

- Donors who were NAT-Non-Reactive (or NAT was not performed) and who were Repeatedly Reactive on a screening test for HIV-1 antibody, with an HIV-1 Western blot or IFA that was Negative (or was not performed), or an HIV-1 Western blot result that was Indeterminate (viral bands may be present). This includes donors previously deferred because of Repeatedly Reactive HIV serologic test results prior to the initiation of testing by NAT.

  These donors may be eligible for reentry only if the HIV-1 p24 antigen EIA (if done) was Negative and if a second, different, licensed HIV-2 EIA was Negative, or, if the second HIV-2 EIA was Repeatedly Reactive, an investigational HIV-2 supplemental test was not Positive. Currently, we have not approved a supplemental (additional, more specific) test for HIV-2.

- Donors who were NAT Non-Reactive and who were Negative on a screening test for HIV-1 antibody, but who were Repeatedly Reactive on an HIV-1 p24 antigen EIA with a Positive or an Indeterminate (that is, an Invalid or a Non-Neutralized) result on the Neutralization test.

a. **To reenter a donor** who meets FDA eligibility criteria (i.e., the donor is otherwise eligible to donate again), we recommend that you do the following (See **Figure 7** and **Table 7**):

i. At least 8 weeks after the original donation obtain a new sample from the donor (no donation is made at this time) and perform follow-up testing using:

(1) 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 or a licensed HIV-1 NAT that is labeled as sensitive for HIV-1 group O and HIV-1 group M variants;

AND

(2) a licensed anti-HIV-1/2 EIA. If the original donor sample was Repeatedly Reactive on the anti-HIV-1/2 EIA, we recommend that you use that same EIA to test this follow-up sample. If the original donor sample was Negative on the anti-HIV-1/2 EIA, we recommend that you use an Alternate EIA that is labeled as sensitive for HIV-1 Group O.

NOTE: If you wish to perform follow-up testing on a donor who is deferred because of HIV-1 test results, you may do so prior to the end of this 8-week waiting period for donor notification purposes or for medical reasons. Negative results on a follow-up HIV-1 test conducted before the 8 week period ends may be useful in donor counseling. However, only a Negative screening test result obtained at least 8 weeks after the NAT-Reactive or Repeatedly Reactive anti-HIV-1/2 or HIV-1 p24 EIA test result would qualify the donor for reentry. If you again obtain a Reactive NAT or a Repeatedly Reactive anti-HIV-1/2 EIA result during this 8-week waiting period, the donor would not be eligible for reentry and we recommend that you defer the donor permanently.

ii. Evaluate the results of the follow-up testing on the donor's new sample as follows:

(1) If the NAT is Reactive and the anti-HIV-1/2 EIA is Repeatedly Reactive, we recommend that you defer the donor permanently.

(2) If the NAT is Reactive and the anti-HIV-1/2 EIA is Negative, we recommend that you defer the donor permanently.

(3) If the NAT is Non-Reactive and the anti-HIV-1/2 EIA is Repeatedly Reactive, you may reconsider the donor for reentry by additional follow-up testing after a second waiting period of 8 weeks.

When there is a persistent anti-HIV-1/2 EIA Repeatedly Reactive result, you may wish to further test the donor's new sample using an HIV-1 Western Blot. If the Western Blot test result is Negative, or an Indeterminate blot pattern has not progressed, you may reconsider the donor for reentry by additional follow-up testing after a second waiting period of 8 weeks. If the Western blot result is Positive, we recommend that you defer the donor permanently.

(4) If the NAT is Non-Reactive and the anti-HIV-1/2 EIA is Negative, you may **reenter the donor** (i.e., the donor is **eligible to donate in the future, provided the donor meets all donor eligibility criteria).**

8. Reentry for Donors Deferred Because of HCV Test Results

Currently, FDA has not approved a process for reentry of donors with the following HCV test results:

- NAT-Reactive for HCV (either by a Discriminatory NAT after a Reactive Multiplex NAT or by a separate NAT for HCV RNA) and anti-HCV EIA Repeatedly Reactive (regardless of HCV RIBA test result).

OR

- NAT-Non-Reactive for HCV (or HCV NAT not performed) and anti-HCV EIA Repeatedly Reactive, HCV RIBA Positive.

FDA has approved a method or a process for reentry of deferred donors in the following classes:

- Donors who were NAT-Reactive and seronegative. This includes donors previously deferred because of Reactive test results on an investigational HCV NAT. The HCV Discriminatory NAT may have been either Positive or Negative. If an Additional NAT for HCV (validated for use with individual donor samples) was performed, it must have been Non-Reactive.

NOTE: If the original donor sample that was NAT-Reactive was Negative on the Discriminatory NAT for HCV but was Positive on the Discriminatory NAT for HIV-1, you may attempt to reenter the donor according to the recommendations in section IV.7. (See **Figure 7** and **Table 7**). If the original donor sample that was NAT-Reactive was Positive or Negative on both the Discriminatory NAT for HCV and on the Discriminatory NAT for HIV-1, you may attempt to reenter the donor according to the recommendations in both sections IV.7 and IV.8 (See **Figures 7** and **8** and **Tables 7** and **8**).

- Donors who were NAT-Non-Reactive (or NAT was not performed) and who were Repeatedly Reactive on a screening test for HCV antibody, with an HCV RIBA that was Indeterminate or Negative (or was not performed). This includes donors previously deferred because of Repeatedly Reactive HCV serologic test results prior to the initiation of testing by NAT.

a. **To reenter a donor** who meets FDA eligibility criteria (i.e., the donor is otherwise eligible to donate again), we recommend that you do the following (See **Figure 8** and **Table 8**):

i. At least 6 months after the original donation obtain a new sample from the donor (no donation is made at this time) and perform follow-up testing using:

(1) A licensed HCV NAT

AND

(2) A licensed anti-HCV EIA.

