At the meeting of the Blood Products Advisory Committee (BPAC) in March 2001, we requested advice on appropriate algorithms for management of donations of human blood and blood components tested by pooled donor sample NAT for both HIV-1 RNA and HCV RNA. In particular, FDA sought comment on actions to be taken in the event of discrepant testing results, such as when the Master Pool is Reactive but individual donor samples test Non-Reactive. Data generated using NAT under IND that was presented in the BPAC meeting showed that in each discrepant case it was the Master Pool that was falsely Reactive, due to contamination either during specimen handling or during the assay run. In response to FDA questions, the BPAC voted to consider the NAT result on samples from individual donors as the definitive test result, and recommended release from quarantine for donations from those donors, on the basis of Non-Reactive test results.

This draft guidance document contains six recommended algorithms for use when NAT-Reactive results are obtained on individual samples or pooled samples from donors of human blood and blood components. This draft guidance also contains recommendations on product disposition, donor deferral criteria, follow-up testing of the donor, donor notification and donor reentry criteria that combine NAT and serologic test results, and lookback. This guidance is not intended to replace manufacturers' instructions for testing using approved tests.

The first and second algorithms (See **Recommendations IV.1.** and **IV.2**, **Figures 1** and **2**, and **Tables 1** and **2**) recommend actions to be taken when a NAT-Reactive result is obtained on an individual sample from a donor of human blood or blood components. The third and fourth algorithms (See **Recommendations IV.3.** and **IV.4**, **Figures 3** and **4**, and **Tables 3** and **4**) recommend actions to deconstruct a comparatively small Reactive Master Pool by testing individual donors. The fifth and sixth algorithms (See **Recommendations IV.5** and **IV.6**, **Figures 5** and **6**, and **Tables 5** and **6**) recommend actions to deconstruct a larger Reactive Master Pool by testing archived or freshly pooled subpools to identify the Reactive individual donor(s).

B. Donor Reentry

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. In addition to these deferrals, the implementation of individual donor sample and pooled donor sample NAT for HIV-1 RNA and HCV RNA has resulted in deferrals of several hundred donors each year due to potentially false Reactive NAT results.

These deferred donors are eligible to be considered for reentry to donate blood or blood components. Under § 610.41(b), a deferred donor subsequently may be found to be suitable as a donor by a re-qualification method or process found acceptable for such purposes by FDA. However, some establishments are not attempting to reenter donors because of the complexity of the current reentry algorithms and concerns about

inappropriately reentering a donor. Although we do not require reentry of donors deferred because of false positive test results, we issued guidance in April of 1992 and August of 1993 on reentry of donors deferred because of HIV or HCV test results (Refs. 5, 7).

For those establishments that choose to perform donor reentry, this guidance recommends criteria for reentry of donors deferred because of Reactive HIV-1 or HCV NAT or certain other test results in accordance with § 610.41. We find these criteria to be acceptable within the meaning of § 610.41(b).

These recommendations include two new reentry algorithms based on the combined use of NAT and serologic testing: one for donors deferred because of HIV-1 test results, and a second for donors deferred because of HCV test results. In this draft guidance we recommend that you consider for reentry three classes of donors deferred because of HIV-1 test results (See **Recommendation IV.7**, **Figure 7**, and **Table 7**):

1. Donors who had HIV NAT-Reactive results but were seronegative. This includes donors previously deferred because of Reactive test results on an investigational HIV-1 NAT.

2. Donors with Non-Reactive NAT who have a Repeatedly Reactive screening test for HIV-1 antibody, and Negative or Indeterminate HIV-1 Western Blot or immunofluorescence assay (IFA) results or an HIV-1 Western Blot or IFA was not performed. This includes donors previously deferred because of Repeatedly Reactive HIV serologic test results prior to the initiation of testing by NAT. This class actually includes three subsets of donors, those with a Western Blot that was: (1) Indeterminate with viral bands present, (2) Indeterminate with non-viral bands only, and (3) Negative or not performed.

