DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, ste 5900 Detroit, MI 49404 313-393-8100	3/3-21/08
	FEI NUMBER 1873033

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Sharon L. Jaksa, CEO

FIRM NAME	STREET ADDRESS
American Red Cross Blood Services	1800 E. Grand River Ave
CITY, STATE AND ZIP CODE Lansing, MI 48912	TYPE OF 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 identify, investigate, and correct a problem and to gain control of suspect or non-conforming blood products. On 1/16/08, a potential mix-up of donor sample test tubes occurred during collections at the Great Lakes Region involving whole blood units (b) (6) and (b) (6). The Detroit National Testing Laboratory (NTL) discovered the potential mix-up on 1/16/08, and notified the Region of the discrepancy. The red blood cells (RBCs) manufactured from the units were distributed on 1/22/08.

a. The NTL notified the Region of receiving too many tubes by (b) (4) Form on 1/17/08; the Region told the NTL that "all samples were acceptable." The samples were tested and released. No exception report was opened to address the failure of the Region to identify a donor sample test tube mix-up that has potential impact on product suitability and requires a thorough investigation and corrective action until 2/7/08. No exception report was opened to address the failure to recognize no action was taken on 1/17/08 when information became available to the Great Lakes Region that the original error occurred.

b. On 1/23/08, the NTL created an exception report (b) (4) for running the samples with the incorrect number of tubes. During that investigation, the NTL contacted the Region on 1/29/08 to quarantine in-house products. They also opened a (b) (4) case to determine whether distributed product should be quarantined. The exception report lists as a probable cause, "miscommunication between region and NTL when region notified by NTL that an extra clot tube was received causing delay in investigation." The exception report was closed on 2/14/08. It does not describe an investigation of and corrective action for the "miscommunication" that resulted in failure to ensure that the affected units and/or their components were immediately quarantined to prevent their distribution prior to completion of a thorough investigation and determination regarding their suitability for distribution.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	Kelley Clark	Kelley Clark, Investigator	3/21/08

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OBSERVATION #2

Failure to perform consignee notification within 48 hours of receiving notification of suspect product and failure to identify, investigate, and correct a problem. On 12/4/07 the Great Lakes Region (GLR) was notified by the Southern California Region (SCR) of a unit collected 6/07 being withdrawn due to post donation information of the donor using injectable drugs in 1992. The GLR failed to forward the information to the (b) (4) in accordance with (b) (4) (b) (4) and the (b) (4) did not learn of the market withdrawal until 1/2/08 when they received written notification directly from the SCR. The product was shipped from the GLR on 7/13/07 to (b) (4)

a. A Biological Product Deviation Report (BPDR) was submitted by the SCR stating consignees were notified on 12/4/07 when the consignees were not notified until 1/2/08.

b. No written procedure has been established to verify consignee notification and market withdrawal or recall are completed within the 48 hour notification time frame, when the affected blood products have been exported from one ARC region to another ARC region.

c. A (b) (4) investigation was initiated on 1/2/08 in response to the employee failing to apply a hold to a suspect product, deviation (b) (4). No CAP was developed within 30 days of the deviation being discovered as required by (b) (4)

OBSERVATION #3

Failure to perform a thorough and prompt investigation. Exception report (b) (4) was created on 6/5/07 for a problem discovered on 5/30/07 during a collections employee's quarterly competency assessment. The employee was observed to incorrectly perform the copper sulfate test for hemoglobin. Two units from the day's collection were quarantined and later destroyed. The scope of initial investigation and Material Review Board review (b) (4) failed to include previous health histories performed by this collection employee as questionable. Not until 12/3/07, six months after discovery of the initial problem, did the region Quality Assurance staff review the investigation for closure and determine that the scope was too narrow. By the time it was determined if previous units could be affected by this error all affected products were transfused and expired. The expanded investigation reviewed the histories performed by this collection employee back to the last passing assessment and found

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the employee had performed 344 donor histories where a passing hemoglobin test was performed. The investigation is still being reviewed as of 3/2008, 9 months after the initial problem was found and 3 months after the second investigation was initiated.

OBSERVATION #4

Failure to promptly implement corrective action related to exception report (b) (4) The problem was discovered 5/4/07 when the region was notified by a customer that a unit labeled as B positive was tested as O negative. The ABO/Rh discrepancy was found to be related to a WBN mix-up. The MRB Investigation found the error occurred at the region and was signed as completed by 5/30/07. The exception report is still open as of 3/8/08 pending completion of the corrective actions. The electronic donor records for the two donors affected by the WBN mix-up and ABO/Rh discrepancy had not been corrected as of the time of this inspection.

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