

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

DISTRICT ADDRESS AND PHONE NUMBER

550 W. Jackson Blvd., Suite 1500
Chicago, IL 60661-4716
(312) 353-5863 Fax: (312) 596-4187
Industry Information: www.fda.gov/oc/industry

DATE(S) OF INSPECTION

10/19/2010 - 10/26/2010*

FEI NUMBER

3001608660

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Karl Jason Gerlach, Quality Director

FIRM NAME

American Red Cross Heart Of America
Blood Services Region

STREET ADDRESS

143 E Main St

CITY, STATE, ZIP CODE, COUNTRY

Galesburg, IL 61401-4612

TYPE ESTABLISHMENT INSPECTED

Donor 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 I OBSERVED:

OBSERVATION 1

Failure to provide adequate space for private examinations of individuals to determine their suitability as blood donors.

Specifically, privacy was not maintained when employee "(b)" screened Donor #(b) (6). While standing outside the screening booth and beside the donor collection area, I could hear "(b)" read the screening questions to Donor #(b) (6) and I could hear Donor #(b) (6) respond to the screening questions.

*** DATES OF INSPECTION:**

10/19/2010(Tue), 10/26/2010(Tue)

**SEE REVERSE
OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Laurie A. Haxel, Investigator

DATE ISSUED

10/26/2010