DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1777 Hardee Ave SW Atlanta, GA 30310 (404)253-1284 Fax:(404)669-4443	3/11/2026-3/19/2026*
	FEI NUMBER 1075944

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Tyrone NMI Peacock, Quality Assurance Consultant

FIRM NAME	STREET ADDRESS
American Red Cross Blood Svcs	4737 University Dr Bldg 3
CITY, STATE, ZIP CODE, COUNTRY Durham, NC 27707-3460	TYPE 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

A written record of the program along with appropriate validation data has not been maintained in situations where backup data is eliminated by computerization or other automated processes.

Specifically, (b) (4) blood establishment computer system version v2021.1.1.6 has not been validated at this location. (b) (4) has been in use at this location since May 9, 2022. This computer application is used by the immunology reference laboratory (IRL) for patient antibody identification, direct antiglobulin testing (DAT), and ABO identification.

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*DATES OF INSPECTION

3/11/2026(Wed), 3/12/2026(Thu), 3/13/2026(Fri), 3/17/2026(Tue), 3/18/2026(Wed), 3/19/2026(Thu)

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Marla A Cassidy, Investigator

X Marla A Cassidy
Investigator
Signed By: 2000537662
Date Signed: 03-19-2026
09:23:26

DATE ISSUED
3/19/2026

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."