3. Donors with a Repeatedly Reactive result on an HIV-1 p24 antigen test and with an Indeterminate (an invalid or a non-neutralized) result on the HIV-1 p24 Neutralization test (Ref. 6). In addition, donors with a Positive result on the HIV-1 p24 antigen Neutralization test also may be eligible for reentry because there are many donors who had (false) positive Neutralization test results who are currently Non-Reactive by HIV-1 NAT and Negative by anti-HIV-1/2 EIA. FDA has advised that it no longer recommends that blood and plasma establishments using certain approved NAT methods perform screening for HIV-1 p24 antigen. If antigen testing continues to be performed concurrent with NAT and antibody testing, donors deferred because of HIV-1 p24 test results would continue to be eligible for reentry.

Data presented at the June 2001 BPAC meeting demonstrated that an 8-week waiting period encompasses the pre-seroconversion window period for HIV-1 with sufficient confidence that Negative tests after at least 8 weeks have passed rule out HIV-1 infection

(Ref. 10). Absent evidence for seroconversion, the Negative NAT on follow-up testing would be evidence that any prior Reactive (but unconfirmed) NAT result was an error.

Accordingly, for all three classes of donors, after a minimum time period of 8 weeks, we recommend that you take a follow-up sample from the donor for testing by both HIV-1 NAT and HIV-1 antibody enzyme immunoassay (EIA). Performing follow-up testing first on a sample from the donor before they donate again may prevent a potentially contaminated unit from being collected and placed in inventory at the blood establishment. If the NAT is Non-Reactive and the EIA is Negative on the follow-up sample, the donor may be reentered. The donor would then be tested again at the time of his/her next donation using the battery of screening tests required under § 610.40(b). Thus, two HIV-1 NAT tests would be performed and must be Non-Reactive and two HIV-1 EIA tests would be performed and must be Negative before a unit from that donor could be used. For purposes of donor counseling, you may choose to test the deferred donor with an HIV-1 NAT and an anti-HIV-1/2 EIA test at any time prior to the end of this 8-week waiting period after the original donation. However, if an HIV-1 NAT is Reactive or an anti-HIV-1/2 EIA is Repeatedly Reactive prior to the end of this 8-week waiting period, the donor would not be eligible for reentry and we recommend that you defer the donor permanently.

In this guidance we recommend that you consider for reentry two classes of donors deferred because of HCV test results. (See **Recommendation IV.8.**, **Figure 8**, and **Table 8**):

1. Donors who had HCV NAT-Reactive results but were seronegative on the HCV antibody test. This includes donors previously deferred because of Reactive test results on an investigational HCV NAT.

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

Data presented at the June 2001 BPAC meeting demonstrated that a 6-month follow-up period encompasses the pre-seroconversion window period with sufficient confidence that Negative serologic tests after at least 6 months have passed rule out HCV infection (Ref. 10).

For purposes of reentering both of these classes of deferred donors, we recommend that a sample be taken from the donor, after a minimum time period of 6 months, for follow-up testing by both HCV NAT and anti-HCV EIA. Current research indicates that detectable viremia may be intermittent or may also be resolved in about 15-25% of cases of HCV infection (Refs. 11, 12). If the NAT is Non-Reactive and the EIA is Negative on the

follow-up sample, the donor may be reentered. For purposes of donor counseling and to detect possible HCV viremia, you may also choose to test the deferred donor with an HCV NAT and an anti-HCV EIA test at any time prior to the completion of this 6-month period after the original donation. However, if an HCV NAT is Reactive or an anti-HCV EIA is Repeatedly Reactive prior to the end of this 6-month period, the donor would not be eligible for reentry and we recommend that you defer the donor permanently.

IV. RECOMMENDATIONS

Currently approved tests on individual donor samples for HIV-1 RNA and HCV RNA may be either Multiplex NAT for the simultaneous detection of HIV-1 RNA and/or HCV RNA or separate tests for the RNA of the two viruses.

