Community Blood Bank of Erie County
2646 Peach St. Erie, PA 16508

COPY

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, the blood center or other regulating bodies.

MATERIALS: Recall/Market Withdrawal-Post Donation Report Form
Donor Lookback/Positive Test Results Form

SCOPE: To include, but not limited to:

- Infectious Disease Test Results - (HBsAg, anti-HCV, Anti HIV-1/2, Anti-HTLV-I/II, anti-HBc, HIV NAT, HCV NAT)
- WNVNAT, ZIKVNAT, and Chagas Lookback: see WNV Testing, Deferral, Reentry Requirements, Chagas Testing: Selection, Lookback & Deferral, and Zika Testing/Deferral/Reentry Requirements procedures
- Positive Anti-A/B Titers- Refer to Processing Whole Blood, Low Titer SOP
- Post Donation Reports (Donor Callbacks) - 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.

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)

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.

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

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.

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. anthraces 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 sited in A.1 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
      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: Zika (ZIKV), Chikungunya (CHIKV) and Dengue Virus:

Notify state agencies when appropriate.

QA will perform regular checks (online) with state department of health and CDC to monitor areas of Zika transmission

A. Post Donation information of confirmed CHIKV or Dengue.
   a. Recall and discard any in-date products collected in the 2 weeks before the onset of symptoms
   b. Defer the donor for 4 weeks following resolution of symptoms of a donor with history of infection: (T49 with comments)

B. Zika Virus
  a. Deferral:
    i. Defer a donor who tests ID NAT reactive for Zika for 120 days from the ID NAT reactive donation or from the resolution of symptoms, whichever timeframe is longer. (T92 deferral code).
    ii. Notify the donor. (see Donor Deferral and Zika Te
    iii. sting/Deferral/Reentry Requirements SOPs)
  b. Product Management
    i. Quarantine and destroy any undistributed in-date blood or blood components collected from the donor in the 120 days prior to the donation that is ID NAT reactive.
    ii. If components were distributed: notify consignee to destroy any in-date blood or blood components.
    iii. Advise transfusion service to inform the transfusion recipient's physician of record regarding potential need for monitoring and counseling the recipient for a possible ZIKV infection

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.

VII. Ebola Virus Infection or Disease (EVD)

A. Blood and Blood Components Collected from Donors at Risk for Ebola Virus Infection or Disease Because of Risk Factors Related to Residency, Travel or Close Contact
  a. Donors who should have been deferred for Risk Factors
    i. Notify Consignees to retrieve, quarantine and destroy in-date blood and blood components
    ii. Retrieval and Quarantine is not recommended for plasma pooled for further manufacturing into products

B. Blood and Blood Components collected from Donors later determined to have Ebola Virus Infection or Disease.
  a. Notify FDA and Dept. of Health as soon as possible upon learning that blood was collected from a donor later determined to have EVD or infection. This applies to blood components collected in the 8 weeks prior to disease onset or any time after disease onset.
  b. Retrieve and Quarantine blood and blood components collected in the 8 weeks prior to disease onset and any time after disease onset.

i. If components were transfused, consignee should notify the transfusion recipient's physician of record regarding the need for notification and monitoring of the recipient.

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

1. Mislabeled blood product
2. Untested or improperly tested blood product distributed
3. Release of a blood product with a positive test result
4. Notification of positive test results from an outside source
5. Products from a donor that did not meet the donor selection criteria
6. Notification from a supplier of a critical supply recall.

PROCEDURE:

Responsibilities: It will be the responsibility of the Laboratory staff performing result review, the QA Department and/or Technical Director or their designee to direct a lookback, retrieval, and 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 "DV3" screen in the "DN" system or by using "DL" in the "LA" subsystem. Print this screen – shift, F1 or print screen

3. The Laboratory staff will generate a Donor Lookback/Positive Test Results form. If product retrieval is not necessary (1st time donor) attach a copy of the DV3 or DL screen to the Donor Lookback/Positive Test Results Form and return to QA.

4. In the DN subsystem, check the "DE" screen to ascertain if the appropriate deferral has been generated.

5. If a recall, market withdrawal or product retrieval is necessary:
    a. Initiate a Recall/Market Withdrawal-Post Donation Report Form.
    b. Using the DL screen in the LA subsystem, check for recent donations (
    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 at CBB:
        i. Notify the Lab staff to quarantine and/or discard all products.
        ii. Document action on the Recall/Market Withdrawal-Post Donation Report 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 or to destroy at the consignee location and send confirmation of destruction.
   iii. When the product is returned, the laboratory staff will discard the product and complete the Recall/Market Withdrawal-Post Donation Report Form form with the date, discard code (if applicable), and their initials. A copy of the CA screen should be attached to the Recall/Market Withdrawal-Post Donation Report Form 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. Refer to the following documents:

