DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 Ext:5301 Fax:(718)662-5661	4/17/2026-4/23/2026* FEI NUMBER 1000137396

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Giovanna S. Roque, Senior Manager, Quality

FIRM NAME	STREET ADDRESS
New York Blood Center Enterprises	3125 Veterans Memorial Hwy
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Ronkonkoma, NY 11779-7644	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

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

Specifically,
a) (b)(4) is used to collect (b)(4) red blood cells via apheresis. Operator's manual requires opening the clamp on the donor line to initiate collection after the whole blood has been collected in the sampling pouch and the pouch is sealed. After the clamp on the donor line is opened, the samples should be collected as soon as possible. On 04/17/2026, collection was not initiated after the sample pouch was filled with whole blood and sealed. Collection was initiated after the samples were collected from the pouch. (b)(4) red blood cells unit # [redacted] was collected.
b) On 04/17/2026, Donor Specialist [redacted] documented that (b)(4) was leveled using (b)(4) levels on the (b)(4) of the instruments, but it did not appear to complete the task. Unit # [redacted] was collected on instrument (b)(4) (first collection of the day) while the (b)(4) level was (b)(4), indicating the instrument was not level. The manufacturer's instructions for use instruct to, "Ensure the instrument is level by adjusting the instrument's [redacted] until the (b)(4)" prior to starting a collection procedure.

***DATES OF INSPECTION**
4/17/2026(Fri), 4/21/2026(Tue), 4/23/2026(Thu)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Irina Gaberman, Investigator	X Irina Gaberman Investigator Signed By: 1300222798 Date Signed: 04-23-2026 08:29:53	4/23/2026

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."