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 you obtain a Reactive Multiplex HIV-1 RNA/HCV RNA NAT result on an individual donor sample, you must do the following (See **Figure 1** and **Table 1**):

a. Follow the manufacturer's instructions, which instruct you to test the Reactive donation using Discriminatory NAT(s) (§ 610.40(b)) (Ref. 13).

i. If the Discriminatory NAT is Reactive for HIV-1 RNA and/or HCV RNA, you must quarantine the unit (§ 610.40(h)). You must not ship or use the unit unless one of the exceptions described in 610.40(h)(2) applies. If you choose not to destroy the unit, you may release it for research or further manufacture with written approval from FDA. If released for one of these uses, you must re-label the unit consistent with the labeling requirements in § 606.121(f) and § 610.40(h). The unit must be labeled as "Biohazard" and with one of the following cautionary statements as applicable:

"Reactive for HIV-1 RNA"

OR
"Reactive for HCV RNA"

OR

"Reactive for HIV-1 RNA and HCV RNA"

AND EITHER

"Caution: For Further Manufacturing Into In Vitro Diagnostic Reagents For Which There Are No Alternative Sources"

OR

"Caution: For Laboratory Research Use Only."

Further, we recommend that you include on the label after the appropriate Reactive test results one of the following statements:

"Increased risk of transmission of HIV"

OR

"Increased risk of transmission of HCV"

OR

"Increased risk of transmission of HIV and HCV."

You must defer the donor (§ 610.41). The donor may be eligible for reentry (See sections IV.7 and IV.8). You must notify the donor of his/her deferral, providing information about the test results (§ 630.6).

We recommend that you perform lookback (product quarantine/retrieval and notification of recipients of prior collections for HIV-1 and/or HCV), as appropriate.

ii. If the Discriminatory NAT is Non-Reactive for both HIV-1 RNA and HCV RNA, you must quarantine the unit and destroy or relabel the unit as described in section IV.1.a.i above. You must defer the donor (§ 610.41). The donor may be eligible for reentry (See sections IV.7 and IV.8). You must notify the donor of his/her deferral, providing information about the test results (§ 630.6). We recommend that you perform lookback for HIV-1 and HCV.

Alternatively, for purposes of donor notification, you may choose to perform another NAT (the original NAT, or Discriminatory NAT(s), or an Additional NAT)) on a new

sample or the same sample from the original donation. If an Additional NAT is performed, we recommend that the test be one that has been validated for use with individual donor samples.

(a) If you perform another test on a sample from the original donation and it is Reactive, you must quarantine the unit and destroy or relabel the unit as described in section IV.1.a.i above. You must defer the donor (§ 610.41). The donor may be eligible for reentry (See sections IV.7 and IV.8). You must notify the donor of his/her deferral, providing information about the test results (§ 630.6). We recommend that you perform lookback for HIV-1 and/or HCV, as appropriate.

(b) If you perform another test on a sample from the donation and it is Non-Reactive, you must quarantine the unit and destroy or relabel the unit as described in section IV.1.a.i above. You must defer the donor (§ 610.41). The donor may be eligible for reentry (See sections IV.7 and IV.8). You must notify the donor of his/her deferral, providing information about the test results (§ 630.6). In this case 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. We recommend that you quarantine/retrieve prior collections; however, due to the low probability that any of the prior collections was infectious, we do not recommend that you notify transfusion recipients.

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 you obtain a Reactive HIV-1 RNA/HCV RNA NAT result for an individual donor sample (not by Multiplex NAT), you must do the following (See **Figure 2** and **Table 2**):

a. Quarantine the unit (§ 610.40(h)).

You must not ship or use the unit unless one of the exceptions described in § 610.40(h)(2) applies. If you choose not to destroy the unit, you may release it for research or further manufacture with written approval from FDA. If released for one of these uses, you must re-label the unit as described in section IV.1.a.i.

b. Defer the donor (§ 610.41). The donor may be eligible for reentry if serologic test results are negative. (See sections IV.7. and IV.8).

c. Notify the donor of his/her deferral including information about the test results (§ 630.6).

d. We recommend that you perform lookback (product quarantine/retrieval and notification of recipients of prior collections for HIV-1 and/or HCV), as appropriate.

Currently approved tests on Master Pools of donor samples for HIV-1 RNA and HCV RNA may be either Multiplex NAT for the simultaneous detection of HIV-1 RNA and/or HCV RNA or separate tests for the RNA of the two viruses.