  - ✓ Investigation of Discrepancies SOP
  - ✓ CSL Quality Requirements and Short Supply Agreement
  - ✓ CSL Plasma Lookback, Changes & Notification policy
  - ✓ Octapharma Lookback/Change Control/Deviation policy
  - ✓ Octapharma Lookback/PDI Requirements
  - ✓ Octapharma Quality Assurance Agreement
  - ✓ Electronic Reporting: Proficiency Tests and Infectious Disease SOP
  - ✓ Biological Product Deviations policy
  - ✓ NYDOH Subpart 58-2.8 (b)

References:
FDA Guidance for Industry:

- Recommendations for Donor Screening, Deferral and Product Management to Reduce the Risk of Transfusion Transmission of Zika Virus
- Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products
- Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease and Variant Creutzfeldt-Jakob Disease by Blood and Blood Products
- "Lookback" for Hepatitis C Virus (HCV): Product Quarantine, Consignee Notification, Further Testing, Product Disposition, and Notification of Transfusion Recipients Based on Donor Test Results Indicating Infection with HCV
- Recommendations for Assessment of Donor Suitability and Blood and Blood Product Safety in Cases of Possible Exposure to Anthrax
- Recommendations for Deferral of Donors and Quarantine and Retrieval of Blood and Blood Products in Recent Recipients of Smallpox Vaccine (Vaccinia Virus) and Certain Contacts of Smallpox Vaccine Recipients
- Recommendations for the Assessment of Donor Suitability and Blood Product Safety in Cases of Suspected Severe Acute Respiratory Syndrome (SARS) or Exposure to SARS
- Revised Recommendations for Reducing the Risk of Zika Virus Transmission by Blood and Blood Components, 8.16
- Recommendations for Assessment of Blood Donor Eligibility, Donor Deferral and Blood Product Management in Response to Ebola Virus, 1.17

21 CFR 610.46-48, 42 CFR 482.27(c)
AABB Standards for Blood Banks and Transfusion Services, 7.4.6, 7.4.6.1
CSL Quality Requirements and Short Supply Agreement
Octapharma Lookback/PDI Requirements
Octapharma Quality Assurance Agreement
NYDOH Subpart 58-2.8 (b)

SOP:
Investigation of Discrepancies
Donor Deferral
Zika Testing/Deferral/Reentry Requirements
WNV Testing/Deferral/Reentry Requirements
Chagas Testing/Deferral/Reentry Requirements
Testing/Deferral/Reentry Requirements
CSL Plasma Lookback, Changes & Notification policy
Biological Product Deviations policy
Octapharma Lookback/Change Control/Deviation policy
Electronic Reporting: Proficiency Tests and Infectious Disease
Processing Whole Blood, Low Titer

Original Effective Date	Revised by	Revision	Supersedes Revision #
3.27.01	D. Pirschel	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 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). 4. Perform consignee notification of all prior products within one week 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) F. 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) G. 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) H. 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) I. 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)	1.005
	D. Pirschel	Remove BRD Union Square address	1.006
	D. Pirschel	Added: 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. 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 Staff will need to identify donors who may have been exposed to HAV during an outbreak. This information	1.007

Original Effective Date	Revised by	Revision	Supersedes Revision #
		may be elicited by utilizing one or more of the following: 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 Asking an additional question during the health history interview in the affected geographic area about possible exposure to the hepatitis A outbreak. These measures should take place for at least 120 days after the date of the last possible exposure. Donor Deferral will be 120 days from the date of the last potential exposure. Defer regardless of reported HAV vaccination status. Post donation information and blood component retrieval If donor was exposed, discard any in-house/in-date components 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. Perform consignee notification Recipient testing (ordered by transfusion service): anti-HAV IgM (the use of HAV RNA is optional If HAV infection is suspected test recipient for elevated liver enzymes. If recipient testing is positive, patient management consistent with Hepatitis A infection should take place at the transfusion service. Notify plasma manufacturer if plasma distributed	
3.27.01	D. Pirschel	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 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.	1.008
	D. Pirschel	DELETED and/or Executive Director, Added: It will be the responsibility of the Laboratory staff performing result review, or to destroy at the consignee location and send confirmation of destruction.	1.009
	D.Pirschel	Deleted: Director, Donor Operations Added: Refer to the following documents: Investigation of Discrepancies procedure CSL Quality Requirements and Short Supply Agreement CSL Plasma Lookback, Changes & Notification policy Octapharma Lookback policy Biological Product Deviations policy NYDOH Subpart 58-2.8 (b) Collections Management	1.010
	D.Pirschel	Added: Director, Donor Services ZIKV Defer for 4 weeks after resolution of symptoms a donor who reports symptoms suggestive of ZIKV that arose within 2 weeks of departure from an area with active transmission of ZIKV. (T87 with date of symptom resolution). Defer for 4 weeks after the last sexual contact with a donor who has had sexual contact with a man who has been diagnosed with ZIKV or who traveled to or resided in an area with active transmission of ZIKV in the 3 months prior to that instance of sexual contact. (T46 with comments) Defer for 4 weeks from the date of his or her departure, a donor who has been a resident of or has traveled to an area with active transmission of ZIKV (T87 with date left area). Product Management Quarantine and destroy any undistributed in-date blood or blood components from the donor. If components were distributed: notify consignee to destroy any in-date blood or blood components. Advise transfusion service to inform the transfusion recipient's physician of record regarding potential need for	1.011

