As discussed in Sections C and D below, 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 HCV RNA, or Single Virus NATs conducted separately for the RNA of the two viruses.

C. Testing, Product Disposition, Donor Management, and Lookback for an Individual Donor Sample that is Reactive on a Multiplex NAT (ID-NAT) after Negative Antibody Screening Tests

If you obtain a reactive Multiplex HIV-1 RNA/HCV RNA NAT result on an individual donor sample (ID-NAT), you must do the following (see Figure 3 and Table 3):

1. Follow the manufacturer's instructions, which instruct you to test the reactive donation using Discriminatory NATs (§ 610.40(b)).

a. 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(§ 610.40(h)(2)(ii)(A). If released for one of these uses, you must appropriately label such blood or blood components as required under § 606.121 or 640.70 and with the "BIOHAZARD" legend. Under § 610.40(h)(2)(ii)(C), except for autologous donations, you must label such human blood and blood components as reactive for the appropriate screening test for evidence of infection due to the identified communicable disease agent(s). We recommend that you use one of the following statements, as applicable:

- "Reactive for HIV-1 RNA" or
- "Reactive for HCV RNA" or
- "Reactive for HIV-1 RNA and HCV RNA".

Under § 610.40(h)(2)(ii)(E), you must also include the following statement, as applicable:

- "Caution: For Further Manufacturing Into In Vitro Diagnostic Reagents For Which There Are No Alternative Sources" or
- "Caution: For Laboratory Research Use Only".

You must defer the donor (§ 610.41). The donor may be eligible for reentry (see sections V.A. and V.B.). You must notify the

donor of his/her deferral, providing information about the test results (§ 630.6).

Under §§ 610.46, 610.47, and 610.48 you must perform lookback (product quarantine/retrieval and notification of recipients of prior collections) for HIV-1 and/or HCV, respectively, as follows:

- If you are an establishment that collects Whole Blood or blood components, including Source Plasma and Source Leukocytes, within 3 calendar days after a donor tests reactive for evidence of HIV-1 and/or HCV infection using the Discriminatory NATs, you must review records dating back 12 months prior to the donor's reactive NAT to identify blood and blood components previously donated by the donor. You must quarantine identified in-date blood and blood components if intended for transfusion or if intended for further manufacture into injectable products (except if pooled), notify consignees so that they may quarantine previously collected in-date blood and blood components, and notify transfusion recipients.

- If you are a consignee of Whole Blood or blood components, including Source Plasma and Source Leukocytes, when notified by the collecting establishment you must quarantine identified previously collected in-date blood and blood components if intended for transfusion or if intended for further manufacture into injectable products (except if pooled). You must notify transfusion recipients who were transfused with blood and blood components collected during the 12 months before the date of the Discriminatory NAT-reactive donation, or notify the recipient's physician of record, of the need for recipient HIV-1 or HCV testing and counseling. You must make reasonable attempts to perform the notification within 12 weeks after receiving the donor's Discriminatory NAT-reactive result for HIV-1 or HCV. If both Discriminatory NATs were reactive, notification of transfusion recipients should specify that the patient should be tested for both HIV-1 and HCV.

b. If the Discriminatory NATs are non-reactive for both HIV-1 RNA and HCV RNA, the sample is "Non-Discriminated Reactive" (NDR)

