

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

DISTRICT ADDRESS AND PHONE NUMBER 158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 Ext:5301 Fax: (718) 662-5661	DATE(S) OF INSPECTION 3/2/2026-3/11/2026* FEI NUMBER 2475795
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Andrea D. Restifo, Vice President, Quality and Clinical Operations

FIRM NAME North Shore University Hospital Northwell Health	STREET ADDRESS 300 Community Dr
CITY, STATE, ZIP CODE, COUNTRY Manhasset, NY 11030-3816	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

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

Specifically,

- a) Your standard operating procedure #10.7.1.10 ver. 6 entitled "Management of Lookbacks, Recalls & Retrospective Calls" states that after receiving lookback information for the products that have been transfused, clinical significance of the lookback/recall/retrospective call will be assessed and documented. On 09/30/2025 and 04/15/2025 blood product distributor informed your Blood Bank that platelet unit # (b) (4), (b) (6), (b) (7)(C) and unit # (b) (4), (b) (6), (b) (7)(C) respectively had positive microbiological 14-day test results. Platelet unit # (b) (4), (b) (6), (b) (7)(C) was transfused on (b) (6), (b) (7)(C) to patient with MRN# (b) (6), (b) (7)(C) and platelet unit # (b) (4), (b) (6), (b) (7)(C) was transfused on (b) (6), (b) (7)(C) to patient with MRN# (b) (6), (b) (7)(C). However, the assessment of clinical significance was not documented.
- b) Your standard operating procedure #10.7.2.08 v.2 entitled "Investigating ABO Discrepancy" requires re-testing of the same specimen and if not resolved, obtaining a new sample. On 07/10/2025, blood specimen samples from patient with MRN# (b) (6), (b) (7)(C) and MRN# (b) (6), (b) (7)(C) were tested and historical ABO/Rh type discrepancy was found for both patients. Investigation found that both samples were incorrectly labeled during accession. There were no new patient samples requested for testing. Accession labels were peeled off and swapped, and the samples were re-tested.

OBSERVATION 2

Failure to maintain quality control and general records.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Irina Gaberman, Investigator	Irina Gaberman Investigator Signed By: 1300222798 Date Signed: 03-11-2026 10:03:37 X	DATE ISSUED 3/11/2026

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Specifically,

- a) Your standard operating procedure #10.7.5.59 Ver.10 entitled "Exchange Transfusion" documents steps in preparation/reconstitution of whole blood from the Red Blood Cells and plasma to achieve hematocrit count of (b) (4) or hematocrit count requested by a physician. On 05/16/2025, reconstituted whole blood for exchange transfusion with desired hematocrit of (b) (6), (b) (7)(C), was requested for patient with MRN# (b) (6), (b) (7)(C). Whole blood unit # (b) (4), (b) (6), (b) (7)(C) was prepared. There are no records showing preparation of reconstituted whole blood unit # (b) (4), (b) (6), (b) (7)(C). In addition, the final hematocrit for reconstituted whole blood unit # (b) (4), (b) (6), (b) (7)(C) was (b) (6), (b) (7)(C). Reconstituted whole blood unit # (b) (4), (b) (6), (b) (7)(C) was transfused on (b) (6), (b) (7)(C) to patient with MRN# (b) (6), (b) (7)(C).
- b) There is no documentation of the irradiation cycles performed at your Blood Bank including the names of the individuals performing irradiation, the count of blood products that were irradiated per cycle, completion of full irradiation cycle and utilizing of "resume cycle" feature when irradiation cycle stops during the irradiation process.
- c) Your standard operating procedure #10.7.5.34 v.7 entitled "Returning and Reissuing of Blood and Blood Components" states: "Whole blood, red blood cell products or plasma products that are returned from an uncontrolled [location, (b) (4) will be discarded". Your Blood Bank computer system performance qualification protocol conducted in May 2025 did not include this blood product return step that (b) (4) after being returned from uncontrolled temperature location.

OBSERVATION 3

Records fail to identify the person performing the work so as to provide a complete history of the work performed.

Specifically,

On 03/02/2026, Blood Bank Technologist (b) (6), (b) (7)(C) was observed loading patient specimens (b) (4), (b) (6), (b) (7)(C) on the (b) (4).

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Irina Gaberman, Investigator	Irina Gaberman Investigator Signed By: 130022798 Date Signed: 03-11-2026 10:03:37 X	DATE ISSUED 3/11/2026

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TYPE ESTABLISHMENT INSPECTED

Blood Bank

However, the (b) (4) showed that Blood Bank Technologist (b) (6), (b) (7)(C) loaded the above samples.

***DATES OF INSPECTION**

3/02/2026(Mon), 3/03/2026(Tue), 3/04/2026(Wed), 3/11/2026(Wed)

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OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Irina Gaberman, Investigator

Irina Gaberman
Investigator
Signed By: 1300222798
Date Signed: 03-11-2026
10:03:37

X

DATE ISSUED

3/11/2026

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."