

TITLE: POLICY: DONOR LOOKBACK/BLOOD PRODUCT RECALL

PURPOSE: To outline a procedure for removing, recalling and/or correcting blood products that do not meet the requirements of the FDA, AABB, or the blood center.

MATERIALS: Recall/Market Withdrawal Form
Donor Lookback Form

SCOPE: To include, but not limited to:

- Viral Test Results - (HBsAg, anti-HCV, Anti HIV-1/2, Anti-HTLV-I/II, anti-HBc, HIV NAT, HCV NAT,
- WNVNAT & Chagas Lookback: see WNV Testing, Deferral, Reentry Requirements and Chagas Testing: Selection, Lookback & Deferral procedures
- Post Donation Reports (Donor Callbacks) - SARS, WNV, CJD, etc.
- Return of Unsuitable Units
- Internal/External Audit Findings
- Notification of positive test results from an outside agency.

DEFINITIONS:

- **Lookback:** a review of a donor's donation history to ascertain whether there are products from previous donation that would require quarantine, further testing and/or notification of consignees and transfusion recipients.
- **Recall:** the removal or correction of a distributed blood product that the FDA considers to be in violation of the laws it administers, and against which the FDA would initiate legal action.
- **Market Withdrawal:** the removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by the FDA or which involves no violation.

POLICY:

I. REACTIVE INFECTIOUS DISEASE TESTING

A. Anti-HIV-1/2, HIV NAT Lookback: for those identified blood and blood components collected:

1. Within 3 calendar days of repeatedly reactive anti-HIV 1/2 test or HIV NAT, retrieve, quarantine and discard any in-date prior collections of blood or blood products from the same donor (perform consignee notification if needed).
2. When supplemental/confirmatory (anti-HIV-2, HIV IFA, HIV-WB) results are positive, perform lookback and consignee notification on all blood products extending back 5 years from the confirmed positive donation or 12 months from the donor's last negative result using an FDA licensed screening test.

B. Anti-HCV, HCV NAT Lookback

1. Within 3 calendar days of repeatedly reactive anti-HCV test or HCV NAT, retrieve, quarantine and discard any in-date prior collections of blood or blood products from the same donor.
2. RNA-reactive or antibody-confirmed positive donors (anti-HCV screening test repeatedly reactive and repeatedly reactive second licensed antibody screen as a supplemental test): Track units distributed from the same donor for 10 years prior to the anti-HCV reactive donation, or to the date 12 months prior to the donor's most recent negative licensed multi-antigen screening test for HCV. Perform consignee notification.

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B. Anti-HCV, HCV NAT Lookback (cont.)

3. When no supplemental/confirmatory testing has been performed, lookback and notification shall extend to January 1, 1988.

C. HBsAg, HBV NAT Lookback

1. Prior collections of in-date blood products should be retrieved, quarantined and discarded.
2. When supplemental/confirmatory (HBsAg neutralization) results are positive, perform lookback and consignee notification on all blood products extending back 5 years from the confirmed positive donation, or 12 months from the donor's last negative result using an FDA licensed screening test.

D. Anti-HBc, Anti-HTLV-I/II Lookback (licensed confirmatory testing is not available)

1. Prior collections of in-date blood products should be retrieved, quarantined and discarded.
2. Consignee notification not required

II. CJD LOOKBACK/WITHDRAWALS

A. Whole Blood & Blood Components Intended for Transfusion and Cellular Blood Components Intended for Further Manufacture into Injectable Products from donors with a CJD Diagnosis or CJD Risk Factors

1. If a donor is diagnosed with CJD or has CJD risk factors, retrieve and destroy all in-date blood components (including Whole Blood and blood components intended for transfusion).
2. Perform consignee notification of all prior products within one week
3. File a BPD if the donor has been diagnosed with CJD. A BPD is not required if the components were collected prior to the implementation of this deferral (5/28/2002)

B. Geographic Risk for CJD and/or Exposure to Bovine Insulin Made in the UK since 1980.

1. Geographic deferrals
 - i. If a donor has geographic risk factors, retrieve and destroy all in-date blood components (including Whole Blood, blood components intended for transfusion and all in-date cellular blood components intended for manufacturing into injectable products under blood center control).
 - ii. Perform consignee notification of all prior products within one week
 - iii. File a BPD for any distributed components collected after implementation of the deferral (5/28/2002)
2. Donors with Exposure to Bovine Insulin Made in the UK since 1980
 - i. If a donor has been exposed to bovine insulin made in the UK since 1980, retrieve and destroy all in-date blood components (including Whole Blood, blood components intended for transfusion and all in-date cellular blood components intended for manufacturing into injectable products under blood center control).
 - ii. Perform consignee notification of all prior products within one week
 - iii. File a BPD for any distributed components collected after implementation of the deferral (5/28/2002)