NOTE: If you wish to perform follow-up testing on a donor who is deferred because of HCV test results, you may do so prior to the end of this 6-month waiting period for donor notification purposes or for medical reasons. Negative results on a follow-up HCV test conducted before the 6-month period ends may be useful in donor counseling. However, only a Negative screening test result obtained at least 6 months after the NAT-Reactive or Repeatedly Reactive anti-HCV test result would qualify the donor for reentry. If you again obtain a Reactive NAT or a Repeatedly Reactive anti-HCV EIA result during this 6-month waiting period, the donor would not be eligible for

reentry and we recommend that you defer the donor permanently.

ii. Evaluate the results of the follow-up testing on the donor's new sample as follows:

(1) If the NAT is Reactive and the anti-HCV EIA is Repeatedly Reactive, we recommend that you defer the donor permanently.

(2) If the NAT is Reactive and the anti-HCV EIA is Negative, we recommend that you defer the donor permanently.

(3) If the NAT is Non-Reactive and the anti-HCV EIA is Repeatedly Reactive, you may reconsider the donor for reentry by additional follow-up testing after a second waiting period of 6 months.

When there is a persistent anti-HCV EIA Repeatedly Reactive result, you may wish to further test the donor's new sample using an HCV RIBA. If the RIBA test result is Negative, you may reconsider the donor for reentry by additional follow-up testing after a second waiting period of 6 months. If the RIBA test result is Positive or Indeterminate, we recommend that you defer the donor permanently.

(4) If the NAT is Non-Reactive and the anti-HCV EIA is Negative, you may **reenter the donor** (i.e., the donor is **eligible to donate in the future, provided the donor meets all donor eligibility criteria).**

V. IMPLEMENTATION

This guidance is being distributed for comment purposes only.

VI. REFERENCES

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2. Glynn SA, Kleinman SH, Wright DJ, Busch MP. International application of the incidence rate/window period model. *Transfusion* 42:966-972 (2002).

3. Dodd RY, Notari EP, Stramer SL. Current prevalence and incidence of infectious disease markers and estimated window period risk in the American Red Cross blood donor population. *Transfusion* 42:975-979 (2002).

4. Fiebig EW, Wright DJ, Rawal BD, et. al. Dynamics of HIV-1 viremia and antibody seroconversion in plasma donors: Implications for diagnosis and staging of primary HIV-1 infection. *AIDS* 17:1871-1879 (2003).

5. FDA Memorandum to All Registered Blood Establishments: "Revised Recommendations for the Prevention of Human Immunodeficiency Virus (HIV-1) Transmission by Blood and Blood Products," April 23, 1992.

6. FDA Memorandum to All Registered Blood and Plasma Establishments: "Recommendations for Donor Screening with a Licensed Test for HIV-1 Antigen," August 8, 1995.

7. FDA Memorandum to All Registered Blood Establishments: "Revised Recommendations for Testing Whole Blood, Blood Components, Source Plasma and Source Leukocytes for Antibody to Hepatitis C Virus Encoded Antigen (Anti-HCV)," August 5, 1993.

8. Federal Register, 11/16/00 (65 FR 69378), Proposed Rule: Current Good Manufacturing Practice for Blood and Blood Components; Notification of Consignees and Transfusion Recipients Receiving Blood and Blood Components at Increased Risk of Transmitting HCV Infection ("Lookback")

9. Federal Register, 12/14/99 (64 FR 71147), Guidance for Industry: In the Manufacture and Clinical Evaluation of *In Vitro* Tests to Detect Nucleic Acid Sequences of Human Immunodeficiency Viruses Types 1 and 2, December 1999.

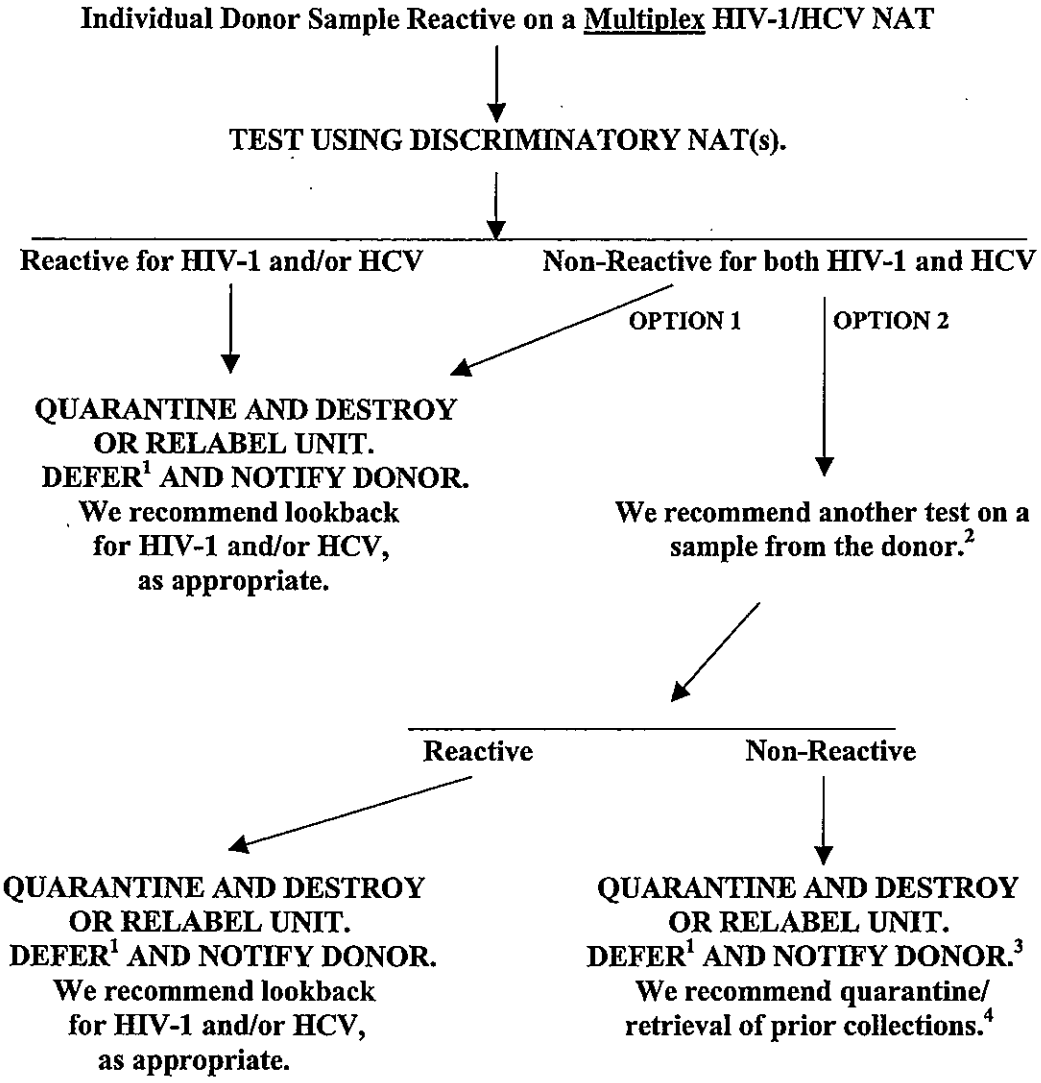
10. Blood Products Advisory Committee, 69th Meeting, June 14, 2001, http://www.fda.gov/ohrms/dockets/ac/cber01.htm-Blood Products Advisory Committee.

