PROCEDURE

Title: Look Back Policy

Procedure #: 2015BLOODBANK61

Institution: Highlands Regional Medical Center

Address: 3600 Highlands Avenue, Sebring Florida 33870

Prepared by: Anita Smith Date: 6/4/2015

Title: Laboratory Administrative Director

Accepted by: _____ Date: 6-5-15

Title: Laboratory Medical Director

Date Patient Testing Implemented: 6/1/2008

Review of procedure every two years

Reviewed by: _____ Date: _____

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Discontinued testing date: _____

Highlands Regional MEDICAL CENTER

Policy Name: Look Back Policy	**Department: Blood Bank-Lab**	
Departmental Review:	**Policy #:**	
INITIATE DATE 06/2008	**DATE REVIEWED/REVISED 09/2009, 05/2013**	**PAGE 1 of 3**

PURPOSE:
To provide a method to identify recipients of blood components from donors subsequently found to have infection with HCV, HBV and HTLV I and to have these recipients informed of the risk of infection.

PROCEDURE:

1. OneBlood, Inc. will notify our facility via a Lookback Notification Letter and Case Report when a donor of a particular blood product we received has been found to be positive for HCV, HBV, HTLV I , anti-HBc or T.cruzi (Chagas) on a subsequent donation.

2. HRMC Blood Bank will investigate the final disposition of the product in question to determine if the product is still in inventory or if it was transfused, if expired and discarded, or transferred to another facility.

3. If the product expired and was discarded, the Case Report form will be completed, returned to OneBlood, Inc. and no further follow-up is necessary.

4. If the product was transferred to another facility and OneBlood has no record of the transfer, HRMC will notify the medical facility that received the product. HRMC will forward the paperwork to the other facility, and since they have the recipient information, the Lookback becomes their responsibility. HRMC will complete the Case Report form and notify OneBlood that the product was transferred and to which facility.

5. If the product is still in inventory, the product will be immediately tagged as quarantined, placed in a biohazard bag. OneBlood will be notified that the unit is in quarantine and await instructions on the return or disposal of the unit.

6. OneBlood must notify HRMC of the results of the FDA-licensed, more specific test or other follow up testing recommended or required by the FDA. Regardless of the test results, HRMC will discard the components in question by placing in a red biohazardous trash bag, which will in turn be incinerated.

7. If the product has been transfused and the recipient is still alive or status unknown:

    a. HRMC Blood Bank will complete the case report form and return it to OneBlood.

    b. HRMC will promptly notify the recipient's attending physician (physician of record) or the physician who ordered the blood by certified/return receipt mail of their patient's potential exposure. The notification will recommend that the physician inform the patient of the Lookback case results, and suggest that the patient be tested and given further information and counseling as needed. The return receipt will be kept in the Lookback file and will be considered documentation of physician notification.

    c. The Blood Bank Medical Director will additionally notify the recipient's physician by telephone

and ask the physician to immediately notify the patient. The telephone contact shall be documented on the Case Report.

d. The Blood Bank will make at least three attempts to notify the patient's physician and document each attempt and the outcome thereof, on the Case Report.

8. If the attending physician is unavailable or declines to notify the recipient or later informs the hospital that he or she was unable to notify the patient, the transfusion service shall assume the responsibility of recipient notification. The recipient notification process requires a minimum of 3 attempts to notify the recipient and must be completed within a maximum of 12 weeks of receipt of the confirmatory testing notification. The attempts and notification should be documented on the Case Report.

9. Recipient notification will include the following information:
   a. A basic explanation of the need for testing
   b. Sufficient information so that the transfusion recipient can make an informed decision about whether to obtain testing
   c. A list of programs or places where the patient can obtain testing and counseling

10. If a state court has judged the patient incompetent, the Medical Director should notify a legal representative designated in accordance with state law. If the patient is a minor at the time of notification, the Medical Director should notify the patient's legal representative or relative. If the patient is deceased, the hospital may discontinue the notification process.

REFERENCES:

1. Current Good Manufacturing Practice for Blood and Blood Components, CBER
2. AABB Technical Manual (15th ed) p675
3. CAP Standards TRM.42170, TRM.42120

Highlands Regional MEDICAL CENTER

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INITIATE DATE 06/2008 **DATE REVIEWED/REVISED** 09/2009, 05/2013 **PAGE 3 of 3**

Reviewed by	Reviewed Date	Reviewed by	Reviewed Date
	8.6.14		
	5.28.15		
	5.29.15		

Initial Implementation Date: _____

Taken out of Service: _____

Reason: _____

Reviewed by: _____ Date: 7/10/13
Department Supervisor

Reviewed by: Angela Lawster Date: 7/8/13
Department Adm. Director

Reviewed by: _____ Date: _____
Department Chief Technologist

Reviewed and Approved by: _____ Date: 7/8/13
Department Medical Director