In general, there are two approaches to resolving a Master Pool that is Reactive on a Multiplex NAT or a Master Pool that is Reactive using separate tests for the RNA of the two viruses. If you would like to directly test all individual donor samples in a Reactive Master Pool, we recommend that you follow the test algorithms described in sections IV.3 and IV.4. These test algorithms are illustrated in **Figures 3** and **4** and described in **Tables 3** and **4**. If you would like to test subpools that are used to construct a NAT-Reactive Master Pool, we recommend that you follow the test algorithms described in sections IV.5 and IV.6. These test algorithms are illustrated in **Figures 5** and **6** and described in **Tables 5** and **6**.

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 you obtain a Reactive Multiplex HIV-1 RNA/HCV RNA NAT result for a Master Pool, the test instructions for use instruct you to perform subsequent testing to identify the donor sample(s) that is (are) NAT-Reactive as the basis for the NAT-Reactive result on the pool. For comparatively small Master Pools, you may wish to directly test individual donor samples (See **Figure 3** and **Table 3**). You must follow the instructions in the package insert for a licensed NAT test that provides a specific testing algorithm. (§ 610.40(b).)

a. If you directly test the samples from individual donors that constituted the Multiplex NAT-Reactive Master Pool, consistent with the manufacturer's instructions you must test the individual donor samples using the same Multiplex NAT method that was used in the original NAT on the Master Pool (§ 610.40(b)) (Ref.13).

NOTE: In some cases the manufacturer's instructions provide for a different sample preparation procedure. However, the primers and probes would be the same as those used in the original NAT on the Master Pool.

i. If all individual donor samples are Non-Reactive, you may release from quarantine all individual donations (if serologic tests on those donor samples are Negative and the donations are otherwise suitable for release). However, you must investigate the unexplained discrepancy in testing (§ 211.192). Laboratory control procedures must make adequate provisions for monitoring the reliability, accuracy, precision, and performance of laboratory test procedures and instruments, and must include adequate identification and handling of all test samples (§ 606.140(b), (c)). Use of supplies and reagents must be in a manner consistent with the instructions provided by the manufacturer (§§ 606.65(e), 610.40(b)). In addition, as part of an overall Quality Assurance program, we recommend that you conduct additional investigation to determine the cause of the initial reactivity of the Master Pool.

ii. If one (or more) individual donor sample(s) is (are) Reactive, perform the steps in section IV.1.a. above.

You may release from quarantine all Non-Reactive individual donations (if serologic tests on those donor samples are Negative and the donations are otherwise suitable for release).

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 you obtain a Reactive result for a NAT for HIV-1 RNA and/or HCV RNA performed separately on a Master Pool, the test instructions for use instruct you to perform subsequent testing to identify the donor sample(s) that is (are) NAT-Reactive as the basis for the NAT-Reactive result on the pool. For comparatively small Master Pools, you may wish to directly test individual donor samples (See **Figure 4** and **Table 4**). You must follow the instructions in the package insert for a licensed NAT that provides a specific testing algorithm (§ 610.40(b)).

a. If you directly test the samples from individual donors that constituted the NAT-Reactive Master Pool, consistent with the manufacturer's instructions you must test the individual donor samples using the same NAT method that was used in the original NAT on the Master Pool (§ 610.40(b)) (Ref. 13).

NOTE: In some cases the manufacturer's instructions provide for a different sample preparation procedure. However, the primers and probes would be the same as those used in the original NAT on the Master Pool.

i. If all individual donor samples are Non-Reactive, you may release from quarantine all individual donations (if serologic tests on those donor samples are Negative and the donations are otherwise suitable for release). However, you must investigate the unexplained discrepancy in testing (§ 211.192). Laboratory control procedures must make adequate provisions for monitoring the reliability, accuracy, precision, and performance of laboratory test procedures and instruments, and must include adequate identification and handling of all test samples (§ 606.140(b), (c)). Use of supplies and reagents must be in a manner consistent with the instructions provided by the manufacturer (§§ 606.65(e), 610.40(b)). In addition, as part of an overall Quality Assurance program, we recommend that you conduct additional investigation to determine the cause of the initial reactivity of the Master Pool.

ii. If one (or more) individual donor sample(s) is (are) Reactive, perform steps a-d in section IV.2. above.

You may release from quarantine all Non-Reactive individual donations (if serologic tests on those donor samples are Negative and the donations are otherwise suitable for release).

