

**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 550 W. Jackson Blvd., Suite 1500 Chicago, IL 60661-4716 (312) 353-5863 Fax: (312) 596-4187		DATE(S) OF INSPECTION 09/10/2008 - 10/17/2008*
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED <b>TO: Michelle M. Heiden, CEO</b>		FBI NUMBER 1473043
FIRM NAME American National Red Cross Heart of America Region	STREET ADDRESS 405 W John H Gwynn Jr Ave	
CITY, STATE, ZIP CODE, COUNTRY Peoria, IL 61605-2440	TYPE ESTABLISHMENT INSPECTED Blood Bank	

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

**DURING AN INSPECTION OF YOUR FIRM I OBSERVED:**

**OBSERVATION 1**

Failure to perform a thorough investigation of an unexplained discrepancy.

When four donors presented for donation between 4/9/2008 and 6/26/2008, the firm became aware that these donors were previously registered using an incorrect gender identity. These donors were not asked the required gender related questions, including those specific to HIV, which resulted in the release of unsuitable product. No complete record review was conducted to determine if additional instances of donors with incorrect gender identities exist within the database nor is there any documentation of an assessment of the database to justify why such a retrospective record review cannot be performed.

Examples of donors that presented to donate and it was discovered that the donor was previously registered with an incorrect gender identity include the following:

1. On 6/26/2008, while performing the health history of female donor (ID (b) (6)), it was discovered that the eBDR reflected an incorrect gender of male. The firm discovered that the discrepancy occurred during the donors prior donation of 4/25/2008 (Unit (b) (6)), at which time the donor was not asked the required gender related questions, including those specific to HIV. The components from Unit (b) (6) were distributed. (Exception No. (b) (4))
2. On 5/30/2008, when the donor (ID (b) (6)) presented for donation, it was discovered that the eBDR reflected an incorrect gender of female. The firm discovered that during a previous donation of 11/30/2007 (Unit (b) (6)), the donor was not asked the required gender related questions, including those specific to HIV. The components from Unit (b) (6) were distributed. (Exception No. (b) (4))
3. On 4/9/2008 while registering female donor (ID (b) (6)) it was discovered that the female

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donor was previously registered as a male donor. The firm discovered that during a previous donation of 8/30/2007 (Unit (b) (6)), the donor was not asked the required gender related screening questions, including those specific to HIV. The components from Unit (b) (6) were distributed. (Exception No. (b) (4))

**OBSERVATION 2**

Written standard operating procedures including all steps to be followed in the collection and processing of blood and blood components for homologous transfusion are not always maintained and followed.

Specifically,

A. Standard operating procedure (b) (4) was not followed. The procedure provides instruction on how to obtain and manage information and components immediately, 24 hours a day, 7 days a week. The procedure states in part that management of suspect components, including gaining control or component retrievals may be necessary at any stage of the manufacturing process including after the manufacturing process is complete. (b) (4) (b) (4) instructs to follow SOP (b) (4) if gaining control has not been performed.

The following are examples of failure to immediately gain control (b) (4) and retrieve suspect components upon receipt of post-donation information:

1. On 5/30/2008 when a male donor, (ID (b) (6)), presented for donation it was identified by the health historian that the record for the donor reflected an incorrect gender of female. The donor history was not reviewed until three days later on 6/3/2008 when it was found that the donor had previously donated on 11/30/2007, (Unit # (b) (6)) but the male specific questions were not asked. The consignee with the recovered plasma was not notified until 6/7/2008 even though the component was still in date.
2. On 4/4/2008 a male donor (ID (b) (6)) presented for donation and reported having sex with another man since 1977. The donor history was not reviewed until three days later on 4/7/2008 when it was found that the donor had previously donated on 5/4/2007 and 11/13/2007. The consignees to which the plasma for transfusion and recovered plasma was distributed, were not

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notified until 4/7/2008 even though components were still in date.

- On 4/4/2008, a donor (ID# (b) (6)) presented for donation and reported having sex with a female who has taken or takes money or drugs or other payment in exchange for sex with the last occurrence of 6/30/2007. The donor history was not reviewed until three days later on 4/7/2008 when it was found that the donor had previously donated on 12/14/2007. The consignee of which the plasma for transfusion was distributed was not notified until 4/7/2008 even though the component was still in date.

B. (b) (4) states to deglycerolize the frozen RBC's according to the manufacturer's operating instructions. The manufacture operating instructions, protocol guide (Chapter 5) indicates that during set up, the blue striped tubing should be closed (clamped) then reopened during dilution. However the firm's procedure titled, (b) (4) states that the clamp on the blue striped line remain open which is inconsistent with manufacture instructions. I observed the deglycerolizing process and noted that the blue striped tubing was not clamped or closed during set up.

**OBSERVATION 3**

A thorough investigation of each reported adverse reaction was not made.

Specifically, the medical director does not perform a complete review of donor adverse reactions. The firm practice is to review only the events related to the current donation and does not consider or determine if any possible adverse reactions may have occurred with the donor during previous donations.

This observation was also cited on the previous FDA 483 (6/12/2007). Your response to the observation indicated that in many cases the medical director will utilize documentation of a donor's previous reactions as one piece of the information in their medical evaluation of donor complications. The employee most knowledgeable of requests for donor records from the medical director indicated an unawareness of any instances when the medical director has requested information to determine if a

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donor had experienced a prior adverse reaction. The employee has held the same position for the past six years.

**\* DATES OF INSPECTION:**  
09/10/2008(Wed), 09/11/2008(Thu), 09/12/2008(Fri), 09/22/2008(Mon), 09/23/2008(Tue), 09/24/2008(Wed), 09/25/2008(Thu), 09/30/2008(Tue), 10/02/2008(Thu), 10/03/2008(Fri), 10/07/2008(Tue), 10/08/2008(Wed), 10/17/2008(Fri)

**FDA EMPLOYEE'S NAME, TITLE, AND SIGNATURE:**

*Laurie A. Haxel*

Laurie A. Haxel, Investigator

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