Original Effective Date	Revised by	Revision	Supersedes Revision #
		monitoring the recipient for a possible ZIKV infection. Deleted: Manager, Donor Recruitment	
3.27.01	D. Pirschel	Added: Notify state agencies when appropriate. QA will perform regular checks (online) with state department of healths and CDC to monitor areas of Zika transmission	1.012
	D. Pirschel	Added: Zika Testing/Deferral/Reentry Requirements Zika Virus Deferral: Defer a donor who tests ID NAT reactive for Zika for 120 days from the ID NAT reactive donation or from the resolution of symptoms, whichever timeframe is longer. (T92 deferral code. Notify the donor of the deferral and request participation in further study. (see Donor Deferral and Zika Testing/Deferral/Reentry Requirements SOPs) Product Management Quarantine and destroy any undistributed in-date blood or blood components collected from the donor in the 120 days prior to the donation that is ID NAT reactive. If components were distributed: notify consignee to destroy any in-date blood or blood components. Advise transfusion service to inform the transfusion recipient's physician of record regarding potential need for monitoring and counseling the recipient for a possible ZIKV infection Zika Testing/Deferral/Reentry Requirements WNV Testing/Deferral/Reentry Requirements Chagas Testing/Deferral/Reentry Requirements Testing/Deferral/Reentry Requirements	1.013
	D. Pirschel	Added: VII. Ebola Virus Infection or Disease (EVD) Blood and Blood Components Collected from Donors at Risk for Ebola Virus Infection or Disease Because of Risk Factors Related to Residency, Travel or Close Contact Donors who should have been deferred for Risk Factors Notify Consignees to retrieve, quarantine and destroy in-date blood and blood components Retrieval and Quarantine is not recommended for plasma pooled for further manufacturing into products Blood and Blood Components collected from Donors later determined to have Ebola Virus Infection or Disease. Notify FDA and Dept. of Health as soon as possible upon learning that blood was collected from a donor later determined to have EVD or infection. This applies to blood components collected in the 8 weeks prior to disease onset or anytime after disease onset. Retrieve and Quarantine blood and blood components collected in the 8 weeks prior to disease onset and any time after disease onset. If components were transfused, consignee should notify the transfusion recipient's physician of record regarding the need for notification and monitoring of the recipient. Recommendations for Assessment of Blood Donor Eligibility, Donor Deferral and Blood Product Management in Response to Ebola Virus, 1.17	1.014
3.27.01	D. Pirschel	Deleted: Executive Director Added: Octapharma Lookback/Change Control/Deviation policy Octapharma Lookback/PDI Requirements Octapharma Quality Assurance Agreement Pres/CEO Collections Management IT Director	1.015
3.27.01	D. Pirschel	Deleted: and request participation in further study Added: ZIKVNAT	1.016
3.27.01	K. Kramer	Added: Positive Anti-A/B Titers- Refer to Processing Whole Blood, Low Titer SOP	1.017

COPY

TITLE: **POLICY: DONOR LOOKBACK/BLOOD PRODUCT RECALL**

REVIEW/APPROVAL/IMPLEMENTATION			
Department Head	**Name**	**Signature**	**Date**
Collections Management	Jennifer Stephany	Jennifer Stephany	9-10-19
Finance Manager	Sarah Uglow	Sarah E Uglow	9/16/19
IT Director	Tracy Riedel-Dorsch	Tracy Riedel-Dorsch	9-17-19
Technical Director	Tracy Collier	Tracy M Collier	9-13-19
QA Director	Kristin Kramer	Kristin Kramer	9-12-19
APPROVED BY:			
Position	**Name**	**Signature**	**Date**
Medical Director	Jeffrey A. Richmond, MD	JR Richmond	9/16/19
Executive Director	Deanna Renaud	Deanna Renaud	9/17/19
IMPLEMENTATION DATE:	OCT 01 2019		

REVIEW			
MEDICAL DIRECTOR	**DATE**	**MEDICAL DIRECTOR**	**DATE**

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RETIRED SOP

SOP RETIRED BY	TITLE	SIGNATURE	DATE RETIRED

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