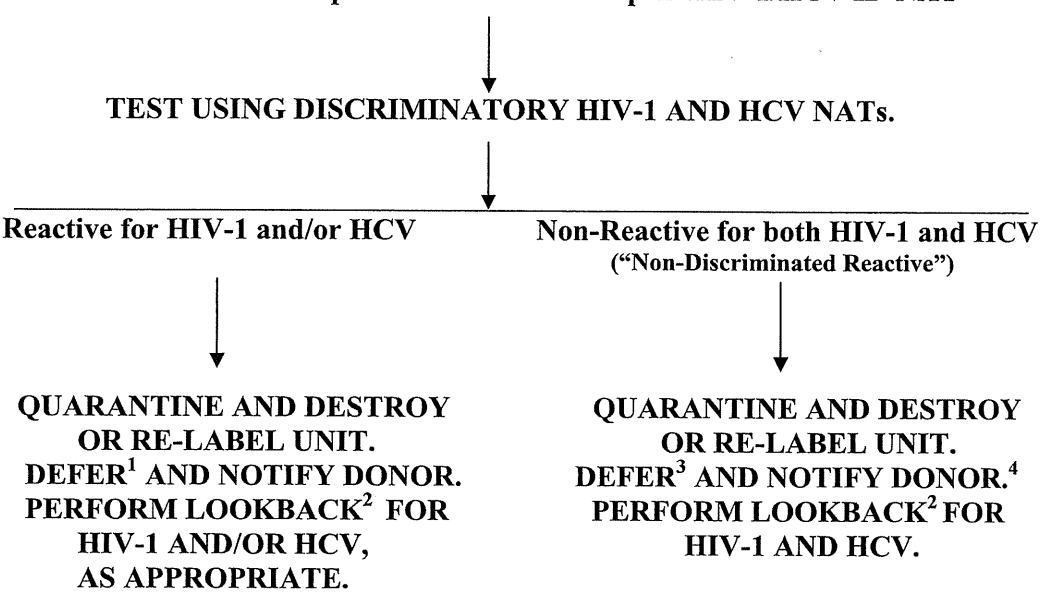
You must quarantine the unit and destroy or re-label the unit as described in section IV.C.1.a.

You must defer the donor (§ 610.41). We recommend that you defer the donor for 6 months. The donor is eligible for reentry after the 6-month waiting period. If you chose to reenter the donor, you may do so at that time without testing a follow-up sample. You must notify the donor of his/her deferral, providing information about the test results (§ 630.6). We recommend that you counsel the donor that the initial test result was very likely a false positive result and that the donor is not infected, but that because of the initial reactive test result he or she will be deferred for 6 months.

You must perform lookback for HIV-1 and HCV under §§ 610.46, 610.47, and 610.48 respectively, as described in section IV.C.1.a. above.

Contains Nonbinding Recommendations

FIGURE 3. Testing, Product Disposition, Donor Management, and Lookback for an Individual Donor Sample that is Reactive on a Multiplex NAT (ID-NAT) after Negative Antibody Screening Tests



[1] The donor may be eligible for reentry (see Figures 5 and 6).

[2] If both Discriminatory NATs were reactive or if both Discriminatory NATs were non-reactive, notification of transfusion recipients should specify that the patient should be tested for both HIV-1 and HCV.

[3] We recommend that you defer the donor for 6 months and, if you choose to reenter the donor, you may do so at that time without testing a follow-up sample.

[4] We recommend that you counsel the donor that the test result was very likely a false positive result and that the donor is not infected, but that because of the initial reactive test result he or she will be deferred for 6 months.

TABLE 3. Testing, Product Disposition, Donor Management, and Lookback for an Individual Donor Sample that is Reactive on a Multiplex NAT (ID-NAT) after Negative Antibody Screening Tests

If:	*Then:*	*After that if:*	*Then:*
Individual Donor Sample Reactive on a Multiplex HIV-1/HCV ID-NAT	**Test the sample using Discriminatory HIV-1 and HCV NATs**	**Reactive for HIV-1 and/or HCV**	**Quarantine and destroy or re-label unit; defer[1] and notify donor; perform lookback[2] for HIV-1 and/or HCV, as appropriate**
		Non-Reactive for both HIV-1 and HCV	**Quarantine and destroy or re-label unit; defer[3] and notify donor[4]; perform lookback[2] for HIV-1 and HCV**

[1] The donor may be eligible for reentry (see Tables 5 and 6).

[2] If both Discriminatory NATs were reactive or if both Discriminatory NATs were non-reactive, notification of transfusion recipients should specify that the patient should be tested for both HIV-1 and HCV.

[3] We recommend that you defer the donor for 6 months and, if you choose to reenter the donor, you may do so at that time without testing a follow-up sample.

[4] We recommend that you counsel the donor that the test result was very likely a false positive result and that the donor is not infected, but that because of the initial reactive test result he or she will be deferred for 6 months.

D. Testing, Product Disposition, Donor Management, and Lookback for an Individual Donor Sample that is Reactive on a Single Virus NAT (ID-NAT) after Negative Antibody Screening Tests

If you obtain a reactive HIV-1 RNA NAT and/or reactive HCV RNA NAT result for an individual donor sample from a test other than a Multiplex NAT, you must do the following (see Figure 4 and Table 4):

1. 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 appropriately label the unit as described in section IV.C.1.a.