11. Alter HJ. To C or not to C: These are the questions. *Blood* 85:1681-1695 (1995).

12. CDC, Recommendations for prevention and control of hepatitis C virus (HCV) infection and HCV-related chronic disease. *MMWR* 47, (RR-19) (1998).

13. See 21 CFR 610.40(b) for licensed test kits or 21 CFR 601.20(a) for licensed in-house assays.

FIGURE 1. TESTING, PRODUCT DISPOSITION, AND DONOR MANAGEMENT FOR AN INDIVIDUAL DONOR SAMPLE THAT IS REACTIVE ON A MULTIPLEX NAT AFTER A NEGATIVE ANTIBODY SCREENING TEST



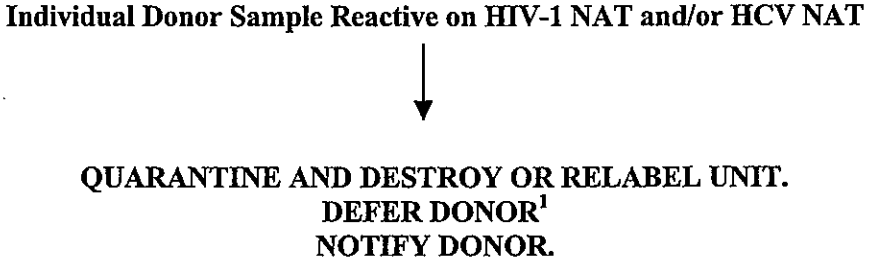
[1] The donor may be eligible for reentry (See Figures 7 and 8).

[2] If you test a new sample from the original donation, you may use the original NAT or Discriminatory NAT(s) or an Additional NAT. Alternatively, you may test the same sample as in the previous NAT tests (e.g., using an Additional NAT).

[3] You may explain to the donor that the test result, while initially Reactive, is not conclusive. There is a slight risk that the initial test result was a Positive result that cannot be excluded without follow-up testing of the donor.

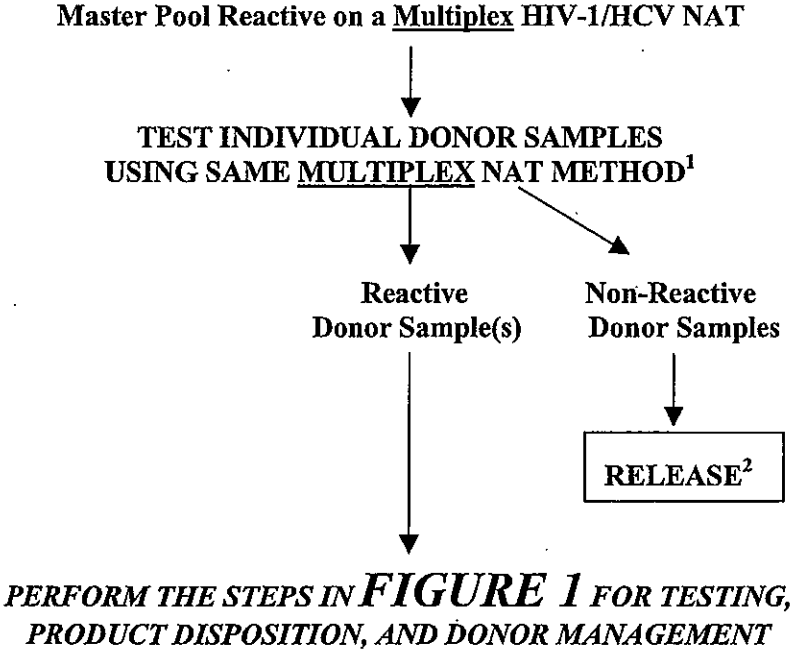
[4] We do not recommend that you notify transfusion recipients.

FIGURE 2. TESTING, PRODUCT DISPOSITION, AND DONOR MANAGEMENT FOR AN INDIVIDUAL DONOR SAMPLE THAT IS REACTIVE ON AN INDIVIDUAL NAT AFTER A NEGATIVE ANTIBODY SCREENING TEST



[1]The donor may be eligible for reentry (See Figures 7 and 8.