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C. Recoverd Plasma from Donors with Geographic Risk Deferrals and/or Exposure to Bovine Insulin Made in the UK since 1980

1. If a donor has geographic risk factors or exposure to bovine insuling made in the UK since 1980, retrieve and destroy all in-date recoverd plasma under blood center control.
NOTE: If the recovered plasma has been sent to the consignee and the products have already been pooled, do not conduct product retrieval or consignee notification for these units
2. Perform consignee notification of all prior products within one week
3. File a BPD for any distributed components collected after implementation of the deferral (5/28/2002)

D. Donors with vCJD, suspected vCJD or CJD and Age Less than 55 Years

1. If a donor has been diagnosed with vCJD, suspected vCJD or CJD and Age Less than 55 Years retrieve and destroy all in-date blood components (including Whole Blood, blood components intended for transfusion, all recovered plasma and all in-date cellular blood components intended for manufacturing into injectable products under blood center control).
2. Perform consignee notification of all prior products within one week
3. File a BPD if the donor has been diagnosed with vCJD, suspected vCJD or CJD and age less than 55 years for any distributed products. FDA requests that they be notified as soon as possible instead of waiting 45 days. Telephone: (301-827-6220)

E. Plasma Derivatives.

1. Plasma derivatives manufactured using plasma from donors with CJD or CJD risk factors, or geographic risk deferrals: do not withdraw pooled plasma, intermediates and plasma derivatives manufactured from these donors
2. Plasma derivatives manufactured using plasma from donors diagnosed with vCJD or suspected vCJD
 - a. Immediated retrieve and destroy any pooled plasma, intermediates, derivatives and other material containing plasma from such a donor.
 - b. Perform consignee notification of all prior products within one week
 - c. File a BPD if the donor has been diagnosed with vCJD, suspected vCJD or CJD and age less than 55 years for any distributed products. FDA requests that they be notified as soon as possible instead of waiting 45 days. Telephone: (301-827-6220)

III. SARS LOOKBACK/WITHDRAWAL

A. Donors with a history of SARS disease that occurred within 28 days prior to donation, SARS exposure within 14 days prior to donation, or SARS disease that occurs within 14 days after donation.

1. Immediately retrieve, quarantine and destroy in-date components.
 - **Note:** If the donor is symptom-free more than 14 days post exposure, product retrieval and quarantine is not necessary.
2. Consignee notification will take place if the components have been transfused.
3. Report cases of SARS to the health department --- this is not a mandatory requirement.
4. BPD to be filed if the product was distributed.

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IV. ANTHRAX

- A. Proven Anthrax Disease
 - 1. Promptly retrieve, quarantine and destroy any in-date components from the time period of known potential donor exposure to B. anthracis or 60 days prior to onset of illness, whichever is the shorter period.
 - 2. Perform consignee notification - same time period applies.
- B. Undiagnosed Post Donation Illness in Potentially Exposed Individuals
 - 1. Product retrieval, quarantine and disposal will occur at the Medical Director's discretion. If product is to be retrieved, the time period cited in a.i. would be used.
 - 2. Consignee notification is not recommended.

V. HEPATITIS A (HAV) OUTBREAK

When alerted to a local outbreak of a Hepatitis A:

NOTE: this process will be activated if the public health authority announces either of the following circumstances:

- A common source outbreak has occurred and post exposure prophylaxis is recommended for groups or individuals
- The potential for outbreak exists due to the discovery of an infected food handler or other common source and post exposure prophylaxis is recommended for groups or individuals

If no post exposure prophylaxis is recommended, the blood center does not need to take action.