2. Defer the donor (§ 610.41). The donor may be eligible for reentry (see sections V.A. and V.B.).

3. Notify the donor of his/her deferral, providing information about the test results (§ 630.6).

4. Perform lookback (product quarantine/retrieval and notification of recipients of prior collections) for HIV-1 and/or HCV under §§ 610.46, 610.47, and 610.48, respectively, as appropriate.

    - If you are an establishment that collects Whole Blood or blood components, including Source Plasma and Source Leukocytes, within 3 calendar days after a donor tests reactive for evidence of HIV-1 and/or HCV infection you must review records dating back 12 months prior to the donor's reactive NAT to identify blood and blood components previously donated by the donor. You must quarantine identified in-date blood and blood components if intended for transfusion or if intended for further manufacture into injectable products (except if pooled), notify consignees so that they may quarantine previously collected in-date blood and blood components, and notify transfusion recipients.

    - If you are a consignee of Whole Blood or blood components, including Source Plasma and Source Leukocytes, when notified by the collecting establishment you must quarantine identified previously collected in-date blood and blood components if intended for transfusion or if intended for further manufacture into injectable products (except if pooled). You must notify transfusion recipients who were transfused with blood and blood components collected during the 12

months before the date of the NAT-reactive donation, or notify the recipient's physician of record, of the need for recipient HIV-1 or HCV testing and counseling. You must make reasonable attempts to perform the notification within 12 weeks after receiving the donor's reactive NAT screening test result for HIV-1 or HCV. If both Single Virus NATs were reactive, notification of transfusion recipients should specify that the patient should be tested for both HIV-1 and HCV.

Contains Nonbinding Recommendations

FIGURE 4. Testing, Product Disposition, Donor Management, and Lookback for an Individual Donor Sample that is Reactive on a Single Virus NAT (ID-NAT) after Negative Antibody Screening Tests

Individual Donor Sample Reactive on HIV-1 ID-NAT and/or HCV ID-NAT

QUARANTINE AND DESTROY OR RE-LABEL UNIT.
DEFER DONOR.[1]
NOTIFY DONOR.

PERFORM LOOKBACK FOR HIV-1 AND/OR HCV, AS APPROPRIATE.

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[1]**The donor may be eligible for reentry (see Figures 5 and 6).**

Contains Nonbinding Recommendations

TABLE 4. Testing, Product Disposition, Donor Management, and Lookback for an Individual Donor Sample that is Reactive on a Single Virus NAT (ID-NAT) after Negative Antibody Screening Tests

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

[1] The donor may be eligible for reentry (see Tables 5 and 6).

V. RECOMMENDATIONS FOR DONOR REENTRY

Note that the reentry of a donor permits prospective donations from a reentered donor who meets donor suitability criteria. It does not affect the status of previous collections from that donor, including donations subject to lookback.

A. Reentry for Donors Deferred Because of Reactive HIV-1/2 Test Results

Currently, FDA has not found acceptable a process for reentry of deferred 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 Single Virus NAT for HIV-1 RNA) and anti-HIV-1 or -2 or anti-HIV-1/2 test RR (regardless of HIV-1 WB 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 Single Virus NAT for HIV-1 RNA) and HIV-1 p24 EIA RR (regardless of anti-HIV-1 or -2 or anti-HIV-1/2 test result);

  OR

- NAT-non-reactive for HIV-1 (or HIV-1 NAT not performed) and anti-HIV-1 or -2 or anti-HIV-1/2 test RR, HIV-1 WB positive (regardless of HIV-1 p24 EIA test result).

  OR

- NAT-non-reactive for HIV-1 (or HIV-1 NAT not performed) and anti-HIV-1 or -2 or anti-HIV-1/2 test RR (regardless of WB or IFA result) and HIV-1 p24 EIA RR (regardless of Neutralization test result).

1. FDA has accepted a method or process for reentry of deferred donors in the following three groups (see Figure 5 and Table 5):

   - **Group I**: Donors who were HIV-1 NAT-reactive (i.e., reactive on a Discriminatory NAT for HIV-1 or on a Single Virus NAT for HIV-1) 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.