FIGURE 3. TESTING, PRODUCT DISPOSITION, AND DONOR MANAGEMENT FOR A MASTER POOL THAT IS REACTIVE ON A MULTIPLEX NAT: RESOLUTION BY TESTING INDIVIDUAL DONOR SAMPLES



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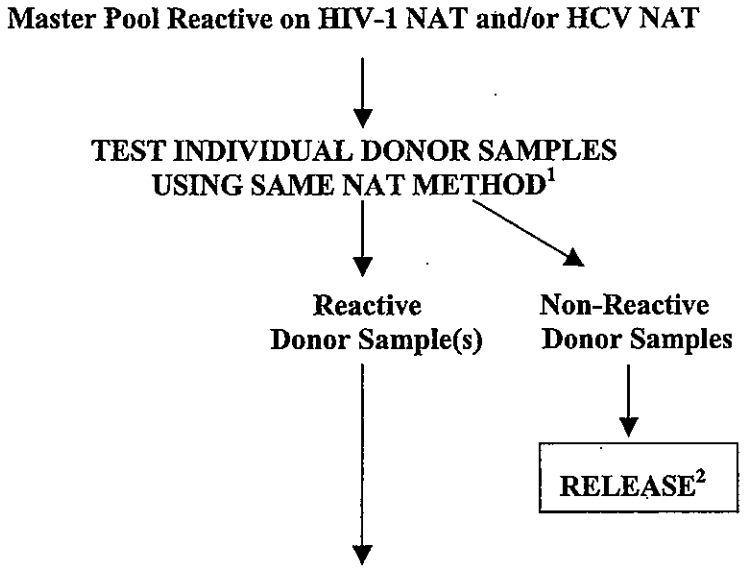
[1] In some cases a different sample preparation procedure may be used per manufacturer's instructions. However, primers and probes should be same as those used in the NAT on Master Pool.

[2] Units may be released only if serologic tests for HIV-1 and HCV are Negative and the units are otherwise suitable for release.

FIGURE 4. TESTING, PRODUCT DISPOSITION, AND DONOR MANAGEMENT FOR A MASTER POOL THAT IS REACTIVE ON AN INDIVIDUAL NAT: RESOLUTION BY TESTING INDIVIDUAL DONOR SAMPLES



PERFORM THE STEPS IN FIGURE 2 FOR TESTING, PRODUCT DISPOSITION, AND DONOR MANAGEMENT

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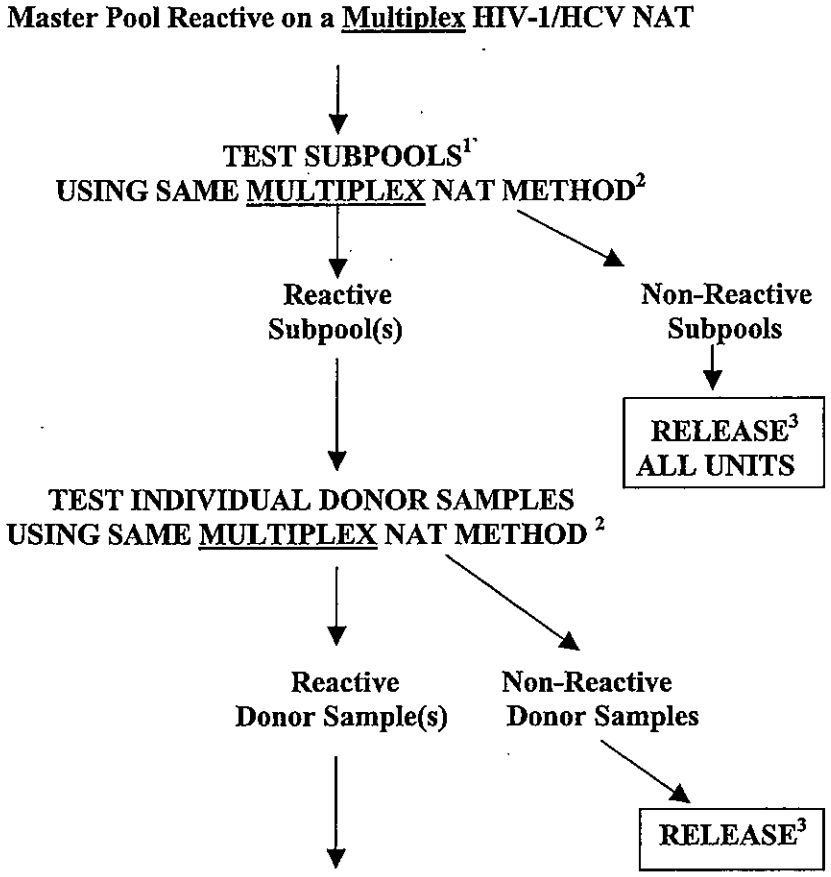
[1] In some cases a different sample preparation procedure may be used per manufacturer's instructions. However, primers and probes should be same as those used in the NAT on Master Pool.

[2] Units may be released only if serologic tests for HIV-1 and HCV are Negative and the units are otherwise suitable for release.

FIGURE 5. TESTING, PRODUCT DISPOSITION, AND DONOR MANAGEMENT FOR A MASTER POOL THAT IS REACTIVE ON A MULTIPLEX NAT: RESOLUTION BY TESTING SUBPOOLS



