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	3/16/2026-4/3/2026* FEI NUMBER 2473015

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Betsy W. Jett, Senior Vice President, Quality and Regulatory Affairs

FIRM NAME	STREET ADDRESS
New York Blood Center Enterprises	601 Midland Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Rye, NY 10580-4000	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

Written standard operating procedures including all steps to be followed in the collection, processing, compatibility testing, storage and distribution of blood and blood components for allogeneic transfusion and autologous transfusion were not always established, maintained, followed and available to personnel in the areas where procedures were performed.

Specifically,

a) Your standard operating procedure NY-SOP-0090 entitled "Preparation of Cryoprecipitated AHF and Pooled Cryoprecipitated AHF":

i) states that cryoprecipitation is accomplished by (b) (4) refrigerator. On 03/16/26, Component Technician (b) (6), (b) (7)(C) . moved a (b) (4) with (b) (4) plasma units from the freezer to the (b) (4) Lab (b) (4) to (b) (4) into the (b) (4) Refrigerator (b) (4) At least three CDP units were observed with a (b) (4) of (b) (4) plasma at the (b) (4) of the bags. Other bags showed signs of thawing or melting. The SOP does not instruct to (b) (4) (b) (4) refrigerator for thawing.

ii) states: "Verify the (b) (4) has a (b) (4) consistency prior to ending the (b) (4) ". On 03/17/2026, at least (b) (4) units (b) (4), (b) (6), (b) (7)(C) and (b) (4), (b) (6), (b) (7)(C) were observed completely thawed without any (b) (4) consistency.

b) Your standard operating procedure #NY-SOP-0596 entitled "Central Supply and Receiving (CSR) Label Control Distribution", section 6.4 states that "(b) (4) labels are (b) (4) to CSR and (b) (4) (b) (4) on the ISBT (b) (4) (Refer to NY-FRM-0783). Review of ISBT (b) (4) (b) (4) for 2025 found that ISBT label (b) (4) is not always documented as (b) (4) or (b) (4) . For

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(b) (4), (b) (4) of the labels was not documented on 09/07/2025, 09/08/2025, 10/24/2025 and 10/25/2025.

c) Your standard operating procedure NY-SOP-0077 entitled "Report of (b) (4) (b) (4) states: "Data from hospital report will be entered into (b) (4) (b) (4) by (b) (4) upon receipt including (b) (4) (b) (4) information as necessary." On (b) (6), (b) (7)(C), suspected transfusion related adverse event resulting in a fatality was reported by a hospital to your firm. However, (b) (4) initiation was documented on 09/14/2025.

d) Your standard operating procedure NY-SOP-0088, entitled "Labeling and Release of Blood Products" section 6.1.1.2 states: "Frozen Plasma components must be (b) (4) to (b) (4) frozen storage (b) (4) to showing any signs of thawing" and section 6.1.1.2.1 states: "Frozen plasma components showing signs of thawing/melting should be (b) (4)." Neither your written procedures nor your Blood Product Inspection Guide explain how to identify signs of thawing/melting.

e) Your standard operating procedure #NY-SOP-0162 entitled "Receiving-Processing Granulocyte Donor" states that when looking for an acceptable (b) (4) granulocyte donor, total white blood cells count must be (b) (4). On (b) (6), (b) (7)(C), (b) (4) granulocyte donor (b) (6), (b) (7)(C) with a count of (b) (4) was accepted and donated granulocytes unit (b) (4), (b) (6), (b) (7)(C) that was released for transfusion on (b) (6), (b) (7)(C). There was no deviation generated to investigate acceptance of an ineligible (b) (4) granulocyte donor as required by your SOP NY-SOP-0001 entitled: "Deviations Management". The SOP states: "As soon as possible and within (b) (4) of discovering the deviation, generate the deviation report in (b) (4)". On 01/08/2025, the Medical Director confirmed that donor (b) (6), (b) (7)(C) was ineligible to donate granulocytes without (b) (4).

f) Your standard operating procedure #NY-SOP-0001, entitled "Deviation Management" states: "As soon as possible and within (b) (4) of discovering the deviation, generate a deviation report in the (b) (4)". On 10/16/2025, leukoreduced whole blood unit (b) (4), (b) (6), (b) (7)(C) failed (b) (4) (b) (4) quality control with reported (b) (6), (b) (7)(C) which was more than the allowed (b) (4) (b) (4). Your standard operating procedure #NY-SOP-0059 entitled "Quality Control Leukocyte Reduced Components" requires the unit to be (b) (4) for investigation but it was not (b) (4).

g) Your standard operating procedure #NY-SOP-0057 entitled "QC of Single Donor Plateletpheresis

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Components" is not detailed enough to describe the preparation of a single unit of platelets with a bag volume more than (b) (4). For example, on (b) (4), (b) (6), volume of the single unit of platelets (b) (4), (b) (6), (b) (7)(C) was (b) (6), (b) (7)(C). There were no instructions on how to process and label this single unit of platelets. The unit was distributed on (b) (6), (b) (7)(C) with final volume of (b) (4), (b) (6), (b).

h) On (b) (4), during blood drive (b) (4), access to the standard operating procedures was not available. There were (b) (4) whole blood and (b) (4) units collected.