NOTE: If the original donor sample that was NAT-reactive was negative on the Discriminatory NAT for HIV-1 or on the Single Virus NAT for HIV-1 but was reactive on the Discriminatory NAT for HCV or on the Single Virus NAT for HCV, you may attempt to reenter the donor according to the recommendations in section V.B. (see Figure 6 and Table 6). If the original donor sample that was NAT-reactive was reactive on both of the Discriminatory NATs for HIV-1 and HCV or on both of the Single Virus NATs for HIV-1 and HCV, you may attempt to reenter the donor according to the recommendations in both sections V.A and V.B (see Figures 5 and 6, and Tables 5 and 6).

- **Group II:** Donors who were NAT-non-reactive (or NAT was not performed) and who were RR on a screening test for HIV-1 or -2 or HIV-1/2 antibody, with an HIV-1 WB or IFA that was indeterminate (viral bands may be present), unreadable, negative, or was not performed. If an HIV-1 IFA was performed to resolve an indeterminate or unreadable HIV-1 WB, the IFA result must not have been positive. This group includes donors previously deferred because of RR HIV-1 or HIV-2 (or combination HIV-1/2) 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 performed) was negative, and
  - if a second, different, licensed HIV-2 test performed on the index donation was negative, or, if the second HIV-2 test was RR, an investigational HIV-2 supplemental test (if performed) was not positive. Performance of an investigational HIV-2 supplemental test (if available) is optional at the present time. Currently, we have not approved a supplemental (additional, more specific) test for HIV-2. If a supplemental test for HIV-2 is licensed in the future, that test should be performed if the second HIV-2 test was RR, and the result of the supplemental test for HIV-2 must not be positive for the donor to be eligible for reentry.

- **Group III:** Donors who were NAT-non-reactive (or NAT was not performed) and who were negative on a screening test for HIV-1 and -2 or HIV-1/2 antibody, but who were RR on an HIV-1 p24 antigen EIA with an indeterminate (that is, a non-neutralized or an invalid) or a positive result on the Neutralization test, even on more than one occasion.

2. 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 5 and Table 5):

   a. 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 ID-NAT for HIV-1 (a Discriminatory NAT for HIV-1 or a Single Virus NAT for HIV-1).

If the original donor sample was reactive on the NAT for HIV-1 (Group I donors), we recommend that you use the same ID-NAT (i.e., the Discriminatory NAT for HIV-1 or the Single Virus NAT for HIV-1) that was run on the original donor sample. If the original NAT is no longer available (e.g., an investigational NAT), we recommend that you use a NAT that has the same sensitivity claims as the original NAT, or greater sensitivity claims (e.g., a NAT labeled in the Intended Use as sensitive for HIV-1 including Group O, if available).

AND

(2) A licensed anti-HIV-1/2 test.

If the original donor sample was RR on the anti-HIV-1 or anti-HIV-1/2 test (Group II donors), we recommend that you use that same test to test this follow-up sample. If the original donor sample was negative on the anti-HIV-1 or anti-HIV-1/2 test (Group I donors or Group III donors), or if the original test is no longer available, we recommend that you use an anti-HIV-1/2 test that is labeled in the Intended Use as sensitive for HIV-1 Group O.

NOTE: For purposes of donor counseling, you may choose to test the deferred donor with an HIV-1 ID-NAT and an anti-HIV-1/2 test at any time prior to the end of this 8-week waiting period after the original donation. However, if an HIV-1 ID-NAT is 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. If an anti-HIV-1/2 test is RR prior to the end of this 8-week waiting period, and a licensed supplemental test for antibodies to HIV-1 (e.g., WB or IFA), if performed, is not positive, you may take another follow-up sample from the donor for testing by both HIV-1 ID-NAT and an anti-HIV-1/2 test after another 8-week waiting period has passed.

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

(1) If the ID-NAT is reactive and the anti-HIV-1/2 test is RR, we recommend that you defer the donor permanently.

(2) If the ID-NAT is reactive and the anti-HIV-1/2 test is negative, we recommend that you defer the donor permanently.