PERFORM THE STEPS IN FIGURE 1 FOR TESTING, PRODUCT DISPOSITION, AND DONOR MANAGEMENT

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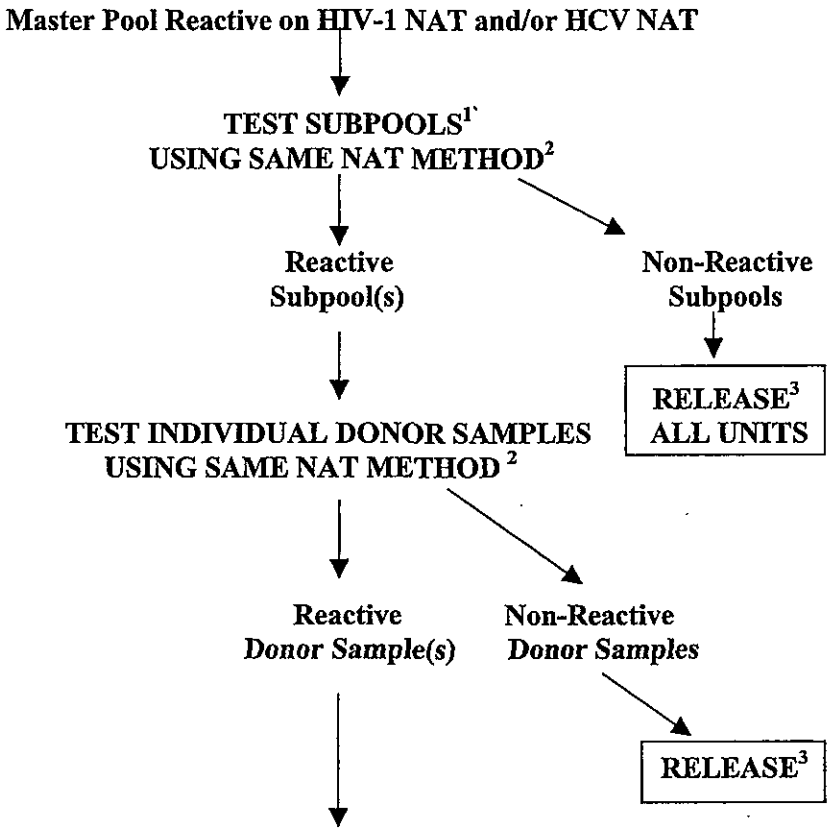
[1] Can be several layers of deconstruction using original or freshly pooled Subpools.

[2] In some cases a different sample preparation procedure may be used per manufacturer's instructions. However, primers and probes should be same as those used in the NAT on Master Pool.

[3] Units may be released only if serologic tests for HIV-1 and HCV are Negative and the units are otherwise suitable for release.

FIGURE 6. TESTING, PRODUCT DISPOSITION, AND DONOR MANAGEMENT FOR A MASTER POOL THAT IS REACTIVE ON AN INDIVIDUAL NAT: RESOLUTION BY TESTING SUBPOOLS



PERFORM THE STEPS IN FIGURE 2 FOR TESTING, PRODUCT DISPOSITION, AND DONOR MANAGEMENT

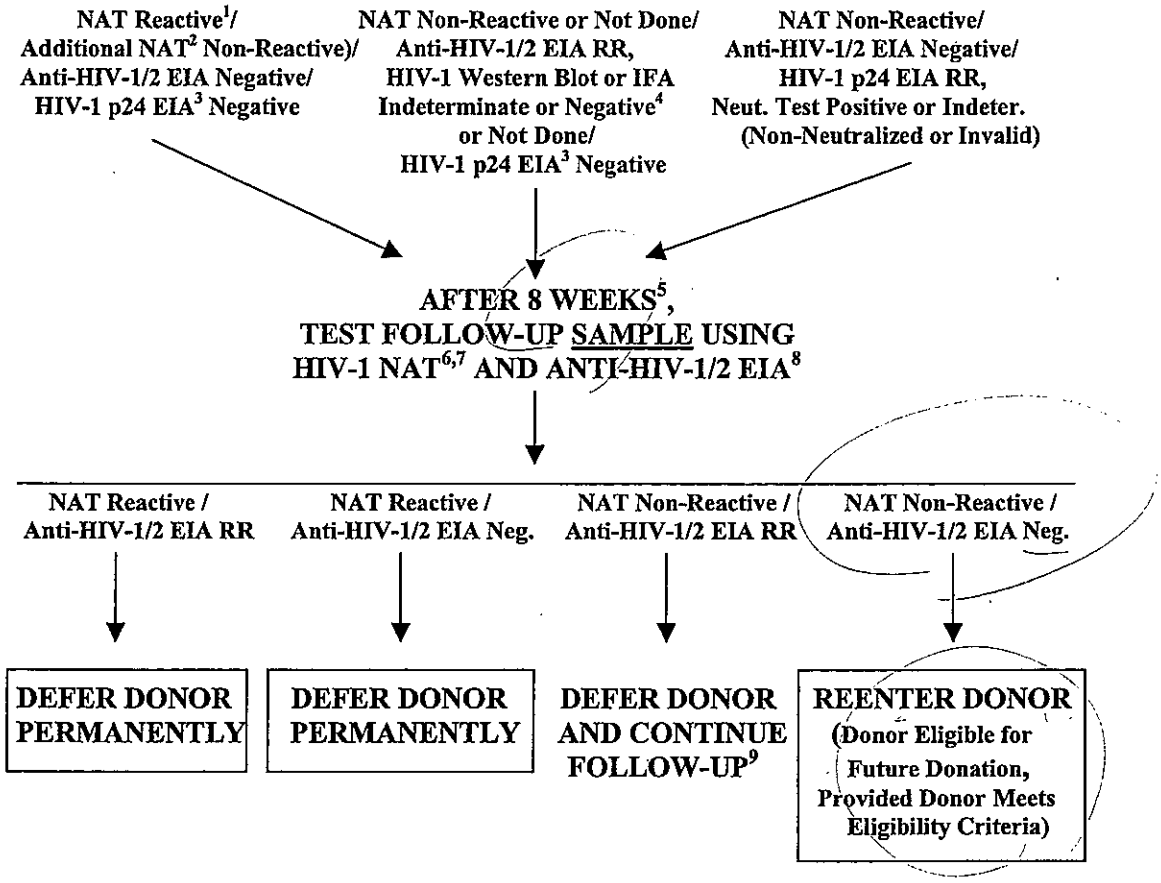
---

[1] Can be several layers of deconstruction using original or freshly pooled Subpools.

[2] In some cases a different sample preparation procedure may be used per manufacturer's instructions. However, primers and probes should be same as those used in the NAT on Master Pool.