5. Testing, Product Disposition, and Donor Management for a Master Pool that is Reactive on a Multiplex NAT: Resolution by Testing Subpools

If you obtain a Reactive Multiplex HIV-1 RNA/HCV RNA NAT result for a Master Pool, the test instructions for use instruct you to perform subsequent testing to identify the donor sample(s) that is (are) NAT-Reactive as the basis for the NAT-Reactive result on the pool. Deconstruction of the NAT-Reactive Master Pool may be performed by testing the subpools, (original or freshly made), that formed the Master Pool. This deconstruction of the Master Pool to determine the basis for the reactivity may involve several layers of testing using original or freshly pooled subpools, followed by testing of individual donor samples in the Reactive subpool(s) (See **Figure 5** and **Table 5**). You must follow the instructions in the package insert for a licensed NAT that provides a specific testing algorithm (§ 610.40(b)).

a. If you test subpools that were used to construct a Multiplex NAT-Reactive Master Pool, consistent with the manufacturer's instructions you must test the original subpools or freshly pooled subpools using the same Multiplex NAT method that was used in the original NAT on the Master Pool (§ 610.40(b)) (Ref. 13).

NOTE: In some cases the manufacturer's instructions provide for a different sample preparation procedure. However, the primers and probes would be the same as those used in the original NAT on the Master Pool.

i. If all subpools are Non-Reactive, you may release from quarantine all individual donations that comprise the Non-Reactive subpools (if serologic tests on those donor samples are Negative and the donations are otherwise suitable for release). However, you must investigate the unexplained discrepancy in testing (§ 211.192). Laboratory control procedures must make adequate provisions for monitoring the reliability, accuracy, precision, and performance of laboratory test procedures and instruments, and must include adequate identification and handling of all

test samples (§ 606.140(b), (c)). Use of supplies and reagents must be in a manner consistent with the instructions provided by the manufacturer (§§ 606.65(e), 610.40(b)). In addition, as part of an overall Quality Assurance program, we recommend that you conduct additional investigation to determine the cause of the initial reactivity of the Master Pool.

ii. If one (or more) of the subpools is (are) Reactive, you may release from quarantine the individual donations that comprise the Non-Reactive subpools (if serologic tests on those donor samples are Negative and the donations are otherwise suitable for release). Consistent with the manufacturer's instructions, you must test the individual donor samples that comprise the Reactive subpool using the same Multiplex NAT method that was used in the original NAT on the Master Pool (§ 610.40(b)) (Ref. 13).

(1) If all individual donor samples are Non-Reactive, you may release from quarantine all individual donations (if serologic tests on those donor samples are Negative and the donations are otherwise suitable for release). However, you must investigate the unexplained discrepancy in testing (§ 211.192). Laboratory control procedures must make adequate provisions for monitoring the reliability, accuracy, precision, and performance of laboratory test procedures and instruments, and must include adequate identification and handling of all test samples (§ 606.140(b), (c)). Use of supplies and reagents must be in a manner consistent with the instructions provided by the manufacturer (§§ 606.65(e), 610.40(b)). In addition, as part of an overall Quality Assurance program, we recommend that you conduct additional investigation to determine the cause of the initial reactivity of the Master Pool.

(2) If one (or more) individual donor sample(s) is (are) Reactive, perform the steps in section IV.1.a. above.

You may release from quarantine all Non-Reactive individual donations (if serologic tests on those donor samples are Negative and the donations are otherwise suitable for release).

6. Testing, Product Disposition, and Donor Management for a Master Pool that is Reactive on an Individual NAT: Resolution by Testing Subpools

If you obtain a Reactive result for a NAT for HIV-1 RNA and/or HCV RNA performed separately on a Master Pool, the test instructions for use instruct you to perform subsequent testing to identify the donor sample(s) that is (are) NAT-Reactive as the basis for the NAT-Reactive result on the pool. Deconstruction of the NAT-Reactive Master Pool may be performed by testing the subpools (original or freshly made), that formed the Master Pool. This deconstruction of the Master Pool to determine the basis for the reactivity may involve several layers of testing using original or freshly pooled subpools, followed by testing of individual donor samples in the Reactive subpool(s) (See **Figure 6** and **Table 6**). You must follow the instructions in the package insert for a licensed NAT that provides a specific testing algorithm. (§ 610.40(b).)

a. If you test subpools that were used to construct a NAT-Reactive Master Pool, consistent with the manufacturer's instructions you must test the original subpools or freshly pooled subpools using the same NAT method that was used in the original NAT on the Master Pool (§ 610.40(b)) (Ref. 13).