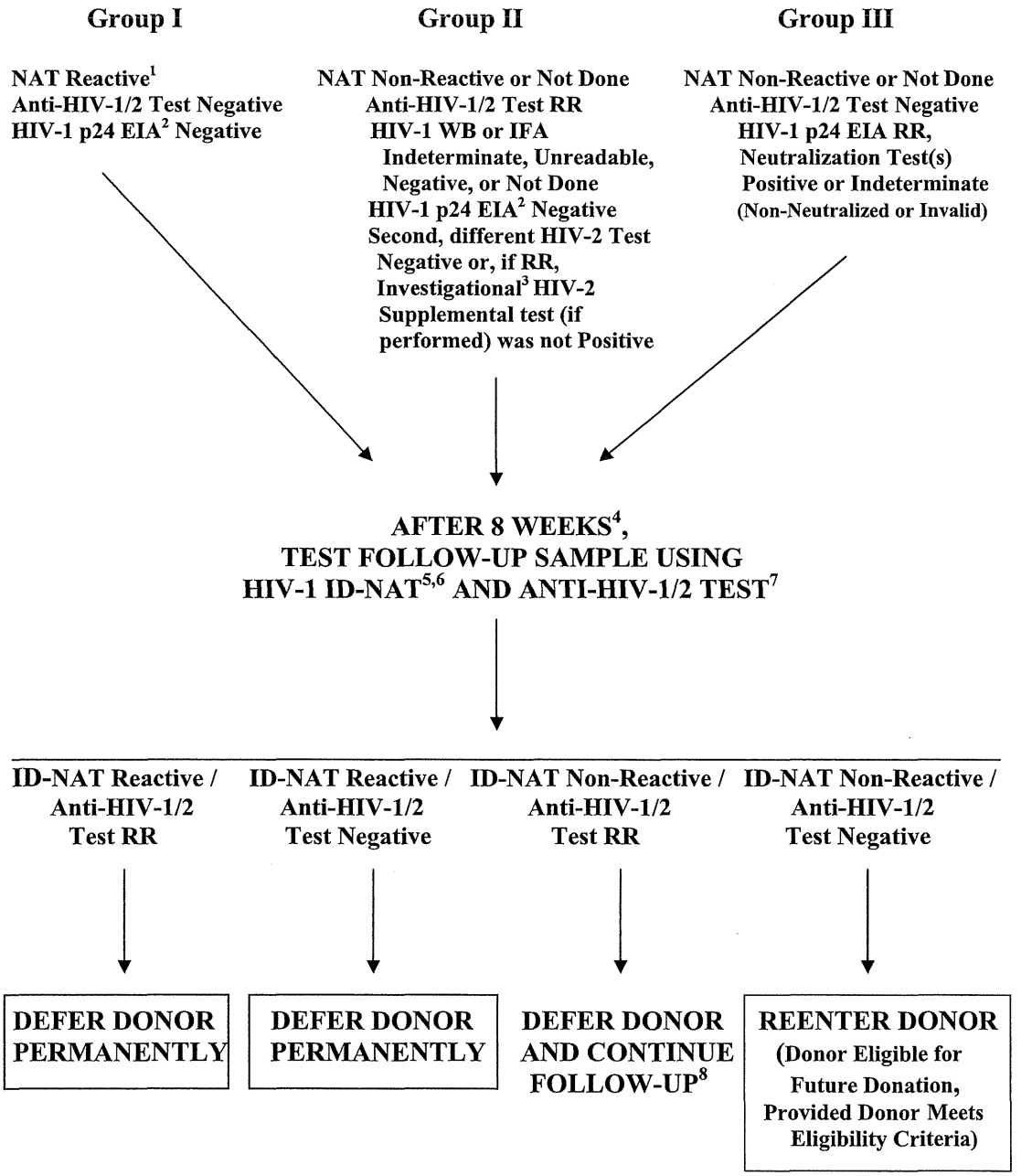
(3) If the ID-NAT is non-reactive and the anti-HIV-1/2 test is RR, you may reconsider the donor for reentry by conducting additional follow-up testing after a second waiting period of 8 weeks.

