DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
22201 23rd Drive SE Bothell, WA 98021-4421 (425) 486-8788 Fax:(425) 483-4996	07/21/2008 - 07/25/2008
	FEI NUMBER 1000307460

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Jennifer L. White, Director, Operational Support

FIRM NAME	STREET ADDRESS
American National Red Cross	12124 NE Ainsworth Circle
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Portland, OR 97220	National Testing Laboratory

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:

This FDA 483 was modified from the original document issued on July 25, 2008. The header has been updated to include the FEI, which was hand written on the original form.

OBSERVATION 1

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

Specifically,

(b) (4) states that "Formal CAPs must be developed for all trends (including trends associated with (b) (4) (b) investigations), (b) (4) investigations..."

Several (b) (4) investigations that I reviewed during the inspection did not have a formal CAP attached. Examples include exceptions (b) (4) both of which were coded as (b) (4) problems. (b) (4) allows for exceptions from this requirement in specific cases for historical trends that are unrelated to the two examples. It does not otherwise allow (b) (4) problems to be closed without a formal CAP.

SEE REVERSE OF THIS PAGE

AMENDED

DATE ISSUED
07/28/2008

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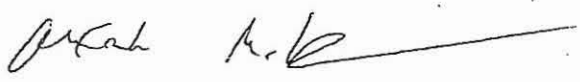
FDA EMPLOYEE'S NAME, TITLE, AND SIGNATURE:



Alexander M. Kay, Investigator

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AMENDED

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