OBSERVATION 2

Failure to maintain quality control and general records.

Specifically,

a) No visual inspection was documented during storage or immediately before distribution for (b) (4) blood products distributed using (b) (4) between (b) (4).

b) On (b) (4), (b) (4) whole blood and (b) apheresis Red Blood Cells units were observed placed in a same (b) (4) at the collection site (blood drive) to be transported to your manufacturing facility. There are no records that the (b) (4) were qualified to maintain whole blood and apheresis Red Blood Cells temperature (placed in the same (b) (4)) during transportation. The temperature of whole blood and Red Blood Cells is not checked upon receipt of the coolers. There were (b) (4) whole blood units and (b) (4) double Red Blood Cells units collected on the blood drive.

c) There was no documentation that label printing was verified for autologous type (b) (6), (b) (units. Autologous Red Blood Cells unit (b) (4), (b) (6), (b) (7)(C) was collected on (b) (6), (b) (7)(C) and labeled on 11/06/2025. The donor tested as (b) (6), (b) (7), but the blood type was too long to fit in the designated space on the label, and the label printed as (b) (6), (b instead of (b) (6), (b) (7). The unit was distributed on (b) (6), (b) (7)(C), (b) (4), (b) (4), and (b) (4).

d) There are no records of receipt, storage and visual inspection of Granulocytes plateletpheresis unit (b) (4), (b) (6), (b) (7)(C), collected on (b) (6), (b) (7)(C), and received at your facility on the (b) (6), (b) (7)(C). On (b) (6), (b) (7)(C), this unit was distributed to the hospital. Your standard operating procedure #NY-SOP-0259 entitled "Distribution and Documentation of Blood Products & Resale Items" requires visual inspection to be documented prior to distribution.

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OBSERVATION 3
Failure to submit a biological product deviation report.

Specifically,
Your standard operating procedure #NY-SOP 0162 entitled, "Receiving-Processing Granulocyte Donor" states that an eligible (b) (4) granulocyte donor must have a total white blood cell count of (b)((b) (4) . On (b) (6), (b) (7)(C), granulocyte donor (b) (6), (b) (7)(C), an (b) (4) donor, with a total white blood cell count of (b) (4) was determined eligible and donated granulocyte unit (b) (4), (b) (6), (b) (7)(C). The unit was released for transfusion on the (b) (6), (b) (7)(C). On 01/08/2025, the Medical Director confirmed that granulocyte donor (b) (6), (b) (7)(C) was ineligible to be an (b) (4) granulocyte donor.

OBSERVATION 4
Failure to use supplies and reagents in a manner consistent with instructions provided by the manufacturer.

Specifically, the manufacturer's instructions for the (b) (4) System with an (b) (4) (b) (4) using (b) (4) for Whole Blood Collection and Filtration of Red Blood Cells with (b) (4) and your written procedure, "NY-(b) (4)-0452 (b) (4) Centrifuge Cup Loading: (b) (4) (b) (4) centrifuge cup, (b) (4) .
On 03/16/26 and 03/18/26, (b) (4) technicians centrifuged whole blood with (b) (4) (b) (4) centrifuge cup. Rather than (b) (4) and (b) (4) (b) (4) . (b) (4) technicians (b) (4) centrifuge cups (b) (4) the blood bags. Examples include unit (b) (4), (b) (6), (b) (7)(C) and units (b) (4), (b) (6), (b) (7)(C) through (b) (4), (b) (6), (b) (7)(C) Since relocating to the current facility on (b) (4) , your firm has manufactured (b) (4) blood products.

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OBSERVATION 5

The personnel responsible for the processing of blood or blood components are not adequate in training and experience, including professional training as necessary to assure competent performance of their assigned functions, and to ensure that the final product has the safety, purity, potency, identity and effectiveness it purports or is represented to possess.