- A. CBB Medical Director or designee will communicate with local health department or public health authority to understand the potential for exposure, the number of people involved, the affected geographic area, and the dates of possible exposure
- B. Staff will need to identify donors who may have been exposed to HAV during an outbreak. This information may be elicited by utilizing one or more of the following:
 - 1. Provide written information to all presenting donors in the affected geographic area about the name of the involved establishment or food outbreak and the dates of possible exposure
 - 2. Asking an additional question during the health history interview in the affected geographic area about possible exposure to the hepatitis A outbreak.
 - 3. These measures should take place for at least 120 days after the date of the last possible exposure.
- C. Donor Deferral will be 120 days from the date of the last potential exposure. Defer regardless of reported HAV vaccination status.
- D. Post donation information and blood component retrieval
 - 1. If donor was exposed, discard any in-house/in-date components
 - 2. Retrieve any distributed products collected during the period from the donor's first potential exposure through 120 days after the date of the donor's last exposure.
 - 3. Perform consignee notification
 - i. Recipient testing (ordered by transfusion service): anti-HAV IgM (the use of HAV RNA is optional)

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- ii. If HAV infection is suspected test recipient for elevated liver enzymes.
- iii. If recipient testing is positive, patient management consistent with Hepatitis A infection should take place at the transfusion service.
- iv. Notify plasma manufacturer if plasma distributed.

VI: Chikungunya (CHIKV) and Dengue Virus:

- A. Post Donation information of confirmed CHIKV or dengue.
 - a. Recall and discard any in-date products collected in the 14 days before the onset of symptoms
 - b. Defer the donor for 28 days following resolution of symptoms: (T49 with comments)

VII. Malaria

- A. Collected from donor who should have been deferred for malaria associated travel:
 - a. Immediately retrieve, quarantine and destroy in-date components.
 - b. Notify Consignees
 - c. Report a BPD to FDA
- B. History/Diagnosis of Malaria
 - a. Immediately retrieve, quarantine and destroy in-date components.
 - b. Notify Consignees
 - i. If transfused, recommend notification to transfusion recipient's physician of record regarding the need for monitoring of the recipient for possible malaria infection for a period of 3 months post-transfusion
 - c. Report a BPD to FDA
- C. Acellular blood components (Frozen plasma products) intended for transfusion or for further manufacturing.
 - a. Quarantine and destroy any undistributed in-date acellular blood components
 - b. No Consignee notification required.

VIII. RECALLS WILL BE PERFORMED IN THE FOLLOWING INSTANCES (NOT LIMITED TO):

- A. Mislabeled Blood Product
- B. Untested or Improperly Tested Blood Product Distributed
- C. Release of a Blood Product With a Positive Test Result
- D. Notification of Positive Test Results From an Outside Source
- E. Products From a Donor That Did Not Meet the Donor Selection Criteria

PROCEDURE:

Responsibilities: It will be the responsibility of the QA Department, Technical Director and/or Executive Director, or their designee to direct any lookback, retrieval, quarantine and disposal action.

1. Lookback/Recall will take priority over any/all blood bank functions. Overtime, if necessary, will automatically be authorized.
2. Institute a search of the donor's previous donation history using the "DV1" screen in the "DN" system. Print this screen – shift, F1.
3. Check the "DE" screen to ascertain if the appropriate deferral has been generated.
4. The Laboratory staff will generate a Donor Lookback form and give it to the DBA or designee. If product retrieval is not necessary (1st time donor), copy of the DV1 screen to the lookback form and return to QA.

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5. If a recall, market withdrawal or product retrieval is necessary:
 - a. Initiate a Recall/Market Withdrawal Form.
 - b. Using the DL screen, check for recent donations (made after 12-31-97 at CBB)
 - c. Donations prior to 12-31-97 at CBB will be reviewed in the LA system as follows:
 - i. =LA
 - ii. QA
 - iii. Select local query
 - iv. Select unit disposition
 - v. Type in unit number
 - vi. Execute (F11)
 - d. If products are in inventory, the Recall/Withdrawal form is given to the laboratory.
 - i. Lab staff will quarantine and discard all products.
 - ii. Document action on the Recall/Withdrawal Form, (date, discard code, initials).
 - e. If products are in a consignee's inventory:
 - i. Document the receiving hospital, the contact spoken to (include date and time), the final disposition of the product (transfused, expired, in inventory).
 - ii. If the product is in the consignee's current inventory, request that they quarantine the product and return it as soon as possible to the blood center for disposal or correction.
 - iii. When the product is returned, the laboratory staff will discard the product and complete the Lookback/Withdrawal form with the date, discard code (if applicable), and their initials. A copy of the CA screen should be attached to the Lookback/Withdrawal form.
 - f. Return all forms to the QA Department for review.