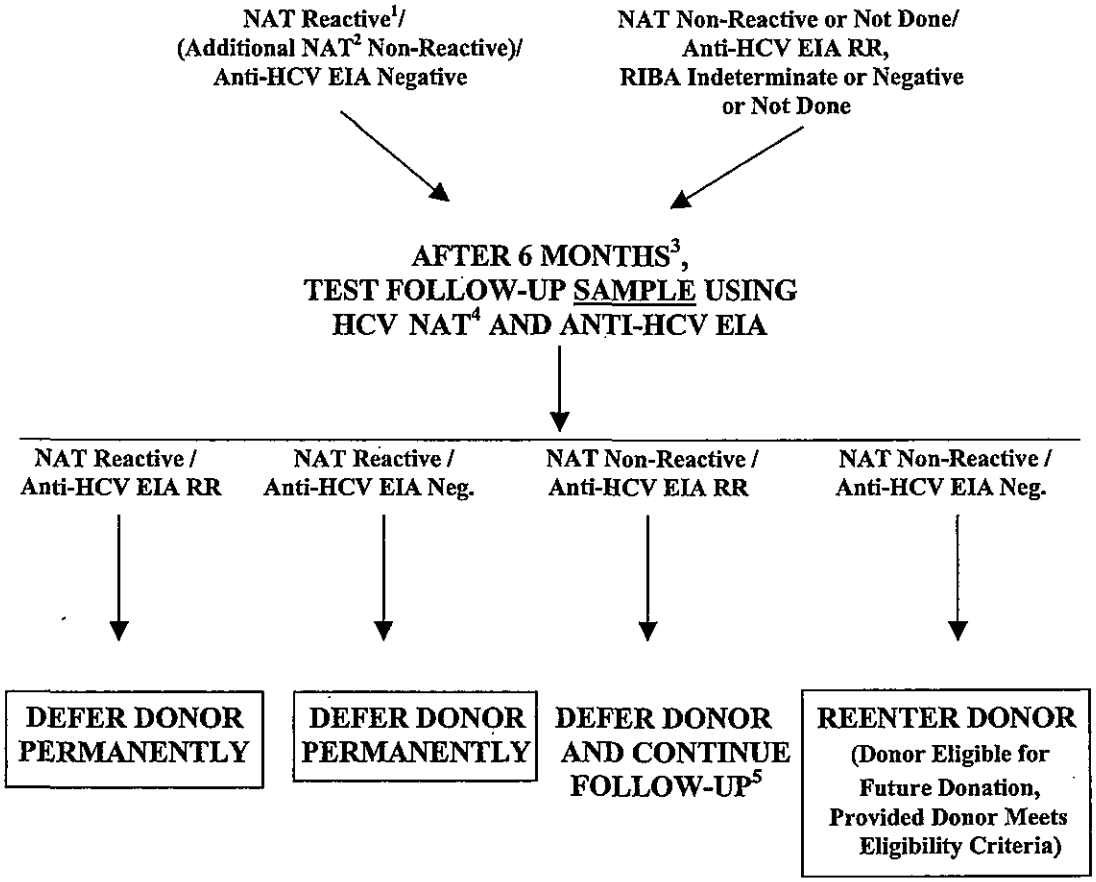
[3] Units may be released only if serologic tests for HIV-1 and HCV are Negative and the units are otherwise suitable for release.

FIGURE 7. REENTRY FOR DONORS DEFERRED BECAUSE OF HIV-1 TEST RESULTS



[1] HIV-1 Discriminatory NAT may be Positive or Negative; however, if Negative and if HCV Discriminatory NAT is Positive, use HCV Reentry Algorithm only (See Figure 8).
[2] An Additional NAT that has been validated for use with individual donor samples.
[3] May not have been performed, depending upon conditions of specific NAT approval.
[4] If a second, different, licensed HIV-2 EIA was Negative or, if Repeatedly Reactive, an investigational HIV-2 Supplemental Test was not Positive.
[5] HIV-1 NAT and/or anti-HIV-1/2 EIA, if performed prior to 8 weeks, must be Negative.
[6] If the original donor sample was Non-Discriminated using Discriminatory NAT for HIV-1 and HCV or was Positive on both of the Discriminatory NAT tests, test a follow-up sample using HCV NAT and Anti-HCV EIA also, as in HCV Reentry Algorithm (See Figure 8).
[7] Using the same NAT (i.e., the Discriminatory NAT for HIV-1) or a NAT labeled as sensitive for HIV-1 Group O and HIV-1 Group M variants.
[8] If the original donor sample was Repeatedly Reactive on the anti-HIV-1/2 EIA, we recommend that you use that same EIA to test this follow-up sample. If the original donor sample was Negative on the anti-HIV-1/2 EIA, we recommend that you use an Alternate EIA that is labeled as sensitive for HIV-1 Group O.
[9] At your option you may further test the donor's sample using HIV-1 Western Blot. If Western Blot is Negative, or if an Indeterminate blot pattern has not progressed, you may reconsider the donor for reentry by additional follow-up testing after a second waiting period of 8 weeks. If Western Blot is Positive, defer the donor permanently.

FIGURE 8. REENTRY FOR DONORS DEFERRED BECAUSE OF HCV TEST RESULTS



[1] HCV Discriminatory NAT may be Positive or Negative; however, if Negative and if HIV-1 Discriminatory NAT is Positive, use HIV-1 Reentry Algorithm only (See Figure 7).

[2] An Additional NAT that has been validated for use with individual donor samples.

[3] HCV NAT and/or anti-HCV EIA, if performed prior to 6 months, must be Negative.

[4] If the original donor sample was Non-Discriminated using Discriminatory NAT for HIV-1 and HCV or was Positive on both of the Discriminatory NAT tests, test a follow-up sample using HIV-1 NAT and Anti-HIV-1/2 EIA also, as in HIV-1 Reentry Algorithm (See Figure 7).