NOTE: In some cases the manufacturer's instructions provide for a different sample preparation procedure. However, the primers and probes would be the same as those used in the original NAT on the Master Pool.

i. If all subpools are Non-Reactive, you may release from quarantine all individual donations that comprise the Non-Reactive subpools (if serologic tests on those donor samples are Negative and the donations are otherwise suitable for release). However, you must investigate the unexplained discrepancy in testing (§ 211.192). Laboratory control procedures must make adequate provisions for monitoring the reliability, accuracy, precision, and performance of laboratory test procedures and instruments, and must include adequate identification and handling of all test samples (§ 606.140(b), (c)). Use of supplies and reagents must be in a manner consistent with

the instructions provided by the manufacturer (§§ 606.65(e), 610.40(b)). In addition, as part of an overall Quality Assurance program, we recommend that you conduct additional investigation to determine the cause of the initial reactivity of the Master Pool.

ii. If one (or more) of the subpools is (are) Reactive, you may release from quarantine the individual donations that comprise the Non-Reactive subpools (if serologic tests on those donor samples are Negative and the donations are otherwise suitable for release). Consistent with the manufacturer's instructions, you must test the individual donations that comprise the Reactive subpool using the same NAT method that was used in the original NAT on the Master Pool (§ 610.40(b)) (Ref. 13).

(1) If all individual donor samples are Non-Reactive, you may release from quarantine all individual donations (if serologic tests on those donor samples are Negative and the donations are otherwise suitable for release). However, you must investigate the unexplained discrepancy in testing (§ 211.192). Laboratory control procedures must make adequate provisions for monitoring the reliability, accuracy, precision, and performance of laboratory test procedures and instruments, and must include adequate identification and handling of all test samples (§ 606.140(b), (c)). Use of supplies and reagents must be in a manner consistent with the instructions provided by the manufacturer (§§ 606.65(e), 610.40(b)). In addition, as part of an overall Quality Assurance program, we recommend that you to conduct additional investigation to determine the cause of the initial reactivity of the Master Pool.

(2) If one (or more) individual donor sample(s) is (are) Reactive, perform steps a-d in section IV.2. above.

You may release from quarantine all Non-Reactive individual donations (if serologic tests on those donor samples are Negative

and the donations are otherwise suitable for release).

7. Reentry for Donors Deferred Because of HIV-1 Test Results

Currently, FDA has not approved a process for reentry of donors with the following HIV-1 test results:

- NAT-Reactive for HIV-1 (either by a Discriminatory NAT after a Reactive Multiplex NAT or by a separate NAT for HIV-1 RNA) and anti-HIV-1/2 EIA Repeatedly Reactive (regardless of HIV-1 Western Blot or IFA or HIV-1 p24 EIA test result);

OR

- NAT-Reactive for HIV-1 (either by a Discriminatory NAT after a Reactive Multiplex NAT or by a separate NAT for HIV-1 RNA) and HIV-1 p24 EIA Repeatedly Reactive (regardless of anti-HIV-1/2 EIA test result);

OR

- NAT-Non-Reactive for HIV-1 (or HIV-1 NAT not performed) and anti-HIV-1/2 EIA Repeatedly Reactive, HIV-1 Western Blot Positive (regardless of HIV-1 p24 EIA test result).

FDA has approved a method or 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 HIV-1 NAT. The HIV-1 p24 antigen EIA may not have been performed if it was replaced by an approved NAT that was validated to replace the HIV-1 p24 antigen test. The HIV-1 Discriminatory NAT may have been either Positive or Negative. If an Additional NAT for HIV-1 (validated for use with individual donor samples) was performed, it must have been Non-Reactive.

  NOTE: If the original donation that was NAT-Reactive was Negative on the Discriminatory NAT for HIV-1 but was Positive on the Discriminatory NAT for HCV, you may attempt to reenter the donor according to the