REPORTING:

- All forms will be completed and documentation attached and returned to the QA Department for review.
- Confirmatory/Supplemental testing will take place according to SOP (Testing/Deferral and Re-entry Requirements)..
- The QA department will perform notification to consignee, health authority and/or plasma manufacturer as required and/or at the direction of the Medical Director

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Original Effective Date	Revised by	Revision	Supersedes Revision #
3.27.01	D. Pirschel	<p>CJD LOOKBACK/WITHDRAWALS Whole Blood & Blood Components Intended for Transfusion and Cellular Blood Components Intended for Further Manufacture into Injectable Products from donors with a CJD Diagnosis or CJD Risk Factors</p> <p>3. If a donor is diagnosed with CJD or has CJD risk factors, retrieve and destroy all in-date blood components (including Whole Blood and blood components intended for transfusion).</p> <p>4. Perform consignee notification of all prior products within one week</p> <p>5. File a BPD if the donor has been diagnosed with CJD. A BPD is not required if the components were collected prior to the implementation of this deferral (5/28/2002)</p> <p>F. Geographic Risk for CJD and/or Exposure to Bovine Insulin Made in the UK since 1980.</p> <p>1. Geographic deferrals</p> <p>i. If a donor has geographic risk factors, retrieve and destroy all in-date blood components (including Whole Blood, blood components intended for transfusion and all in-date cellular blood components intended for manufacturing into injectable products under blood center control).</p> <p>ii. Perform consignee notification of all prior products within one week</p> <p>iii. File a BPD for any distributed components collected after implementation of the deferral (5/28/2002)</p> <p>2. Donors with Exposure to Bovine Insulin Made in the UK since 1980</p> <p>i. If a donor has been exposed to bovine insulin made in the UK since 1980, retrieve and destroy all in-date blood components (including Whole Blood, blood components intended for transfusion and all in-date cellular blood components intended for manufacturing into injectable products under blood center control).</p> <p>ii. Perform consignee notification of all prior products within one week</p> <p>iii. File a BPD for any distributed components collected after implementation of the deferral (5/28/2002)</p> <p>G. Recoverd Plasma from Donors with Geographic Risk Deferrals and/or Exposure to Bovine Insulin Made in the UK since 1980</p> <p>1. If a donor has geographic risk factors or exposure to bovine insuling made in the UK since 1980, retrieve and destroy all in-date recoverd plasma under blood center control.</p> <p>NOTE: If the recovered plasma has been sent to the consignee and the products have already been pooled, do not conduct product retrieval or consignee notification for these units</p> <p>2. Perform consignee notification of all prior products within one week</p> <p>3. File a BPD for any distributed components collected after implementation of the deferral (5/28/2002)</p> <p>H. Donors with vCJD, suspected vCJD or CJD and Age Less than 55 Years</p> <p>1. If a donor has been diagnosed with vCJD, suspected vCJD or CJD and Age Less than 55 Years retrieve and destroy all in-date blood components (including Whole Blood, blood components intended for transfusion, all recovered plasma and all in-date cellular blood components intended for manufacturing into injectable products under blood center control).</p> <p>2. Perform consignee notification of all prior products within one week</p> <p>3. File a BPD if the donor has been diagnosed with vCJD, suspected vCJD or CJD and age less than 55 years for any distributed products. FDA requests that they be notified as soon as possible instead of waiting 45 days. Telephone: (301-827-6220)</p> <p>I. Plasma Derivatives.</p> <p>1. Plasma derivatives manufactured using plasma from donors with CJD or CJD risk factors, or geographic risk deferrals: do not withdraw pooled plasma, intermediates and plasma derivatives manufactured from these donors</p> <p>2. Plasma derivatives manufactured using plasma from donors diagnosed with vCJD or suspected vCJD</p> <p>a. Immediated retrieve and destroy any pooled plasma, intermediates, derivatives and other material containing plasma from such a donor.</p> <p>b. Perform consignee notification of all prior products within one week</p> <p>c. File a BPD if the donor has been diagnosed with vCJD, suspected vCJD or CJD and age less than 55 years for any distributed products. FDA requests that they be notified as soon as possible instead of waiting 45 days. Telephone: (301-827-6220)</p>	1.005
	D. Pirschel	Remove BRD Union Square address	1.006
	D. Pirschel	<p>Added: HEPATITIS A (HAV) OUTBREAK When alerted to a local outbreak of a Hepatitis A: <input type="checkbox"/> NOTE: this process will be activated if the public health authority announces either of the following circumstances:</p> <ul style="list-style-type: none"> • A common source outbreak has occurred and post exposure prophylaxis is recommended for groups or individuals • The potential for outbreak exists due to the discovery of an infected food handler or other common source and post exposure prophylaxis is recommended for groups or individuals <p>If no post exposure prophylaxis is recommended, the blood center does not need to take action.</p> <p>E. CBB Medical Director or designee will communicate with local health department or public health authority to understand the potential for exposure, the number of people involved, the affected geographic area, and the dates of possible exposure</p> <p>F. Staff will need to identify donors who may have been exposed to HAV during an outbreak. This information may be elicited by utilizing one or more of the following:</p>	1.007

