DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
109 Holton Street Winchester, MA 01890 (781)587-7500 Fax:(781)587-7556	5/4/2026-5/6/2026
	FEI NUMBER 3020324041

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Robert J. Berg, Site Supervisor

FIRM NAME	STREET ADDRESS
The American National Red Cross	99 Indian Field Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Greenwich, CT 06830-7213	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 WE OBSERVED:

OBSERVATION 1

Written standard operating procedures including all steps to be followed in the collection of blood and blood components for allogeneic transfusion and autologous transfusion were not always established, maintained and followed.

Specifically,
a) Your standard operating procedure #15.3.639 entitled "WI: Using the (b) (4) Device" instructs to select (b) (4) in the parameters (b) (4) if the suggested parameters will not be used. Suggested parameters are listed in (b) (4) (b) (4) document dated 10/2023, but do not include adjustments of the volume of the whole blood processed (WBP). On (b) (6), (b) (7)(C), the WBP number was observed being adjusted (b) (4) (b) (4) to select the optimal plateletpheresis procedure during the apheresis donations (b) (4), (b) (6), (b) (7)(C) and (b) (4), (b) (6), (b) (7)(C).
b) Your standard operating procedure #15.3.600 entitled "WI: Collecting a Whole Blood Unit from an Allogeneic Donor" directs to select (b) (4) to capture start time. This time can be adjusted to the (b) (4). On (b) (6), (b) (7)(C), whole blood unit (b) (4), (b) (6), (b) (7)(C) start time was captured (b) (4) from the (b) (4) of the draw. However, time in your (b) (4) system that documents collections of whole blood was not adjusted to reflect it.
c) On (b) (6), (b) (7)(C), prior to collection of platelet unit (b) (4), (b) (6), (b) (7)(C), the donor experienced (b) (6), (b) (7)(C), (b) (4) to the apheresis kit. There is no standard operating procedure that would describe the steps and conditions for (b) (4).

OBSERVATION 2

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Irina Gaberman, Investigator Chanel E Crawford, Investigator	X Irina Gaberman Investigator Signed By: 1300222798 Date Signed: 05-06-2026 07:02:09	5/6/2026

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Failure to maintain donor, processing, quality control and general records.

Specifically,
a) There are no records for unit (b) (4), (b) (6), (b) (7)(C) and unit (b) (4), (b) (6), (b) (7)(C) On 05/04/2026, apheresis collection kits installed and collection specimen tubes were labeled with the above unit identification numbers, apheresis machines primed and donations were observed being programmed on the machines.
b) Your Standard Operating Procedure #REF-0000326 entitled "REF: Problem Management Overview" requires investigation of non-conformances (NC). Review of the Non-Conformances for 2025-2026 found that the investigations are not always complete and do not include root cause analysis with the staff involved. Some examples are: NC-0658668, NC-0680935, NC-0676473.

OBSERVATION 3
Failure to use supplies and reagents in a manner consistent with instructions provided by the manufacturer.

Specifically,
(b) (4)
(b) (4) whole blood collection bag:
a) Package instructions, state: (b) (4)
(b) (4) On 05/04/2026, the (b) (4) (b) (4) containing (b) (4) unused whole blood collection bags was observed opened for (b) (4) (b) (4). On 05/05/2026, the (b) (4) containing (b) (4) unused whole blood collection bags was observed opened for (b) (4).
b) Package insert states: (b) (4)
(b) (4). On (b) (6), (b) (7)(C), (b) (4) whole blood collection units were observed being removed from the overwrap but were not inspected. The following units of the whole blood were collected: (b) (4), (b) (6), (b) (7)(C) and

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(b) (6), (b) (7)(C).

OBSERVATION 4

Failure to store platelets immediately after resuspension at 20 to 24 degrees Celsius with continuous gentle agitation.

Specifically,
On 05/04/2026, (b) (4) bags of platelet unit (b) (4), (b) (6), (b) (7)(C) were placed on the (b) (4) in the processing/packaging room (b) (4) to the manufacturing facility. However, there was no temperature monitoring performed in this room. (b) (4) platelet units were collected on (b) (6), (b) (7)(C).

X Chanel E Crawford
Investigator
Signed By: CHANEL E. CRAWFORD -S
Date Signed: 05-06-2026 07:02:48

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EMPLOYEE(S) SIGNATURE
Irina Gaberman, Investigator
Chanel E Crawford, Investigator

X Irina Gaberman
Investigator
Signed By: 1300222798
Date Signed: 05-06-2026 07:02:09

DATE ISSUED
5/6/2026

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."