Specifically,
On 03/16/2026, a (b) (4) with at least (b) (4) plasma units was removed from the freezer by Component Technician (b) (6), to the (b) (4) room (ambient temperature setting) in order to prepare a (b) (4) (b) (4) " by (b) (4) each unit and creating labels. At least (b) (plasma units were observed having a (b) (4) of thawed plasma at the (b) (4) of the plasma bag with other bags showing signs of thawing/melting. Review of the training records for (b) (6), found that this employee was trained on (b) (6), (b) (7)(C) on the (b) (4) Refrigerator (b) (4) " preparation and not on handling and preparing (b) (4) products for Cryoprecipitated AHF manufacturing.

OBSERVATION 6

Failure to maintain temperatures during shipment of Red Blood Cells between 1 and 10 °C.

Specifically,
(b) (4) bags of Red Blood Cells unit (b) (4), (b) (6), (b) (7)(C), collected on (b) (6), (b) (7)(C) at (b) (6), (b) (7)(C, were left at Donor Center site (b) (4) as stated in deviation #DEV-2025-2245. These RBC units were delivered to your manufacturing facility on (b) (6), (b) (7)(C) at (b) (6), (b) (7)(C. The temperature of RBC unit (b) (4), (b) (6), (b) (7)(C) (b) (4) was (b) (4) and (b) (4) . Both units were put into the inventory and distributed to the hospitals on (b) (6), (b) (7)(C).

OBSERVATION 7

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Records are not concurrently maintained with the performance of each significant step in the processing, storage and distribution of each unit of blood and blood components so that all steps can be clearly traced.

Specifically,
a) Records do not identify who performed significant steps in component preparation or when they were performed, including centrifugation, plasma separation, (b) (4) solution, or the (b) (4) (b) (4). The centrifuge equipment and centrifuge program used for whole blood separation are not identified. The process from centrifugation to the end of filtration is documented as a (b) (4) date and (b) (4) entry, often by a different technician (b) (4) the processing steps were performed. For example, on (b) (6), (b) (7)(C), we observed manufacturing of unit (b) (4), (b) (6), (b) (7)(C) and on (b) (6), (b) (7)(C) unit (b) (4), (b) (6), (b) (7)(C). There were (b) (4) blood components manufactured in (b) (4); however, equipment and program used to centrifuge whole blood units and the individuals performing separation of whole blood were not documented.
b) On 03/23/2026, I observed Donor Specialist (b) (6), (b). document that they verified that (b) (4) (b) (4) and (b) (4) were level using (b) (4) on the (b) (4) (b) (4), but they did not appear to complete the task. Unit (b) (4), (b) (6), (b) (7)(C) was collected on instrument (b) (4) while the (b) (4) was (b) (4) (b) (4), indicating the instrument was not level. The manufacturer's instructions for use instruct to, "Ensure the instrument is level by (b) (4) until the (b) (4) (b) (4) to starting a collection procedure.
c) (b) (4) Procedure Records, used to document each step during apheresis collections, do not always show the name of individuals who entered or changed collection parameters or answered warnings or alarms. Examples include:

i. "(b) (4)" is listed for entering the blood type, hemoglobin measurement, platelet count, and procedure selection, as well as (b) (4) the (b) (4) in response to instrument warnings during the collection of (b) (4) unit (b) (4), (b) (6), (b) (7)(C) on (b) (6), (b) (7)(C)

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ii."(b) (4)" is listed as adjusting the (b) (4) during the collection of (b) (4) unit (b) (4), (b) (6), (b) (7)(C) on (b) (6), (b) (7)(C)

d) On (b) (6), (b) (7)(C), red blood cells unit (b) (4), (b) (6), (b) (7)(C) was irradiated. On 05/20/2025, the unit was labeled and put into available inventory, but it was not modified in the blood establishment computer system (BECS) or relabeled to indicate it was irradiated. The unit remained available for distribution in BECS as a non-irradiated product until it was destroyed on (b) (6), (b) (7)(C).

OBSERVATION 8

Failure to provide one or more segments with each unit of Red Blood Cells when (b) (4).

Specifically, complaints COMP-2024-0052 and COMP-2024-0212 were received on 03/18/2024 and 10/03/2024 alleging that customers received red blood cell units (b) (4), (b) (6), (b) (7)(C) and (b) (4), (b) (6), (b) (7)(C) without any attached segments for testing. The units were returned, and an investigation confirmed that zero segments remained attached to the units. The removed segments could not be located. On (b) (6), (b) (7)(C), these units were (b) (4) without segments or accompanying instructions for sampling.

***DATES OF INSPECTION**

3/16/2026(Mon), 3/17/2026(Tue), 3/18/2026(Wed), 3/19/2026(Thu), 3/20/2026(Fri), 3/23/2026(Mon), 3/24/2026(Tue), 3/25/2026(Wed), 3/27/2026(Fri), 4/03/2026(Fri)

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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."