(4) When there is a persistent anti-HIV-1/2 RR result, you may wish to further test the donor's new sample using a licensed supplemental test for antibodies to HIV-1 such as a WB or IFA. If the WB or IFA test result is indeterminate, unreadable, or negative, you may reconsider the donor for reentry by conducting follow-up testing after one or more additional waiting period of 8 weeks. If the WB or IFA result is positive, we recommend that you defer the donor permanently.

(5) If the ID-NAT is non-reactive and the anti-HIV-1/2 test 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).

Contains Nonbinding Recommendations

FIGURE 5. Reentry for Donors Deferred Because of Reactive HIV-1/2 Test Results



Footnotes for FIGURE 5.

[1] **Reactive on a Discriminatory NAT for HIV-1 or on a Single Virus NAT for HIV-1.**

[2] **May not have been performed, depending upon the conditions of the specific NAT approval.**

[3] **Performance of an investigational HIV-2 supplemental test (if available) is optional. If a supplemental test is licensed in the future it should be performed and it must not have been positive for the donor to be eligible for reentry.**

[4] **HIV-1 ID-NAT and/or an anti-HIV-1/2 test, if performed during the 8 week waiting period, must be negative for the donor to be eligible for reentry.**

[5] **If the original donor sample was reactive on both of the Discriminatory NAT tests for HIV-1 and HCV, we recommend that you test a follow-up sample using HCV ID-NAT and an anti-HCV test also, as in the HCV Reentry Algorithm (see Figure 6).**

[6] **If the original donor sample was reactive on the NAT for HIV-1 (Group I donors), we recommend that you use the same ID-NAT (i.e., the Discriminatory NAT for HIV-1 or the Single Virus NAT for HIV-1) that was run on the original donor sample. If the original NAT is no longer available (e.g., an investigational NAT), we recommend that you use a NAT that has the same sensitivity claims as the original NAT or greater sensitivity claims (e.g., a NAT labeled in the Intended Use as sensitive for HIV-1 including Group O, if available).**

[7] **If the original donor sample was RR on the anti-HIV-1/2 test (Group II donors) we recommend that you use that same test to test this follow-up sample. If the original donor sample was negative on the anti-HIV-1/2 test (Group I donors or Group III donors) or if the original test is no longer available, we recommend that you use an anti-HIV-1/2 test that is labeled in the Intended Use as sensitive for HIV-1 including Group O.**

[8] **At your option you may further test the donor's sample using HIV-1 WB or IFA. If WB or IFA is negative, unreadable, or indeterminate, you may reconsider the donor for reentry by conducting follow-up testing after one or more additional waiting period of 8 weeks. If WB or IFA is positive, we recommend that you defer the donor permanently.**

TABLE 5. Reentry for Donors Deferred Because of Reactive HIV-1/2 Test Results

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

Contains Nonbinding Recommendations

Footnotes for TABLE 5.

[1] Reactive on a Discriminatory NAT for HIV-1 or on a Single Virus NAT for HIV-1.

[2] May not have been performed, depending upon the conditions of the specific NAT approval.

[3] Performance of an investigational HIV-2 supplemental test (if available) is optional. If a supplemental test is licensed in the future it should be performed and it must not have been positive for the donor to be eligible for reentry.

[4] HIV-1 ID-NAT and/or an anti-HIV-1/2 test, if performed during the 8 week waiting period, must be negative for the donor to be eligible for reentry..

[5] If the original donor sample was reactive on both of the Discriminatory NAT tests for HIV-1 and HCV, we recommend that you test a follow-up sample using HCV ID-NAT and an anti-HCV test also, as in the HCV Reentry Algorithm (see Figure 6).

[6] If the original donor sample was reactive on the NAT for HIV-1 (Group I donors), we recommend that you use the same ID-NAT (i.e., the Discriminatory NAT for HIV-1 or the Single Virus NAT for HIV-1) that was run on the original donor sample. If the original NAT is no longer available (e.g., an investigational NAT), we recommend that you use a NAT that has the same sensitivity claims as the original NAT or greater sensitivity claims (e.g., a NAT labeled in the Intended Use as sensitive for HIV-1 including Group O, if available).

[7] If the original donor sample was RR on the anti-HIV-1/2 test (Group II donors) we recommend that you use that same test to test this follow-up sample. If the original donor sample was negative on the anti-HIV-1/2 test (Group I donors or Group III donors) or if the original test is no longer available, we recommend that you use an anti-HIV-1/2 test that is labeled in the Intended Use as sensitive for HIV-1 including Group O.