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		<ol style="list-style-type: none"> 1. Provide written information to all presenting donors in the affected geographic area about the name of the involved establishment or food outbreak and the dates of possible exposure 2. Asking an additional question during the health history interview in the affected geographic area about possible exposure to the hepatitis A outbreak. 3. These measures should take place for at least 120 days after the date of the last possible exposure. <p>G. Donor Deferral will be 120 days from the date of the last potential exposure. Defer regardless of reported HAV vaccination status.</p> <p>H. Post donation information and blood component retrieval</p> <ol style="list-style-type: none"> 1. If donor was exposed, discard any in-house/in-date components 2. Retrieve any distributed products collected during the period from the donor's first potential exposure through 120 days after the date of the donor's last exposure. 3. Perform consignee notification <ol style="list-style-type: none"> i. Recipient testing (ordered by transfusion service): anti-HAV IgM (the use of HAV RNA is optional) ii. If HAV infection is suspected test recipient for elevated liver enzymes. iii. If recipient testing is positive, patient management consistent with Hepatitis A infection should take place at the transfusion service. <p>Notify plasma manufacturer if plasma distributed</p>	
	<p>D. Pirschel</p>	<p>Deleted: The Data Base Administrator (DBA) or designee will be responsible for researching computer records and completing the initial and final disposition on the Blood Product/Recall. In the event the DBA is unavailable, the person performing supervisory review will be responsible for performing this step. Generate a Product Return/Discard Request to be given to the courier when the product is retrieved. Form: Product Return/Discard Request Recipient notification, testing and follow-up will be at the consignee's direction and supplemental test with RIBA 2.0 or higher is reactive</p> <p>Added: Chikungunya (CHIKV) and Dengue Virus: Post Donation information of confirmed CHIKV or dengue. Recall and discard any in-date products collected in the 14 days before the onset of symptoms Defer the donor for 28 days following resolution of symptoms: (T49 with comments) WNVNAT & Chagas Lookback: see WNV Testing, Deferral, Reentry Requirements and Chagas Testing: Selection, Lookback & Deferral procedures RNA-reactive or antibody-confirmed positive donors (anti-HCV screening test repeatedly reactive and repeatedly reactive second licensed antibody screen as a supplemental test): Track units distributed from the same donor for 10 years prior to the anti-HCV reactive donation, or to the date 12 months prior to the donor's most recent negative licensed multi-antigen screening test for HCV. Perform consignee notification.</p>	<p>1.008</p>

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REVIEW/APPROVAL/IMPLEMENTATION			
Department Head	Name	Signature	Date
Manager, Admin.Services			
Manager, Mobile Recruitment	Deanna Renaud	<i>Deanna Renaud</i>	8/6/14
Technical Director	Janet Vieyra	<i>J. Vieyra</i>	8-6-14
QA Director	Diane Pirschel	<i>D. Pirschel</i>	8-6-14
Director, Donor Operations	Bernadette Myers	<i>B. Myers</i>	8-6-14
APPROVED BY:			
Position	Name	Signature	Date
Medical Director	Jeffrey A. Richmond, MD	<i>J. Richmond</i>	8-6-14
Executive Director	Steven Beeler	<i>S. Beeler</i>	8-17-14
IMPLEMENTATION DATE: AUG 18 2014			

ANNUAL

REVIEW

MEDICAL DIRECTOR	DATE	MEDICAL DIRECTOR	DATE

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RETIRED SOP

SOP RETIRED BY	TITLE	SIGNATURE	DATE RETIRED
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LAB	DBA	CBB	BRDM
HR	ED	Mgr. MR	PANY
			WNYV