DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax: (313) 393-8139 Industry Information: www.fda.gov/oc/industry	05/25/10-06/16/10
	FEI NUMBER 1000306317

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Robert V. Markey, Chief Executive Officer, Biomedical Services

FIRM NAME	STREET ADDRESS
American National Red Cross, National Testing Lab	100 Eliot Street
CITY, STATE AND ZIP CODE Detroit, MI 48201-2408	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 WE OBSERVED:

OBSERVATION 1

Annual competency reviews and/or quality assurance process reviews of (b) (4) operators did not effectively identify steps which were not being correctly performed according to work instructions, package inserts or operator's manuals.

Specifically,

A.) Twenty-one of 31 employees performing addition of reagents to the (b) (4) were not following either the Work Instruction: (b) (4) or the package insert, both of which direct personnel to gently invert rare reagents prior to placement on the machine. Beginning in 2007, this step was incorrectly performed for approximately 2+ years according to exception report E-0542911. Competency assessments performed during this time period have required assessors to use this work instruction to ensure appropriate rare reagent loading. No personnel were found to have failed the competency reviews (as indicated by the failure to correctly complete 1 or more required tasks) during this time.

B.) Employees of Detroit NTL completing the task of replacement of purge solution on the (b) (4) were not performing a portion of this process correctly according to both the (b) (4) and the (b) (4) User's Manual. Both of these references require replacement of the cap and stem assembly with a new assembly. Beginning in April 2008, this step was incorrectly performed for approximately 2 years according to exception report E-0796638. During this time period, all competency assessments completed for these personnel required assessors to use this work instruction to ensure correct purge solution mixing and loading, including replacement of the cap assembly. No personnel were found to have failed the competency reviews during this time. In 2009, Quality Process Reviews which specifically included an assessment of the preparation and loading of (b) (4) purge solution to ensure the direction "If a new solution, add new cap and stem assembly" was being followed were completed in the Viral Processing Laboratory. Reviews indicated that this step was completed and/or adequately understood by all employees operating (b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
		Barbara A. Rusin, Investigator L'Oreal D. Fowlkes, Investigator Sherri J. Blessman, Investigator	06/16/10

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax: (313) 393-8139 Industry Information: www.fda.gov/oc/industry	05/25/10-06/16/10
	FEI NUMBER 1000306317

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Robert V. Markey, Chief Executive Officer, Biomedical Services

FIRM NAME	STREET ADDRESS
American National Red Cross, National Testing Lab	100 Eliot Street
CITY, STATE AND ZIP CODE Detroit, MI 48201-2408	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.

OBSERVATION 2

Failure to adequately investigate and correct a problem.

Specifically, on 02/05/10 review of proficiency testing attestation forms completed between 01/01/09 and 12/31/09 was performed by a quality control supervisor. This review indicated that of the 23 reviewed attestations, 2 were missing signatures for employees who performed proficiency tests. This problem was logged as Level 1 exception E-0744002. A communication was sent to "all Detroit NTL supervisors of the VTL, APL and NAT, QC supervisor/lead and production managers/BOT stating the importance of attestation form signatures and supervisors roles in verifying that signatures are captured at the time of testing."

During the current inspection, it was discovered that there were an additional 13 employees who completed proficiency tests between the dates of 01/01/09 and 12/31/09, but did not sign attestations. During that time period a total of 93 employees completed proficiency testing. Exceptions E-0816805 and E-0818851 were logged on 06/03/10 and 06/08/10, respectively, in regards to these findings. Both exceptions are related to issue I-0020416-FC which is currently open to document investigation of root cause(s) and development and implementation of corrective action plan(s). These exceptions also document the added findings during the inspection that between the dates of 11/01/08 and 12/31/08, 7 employees completed proficiency tests, with 1 not having signed the correct attestation; and since 01/01/10, a total of 38 employees have completed proficiency tests, with 4 not having signed the appropriate attestation.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	Barbara A. Rusin L'Oreal D. Fowlkes Sherri J. Blessman	Barbara A. Rusin, Investigator L'Oreal D. Fowlkes, Investigator Sherri J. Blessman, Investigator	06/16/10