[5] At your option you may further test the donor's sample using HCV RIBA. If RIBA is Negative, you may reconsider the donor for reentry by additional follow-up testing after a second waiting period of 6 months. If RIBA is Positive or Indeterminate, defer the donor permanently.

TABLE 1. TESTING, PRODUCT DISPOSITION, AND DONOR MANAGEMENT FOR AN INDIVIDUAL DONOR SAMPLE THAT IS REACTIVE ON A MULTIPLEX NAT AFTER A NEGATIVE ANTIBODY SCREENING TEST

If:	*Then:*	*After that if:*	*Then:*	*After that if:*	*Then:*
Individual Donor Sample Reactive on a Multiplex HIV-1/HCV NAT	Test the sample using Discriminatory NAT(s)	Reactive for HIV-1 and/or HCV	Quarantine and destroy or relabel unit; defer[1] and notify donor; we recommend lookback for HIV-1 and/or HCV as appropriate		
		Non-Reactive for both HIV-1 and HCV	Quarantine and destroy or relabel unit; defer[1] and notify donor; we recommend lookback for HIV-1 and/or HCV as appropriate		
			OR: We recommend another test[2] on a sample from the donor.	Another test is Reactive	Quarantine and destroy or relabel unit; defer[1] and notify donor; we recommend lookback for HIV-1 and/or HCV as appropriate
				Another test is Non-Reactive	Quarantine and destroy or relabel unit; defer[1] and notify donor[3]; We recommend quarantine/ retrieval of prior collections[4]

[1] The donor may be eligible for reentry (See Figures 7 and 8).
[2] If you test a new sample from the original donation, you may use the original NAT or Discriminatory NAT(s) or an Additional NAT. Alternatively, you may test the same sample as in the previous NAT tests (e.g., using an Additional NAT).
[3] You may explain to the donor that the test result, while initially Reactive, is not conclusive. There is a slight risk that the initial test result was a Positive result that cannot be excluded without follow-up testing of the donor.
[4] We do not recommend that you notify transfusion recipients.

TABLE 2. TESTING, PRODUCT DISPOSITION, AND DONOR MANAGEMENT FOR AN INDIVIDUAL DONOR SAMPLE THAT IS REACTIVE ON AN INDIVIDUAL NAT AFTER A NEGATIVE ANTIBODY SCREENING TEST

If:	*Then:*
Individual Donor Sample Reactive on HIV-1 NAT and/or HCV NAT	**Quarantine the unit**
	Destroy or relabel the unit
	Defer the donor[1]
	Notify the donor
	We recommend lookback for HIV-1 and/or HCV, as appropriate

[1] **The donor may be eligible for reentry (See Figures 7 and 8).**

TABLE 3. TESTING, PRODUCT DISPOSITION, AND DONOR MANAGEMENT FOR A MASTER POOL THAT IS REACTIVE ON A MULTIPLEX NAT: RESOLUTION BY TESTING INDIVIDUAL DONOR SAMPLES

If:	*Then:*	*After that if:*	*Then:*
Master Pool Reactive on a Multiplex HIV-1/HCV NAT	Test the individual donor samples using same Multiplex NAT method[1]	Reactive donor sample(s)	Perform the steps in Table 1 for Testing, Product Disposition, and Donor Management
		Non-Reactive donor samples	Release[2]

[1] In some cases a different sample preparation procedure may be used per manufacturer's instructions. However, primers and probes should be same as those used in NAT on Master Pool.

[2]Units may be released only if serologic tests for HIV-1 and HCV are Negative and the units are otherwise suitable for release.

TABLE 4. TESTING, PRODUCT DISPOSITION, AND DONOR MANAGEMENT FOR A MASTER POOL THAT IS REACTIVE ON AN INDIVIDUAL NAT: RESOLUTION BY TESTING INDIVIDUAL DONOR SAMPLES

If:	*Then:*	*After that if:*	*Then:*
Master Pool Reactive on HIV-1 NAT and/or HCV NAT	Test the individual donor samples using same NAT method[1]	Reactive donor sample(s)	Perform the steps in Table 2 for Testing, Product Disposition, and Donor Management
		Non-Reactive donor samples	Release[2]

[1] In some cases a different sample preparation procedure may be used per manufacturer's instructions. However, primers and probes should be same as those used in NAT on Master Pool.

[2]Units may be released only if serologic tests for HIV-1 and HCV are Negative and the units are otherwise suitable for release.

TABLE 5. TESTING, PRODUCT DISPOSITION, AND DONOR MANAGEMENT FOR A MASTER POOL THAT IS REACTIVE ON A MULTIPLEX NAT: RESOLUTION BY TESTING SUBPOOLS

<table>
<tr><th>If:</th><th>Then:</th><th>After that if:</th><th>Then:</th><th>After that if:</th><th>Then:</th></tr>
<tr><td rowspan="3">Master Pool Reactive on a Multiplex HIV-1/HCV NAT</td><td rowspan="3">Test subpools[1] using same Multiplex NAT method[2]</td><td rowspan="2">Reactive subpool(s)</td><td rowspan="2">Test the individual donor samples using same Multiplex NAT method[2]</td><td>Reactive donor sample(s)</td><td>Perform the steps in Table 1 for Testing, Product Disposition, and Donor Management</td></tr>
<tr><td>Non-Reactive Donor samples</td><td>Release[3]</td></tr>
<tr><td>Non-Reactive subpool(s)</td><td>Release all units[3]</td><td></td><td></td></tr>
</table>

[1] Can be several layers of deconstruction using original or freshly pooled Subpools.

[2] In some cases a different sample preparation procedure may be used per manufacturer's instructions. However, primers and probes should be same as those used in the NAT on Master Pool.

[3] Units may be released only if serologic tests for HIV-1 and HCV are Negative and the units are otherwise suitable for release.

