

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

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DATE(S) OF INSPECTION
7/12-16/2010, 7/21/2010
FEI NUMBER
1873031

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Ms. Sharyn L. Whitman, Chief Executive Officer

FIRM NAME
American National Red Cross Indiana-Ohio Region

STREET ADDRESS
1212 E California Rd

CITY, STATE AND ZIP CODE
Fort Wayne, IN 46825-5812

TYPE OF ESTABLISHMENT INSPECTED
ARC Regional Blood Donor Services

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: A failure to follow the Amended Consent Decree of Permanent Injunction #93-0949 dated April 15, 2003 Paragraph IV.B.1 (c) and (d): requiring implementation and monitoring of detailed corrective action plans.

Specifically, Corrective Actions #1 and #2 implemented for Issue (b) (4) (failure to perform the reconciliation of test results) do not specifically address the root causes identified by the investigation and they do not describe the timeframe for effectiveness checks (ECs) or actions to be taken when the ECs do not reflect the required improvements. In addition, these Corrective Actions were not completed within the designated timeframes.

Donor notification of test results, the addition of donors to the National Donor Deferral Registry (NDDR) and the Look Back process do not begin until confirmatory test results are reconciled at the Donor Client Services Center (DCSC). Indiana -Ohio Region Exception report # (b) (4) was created on April 6, 2010 when it was discovered that DCSC in Charlotte failed to enter Anti-HTLV reactive confirmatory test results by 01/08/2010 and therefore failed to submit a donor to the NDDR by 02/08/2010. Once discovered, this Exception was merged with 27 Exceptions from other regions into an existing DCSC Issue report (b) (4) created on 03/11/2010.

Corrective Actions were to have been completed and signed off by 7/11/2010. As of 7/16/2010, they were not completed in the (b) (4). The Effectiveness Checks did not show a due date in (b) (4) because the Corrective Actions had not been completed.

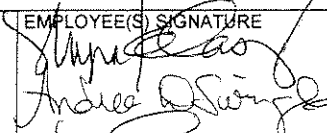
The Root Cause Investigation for this Issue was closed and approved on 05/11/2010 citing the following probable causes:

1. No defined process in how test results are distributed and accounted for by the Charlotte, NC DCSC teams
2. No defined due date for reconciliation of test results
3. No defined method for accessing and interpreting current positive test results for a donor

DCSC's Corrective Action #1 does not define an exact process for how test results will be distributed and accounted for and when the reconciliations will be due. It does not specify what Standard Operating procedures or employee duties and responsibilities will be changed.

Corrective Action #2 suggests a method to more easily identify new positive test results, but does not define how they will ensure this method is used by the staff.

The interim Qualitative Effectiveness check merely states it will be deemed effective if the Corrective Actions were put into place. The Quantitative Effectiveness Check does not have an implementation date or a duration for which improvements must be sustained. There are no follow up actions required if corrective actions do not produce the desired 67% reduction in problems related to Late Test Result Entry.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) Myra K. Casey, Investigator Andrea D. Swingle, Investigator Dawn Coleniac, Investigator	DATE ISSUED 7/21/2010
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OBSERVATION #2:

Failure to perform a thorough investigation, including conclusions and follow up of each reported donor adverse reaction.

Specifically, we reviewed 24 of the 51 "Major" Donor Adverse Event files from September 1, 2009 and found the following delinquent or missed reviews:

1. The Medical Director review was not completed on 3 Donor Reaction and Injury Reports (DRIRs) and it was completed over 3 weeks after the reaction on 9 others. One of the DRIRs missing the Medical Director review (Case # (b) (6) involved a donor under age 19 who experienced a twisted ankle during a "less than one minute" loss of consciousness with prolonged recovery.
2. The "Final Quality Review" of the Donor Reaction and Injury Report was not performed on 11 of the 24 reactions and was performed more than 2 months after the Medical Director Review on 4 occasions.
3. The Process Verification signature in Section G was missing on 4 of the 5 available Donor Status Change Records (DSCRs). Two of the six files requiring unit discard did not include the DSCR for our review.
4. The Process Verification signature was missing on 3 of the 4 available Component Status Change Records (CSCRs). Two of the 6 files requiring unit discard did not include a CSCR

In addition, we found deficiencies on the following Adverse Event records:

1. 5 Donor Reaction and Injury Reports had missing or incorrect entries.
2. 2 of the Donor Status Change Records had missing or incorrect entries. For example, the DSCR for Case ID# (b) (6) (donation date 12/17/2009) only recorded that a Post Donation Information (PDI) assertion was removed on 12/18/09 (which equates to removing the hold on the unit). When we verified the unit disposition in the computer, the software indicated a Quarantine and Labeling hold was applied 12/20/2009 and removed on 12/21/2009. A Medical Hold was then applied on 1/7/2010. The Medical Director review was not completed until 01/10/2010; he determined the unit should be discarded due to donor reported signs of phlebitis. A Not for Transfusion hold was applied 01/14/2010. The unit was subsequently discarded.
3. 1 Component Status Change Record was not completed as the final disposition of the unit was not entered.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) Myra K Casey, Investigator Andrea D. Swingle, Investigator Dawn C Olenyack, Investigator	DATE ISSUED 07/21/2010
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