[8] At your option you may further test the donor's sample using HIV-1 WB or IFA. If WB or IFA is negative, unreadable, or indeterminate, you may reconsider the donor for reentry by conducting follow-up testing after one or more additional waiting period of 8 weeks. If WB or IFA is positive, we recommend that you defer the donor permanently.

Contains Nonbinding Recommendations

B. Reentry for Donors Deferred Because of Reactive HCV Test Results

Currently, FDA has not found acceptable a process for reentry of deferred 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 test RR (regardless of HCV RIBA test result).

  OR

- NAT-non-reactive for HCV (or HCV NAT not performed) and anti-HCV test RR, HCV RIBA positive.

1. FDA has accepted a method or process for reentry of deferred donors in the following two groups (see Figure 6 and Table 6):

   - **Group A:** Donors who were HCV NAT-reactive (i.e., reactive on a Discriminatory NAT for HCV or on a Single Virus NAT for HCV) and seronegative. This includes donors previously deferred because of reactive test results on an investigational HCV NAT.

     NOTE: If the original donor sample that was NAT-reactive was negative on the Discriminatory NAT for HCV or on the Single Virus NAT for HCV but was reactive on the Discriminatory NAT for HIV-1 or on the Single Virus NAT for HIV-1, you may attempt to reenter the donor according to the recommendations in section V.A. (see Figure 5 and Table 5). If the original donor sample that was NAT-reactive was reactive on both of the Discriminatory NATs for HIV-1 and HCV or on both of the Single Virus NATs for HIV-1 and HCV, you may attempt to reenter the donor according to the recommendations in both sections V.A and V.B (see Figures 5 and 6 and Tables 5 and 6).

   - **Group B:** Donors who were NAT-non-reactive (or NAT was not performed) and who were RR on a screening test for HCV antibody, with an HCV RIBA that was indeterminate or negative or was not performed. This group includes donors previously deferred because of RR HCV serologic test results prior to the initiation of testing by NAT.

2. 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 6 and Table 6):

a. 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 ID-NAT for HCV (a Discriminatory NAT for HCV or a Single Virus NAT for HCV).;

If the original donor sample was reactive on the NAT for HCV (Group A donors), we recommend that you use the same ID-NAT (i.e., the Discriminatory NAT for HCV or the Single Virus NAT for HCV) that was run on the original donor sample. If the original NAT is no longer available (e.g., an investigational NAT) we recommend you use a NAT that has the same sensitivity claims as the original NAT or greater sensitivity claims.

AND

(2) A licensed anti-HCV test.

If the original donor sample was RR on the anti-HCV test (Group B donors), we recommend that you use that same test or a later, more sensitive version (i.e., HCV EIA version 3.0 or later) to test this follow-up sample.

NOTE: For purposes of donor counseling and to detect possible HCV viremia, you may also choose to test the deferred donor with an HCV ID-NAT and an anti-HCV test at any time prior to the completion of the 6-month period after the original donation. However, if an HCV ID-NAT is 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. If an anti-HCV test is RR prior to the end of this 6-month waiting period, and a licensed supplemental test for antibodies to HCV (e.g., RIBA), if performed, is not positive, you may take another follow-up sample from the donor for testing by both HCV ID-NAT and an anti-HCV test after another 6-month waiting period has passed.

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

(1) If the ID-NAT is reactive and the anti-HCV test is RR, we recommend that you defer the donor permanently.

(2) If the ID-NAT is reactive and the anti-HCV test is negative, we recommend that you defer the donor permanently.

(3) If the ID-NAT is non-reactive and the anti-HCV test is RR, you may reconsider the donor for reentry by conducting additional follow-up testing after a second waiting period of 6 months.

(4) When there is a persistent anti-HCV RR test result, you may wish to further test the donor's new sample using a licensed supplemental test for antibodies to HCV such as RIBA. If the RIBA test result is negative or indeterminate, you may reconsider the donor for reentry by conducting follow-up testing after one or more additional waiting period of 6 months. If the RIBA test result is positive, we recommend that you defer the donor permanently.

(5) If the ID-NAT is non-reactive and the anti-HCV test 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).