TABLE 6. TESTING, PRODUCT DISPOSITION, AND DONOR MANAGEMENT FOR A MASTER POOL THAT IS REACTIVE ON AN INDIVIDUAL NAT: RESOLUTION BY TESTING SUBPOOLS

If:	*Then:*	*After that if:*	*Then:*	*After that if:*	*Then:*
Master Pool Reactive on HIV-1 NAT and/or HCV NAT	Test subpools[1] using same NAT method[2]	Reactive Subpool(s)	Test the individual donor samples using same NAT Method[2]	Reactive donor sample(s)	Perform the steps in Table 2 for Testing, Product Disposition, and Donor Management
				Non-Reactive donor samples	Release[3]
		Non-Reactive Subpools	Release all units[3]		

[1] Can be several layers of deconstruction using original or freshly pooled Subpools.

[2] In some cases a different sample preparation procedure may be used per manufacturer's instructions. However, primers and probes should be same as those used in the NAT on Master Pool.

[3] Units may be released only if serologic tests for HIV-1 and HCV are Negative and the units are otherwise suitable for release.

TABLE 7. REENTRY FOR DONORS DEFERRED BECAUSE OF HIV-1 TEST RESULTS

If:	*Then:*	*After that if:*	*Then:*
NAT Reactive[1] / (Additional NAT[2] Non-Reactive)/ Anti-HIV-1/2 EIA Negative/ HIV-1 p24 EIA[3] Negative OR NAT Non-Reactive or Not Done/ Anti-HIV-1/2 EIA RR, HIV-1 WB or IFA Indeterminate or Negative[4] or Not Done/ HIV-1 p24 EIA[3] Negative OR NAT Non-Reactive/ Anti-HIV-1/2 EIA Negative/ HIV-1 p24 EIA RR, Neut.Test Positive or Indeterminate (Non-Neutralized or Invalid)	After 8 weeks[5] test follow-up sample using HIV-1 NAT[6,7] and Anti-HIV-1/2 EIA[8]	NAT Reactive/ Anti-HIV-1/2 EIA RR	Defer donor permanently
		NAT Reactive/ Anti-HIV-1/2 EIA Negative	Defer donor permanently
		NAT Non-Reactive/ Anti-HIV-1/2 EIA RR	Defer donor and continue follow-up[9]
		NAT Non-Reactive/ Anti-HIV-1/2 Negative	REENTER DONOR (Donor eligible for future donation, provided donor meets eligibility criteria)

[1]HIV-1 Discriminatory NAT may be Positive or Negative; however, if Negative and if HCV Discriminatory NAT is Positive, use HCV Reentry Algorithm only (See Table 8).
[2]An Additional NAT that has been validated for use with individual donations.
[3]May not have been performed, depending upon conditions of specific NAT approval.
[4]If a second, different, licensed HIV-2 EIA was Negative or, if Repeatedly Reactive, an investigational HIV-2 Supplemental Test was not Positive.
[5]HIV-1 NAT and/or anti-HIV-1/2 EIA, if performed prior to 8 weeks, must be Negative.
[6]If the original donor sample was Non-Discriminated using Discriminatory NAT for HIV-1 and HCV or was Positive on both of the Discriminatory NAT tests, test a follow-up sample using HCV NAT and Anti-HCV EIA also, as in HCV Reentry Algorithm (See Table 8).
[7]Using the same NAT (i.e., the Discriminatory NAT for HIV-1) or a NAT labeled as sensitive for HIV-1 Group O and HIV-1 Group M variants.
[8]If the original donor sample was Repeatedly Reactive on the anti-HIV-1/2 EIA, we recommend that you use that same EIA to test this follow-up sample. If the original donor sample was Negative on the anti-HIV-1/2 EIA, we recommend that you use an Alternate EIA that is labeled as sensitive for HIV-1 Group O.
[9]At your option you may further test the donor's sample using HIV-1 Western Blot. If Western Blot is Negative, or if an Indeterminate blot pattern has not progressed, you may reconsider the donor for reentry by additional follow-up testing after a second waiting period of 8 weeks. If Western Blot is Positive, defer the donor permanently.

TABLE 8. REENTRY FOR DONORS DEFERRED BECAUSE OF HCV TEST RESULTS

If:	*Then:*	*After that if:*	*Then:*
NAT Reactive[1]/ (Additional NAT[2] Non-Reactive)/ Anti-HCV EIA Negative OR NAT Non-Reactive or Not Done/ Anti-HCV EIA RR, RIBA Indeterminate or Negative or Not Done	After 6 months[3] test follow-up sample using HCV NAT[4] and Anti-HCV EIA	NAT Reactive/ Anti-HCV EIA RR	Defer donor permanently
		NAT Reactive/ Anti-HCV EIA Negative	Defer donor permanently
		NAT Non-Reactive/ Anti-HCV EIA RR	Defer donor and continue follow-up[5]
		NAT Non Reactive/ Anti-HCV EIA Negative	REENTER DONOR (Donor eligible for future donations, provided donor meets eligibility criteria)

[1] HCV Discriminatory NAT may be Positive or Negative; however, if Negative and if HIV-1 Discriminatory NAT is Positive, use HIV-1 Reentry Algorithm only (See Table 7).

[2] An Additional NAT that has been validated for use with individual donations.

[3] HCV NAT and/or anti-HCV EIA, if performed prior to 6 months, must be Negative.

[4] If the original donor sample was Non-Discriminated using Discriminatory NAT for HIV-1 and HCV or was Positive on both of the Discriminatory NAT tests, test a follow-up sample using HIV-1 NAT and Anti-HIV-1/2 EIA also, as in HIV-1 Reentry Algorithm (See Table 7).

[5] *At your option you may further test the donor's sample using HCV RIBA. If RIBA is Negative, you* may reconsider the donor for reentry by additional follow-up testing after a second waiting period of 6 months. If RIBA is Positive or Indeterminate, defer the donor permanently.