DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Customhouse, Rm 900 2nd & Chestnut St Philadelphia, PA 19106 (215) 597-4390 Fax:(215) 597-0875 Industry Information: www.fda.gov/oc/industry	05/24/2010 - 06/04/2010* FEI NUMBER 2573021

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Laurene Kast Cianfrani, Senior Director, Customer Relations Management

FIRM NAME	STREET ADDRESS
American National Red Cross, Penn Jersey Region	700 Spring Garden St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Philadelphia, PA 19123-3508	American Red Cross Regional Blood Center

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 WE OBSERVED:

OBSERVATION 1

Failure to perform a thorough investigation and make a record of the conclusions and follow-up of an unexplained discrepancy.

Specifically, Exception E-0585021 was initiated on 5/21/09 when a staff member was observed performing an arm preparation inappropriately. The employee's last quarterly arm scrub assessment was conducted on 3/8/09. A total of 359 whole blood numbers were involved. The Donor and Client Support Center (DCSC) was notified on 5/22/09 to gain control of the products. (DCSC is responsible for performing component notifications and retrieval.) A Corporate Material Review Board (cMRB) Investigation, cMRB Log Number: 09-104, was held 6/3/09 and determined all in-date distributed components should be recalled. Component Status Change Record (P200905221516o34-CSCR) was initiated by DCSC to document the notification and retrieval of the components manufactured from the units. The initial gain control activities were performed within the required 48 hour timeframe, however, consignees were not notified of the recall for three in-date AS-1 red blood cells (RBC's) manufactured from units 022FN10611-expiration date 5/21/09, 022FN10613-expiration date 5/21/09, and 022FN10616-expiration date 5/21/09. NRM (not Retrieved per MRB decision; components not affected) was documented on the CSCR for the final disposition of the three AS-1 RBC's. On 4/5/10, the Center for Biologics Evaluation and Research (CBER) contacted Penn-Jersey Region Quality Assurance (QA) and requested recall information for this problem. Subsequent to the CBER notification, Penn-Jersey QA reviewed the recall file and noted that the consignees for the three AS-1 RBC's had not been notified of the recall. On 4/29/10, Penn-Jersey QA notified DCSC of the need to send recall notifications to the consignees. Written notification of the recall was not sent to consignees until 5/28/10. A problem (E-0813697) was not logged into the Automated Problem Management System regarding the failure to follow up on the recall until 6/2/10.

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 followed.

Specifically,

	EMPLOYEE(S) SIGNATURE	DATE ISSUED
SEE REVERSE OF THIS PAGE	Kimberly A. Dux, Investigator Michele M. Falchek, Investigator Michele M. Falchek John M. Mastalski, Investigator	06/04/2010

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A) Work Instruction: Performing a Retrieval or Notification of Transfusable Components, Doc No 11.3.009, Version 1.4, is not always followed in regards to meeting the timeline for final written notification to consignees. The work instruction requires the final notification letter to be sent to the consignee no later than 10 days from the end of the initial 30-day notification. For example:

1. Exception report, E-0501484, was initiated on 1/9/09 because a male donor was registered as female at the collection site for units 022FX59161 and 022KH15433. Job Aid: Guidelines for Blood Component Retrieval, Doc No 11.4.ja004, Version 1.8, requires retrieval for units collected with an incomplete donor health history. Component Status Change Record (C200901092131o2i-CSCR) was initiated by DCSC to document the notification and retrieval of the components manufactured from the units. Initial written consignee notification was sent on 1/9/09 regarding both units. Final written notification for the leukoreduced platelet component of unit 022FX59161 was not sent until 5/28/09. The final disposition for the frozen plasma component of unit 022KH15433 is listed as transfused on the Component Status Change Record, however, the disposition form is missing from the case file and the final disposition could not be verified. The late notification and missing disposition form were not noted in the CSCR review performed by a Process Verifier on 7/29/09. Problems (E-0815389, E-0815595) were not logged into the Automated Problem Management System (APMS) for the missed timeline and the missing document until 6/2/10.

2. Exception E-0768118 was initiated on 3/14/10 when a staff member was observed performing an arm preparation inappropriately. The employee was released to task on 12/23/09. A total of 189 whole blood numbers were involved. A Corporate Material Review Board (cMRB) Investigation, cMRB Log Number: 10-052, was held 3/24/10 and determined all in-date distributed transfusable components collected by the employee should be recalled. Component Status Change Record (P201003160843o12-CSCR) was initiated by DCSC to document the notification and retrieval of the components manufactured from the units. The initial gain control activities were performed within the required 48 hour timeframe. The initial written notification was performed within the required timeframe (4/6/10), however, not all consignees received the second written notification in the required timeframe. For example, three frozen plasma (022FN15424, 022FN15436, 022FS93673) and one fresh frozen plasma (022FL08701) had second notifications sent to consignees on 5/26/10. Recall information for this problem was requested by FDA on the first day of the inspection (5/24/10). Problem E-0812003 was logged into the APMS on 5/26/10 for the missed timeframe.

B) Directive: Managing Test Results, Donor Notification, and Counseling, Doc No 14.2.008, Version 1.2, states under notifications to health departments and third parties, "the Donor and Client Support Center and each facility are required to know and follow the health departments for the states or localities they serve." During lookback record review, five of the sixteen lookback files that had confirmed positive test results for Human Immunodeficiency Virus, did not contain notifications to the local or state health departments (DCSC-P-022-LB-HIV00949, DCSC-P-022-LB-HIV01436/37, DCSC-P-022-LB-HIV02216, DCSC-P-022-LB-HIV02114, and DCSC-P-022-LB-HIV02163). Problem E-0816514 was logged into the Automated Problem Management System on 6/3/10 regarding not notifying the state for the five lookback cases.

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*** DATES OF INSPECTION:**
05/24/2010(Mon), 05/25/2010(Tue), 05/26/2010(Wed), 05/27/2010(Thu), 05/28/2010(Fri), 06/01/2010(Tue), 06/02/2010(Wed), 06/03/2010(Thu), 06/04/2010(Fri)

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