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	4/27/2026-5/1/2026* FEI NUMBER 2472215

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mathew Foley, MD, VP & Chief Medical Officer

FIRM NAME	STREET ADDRESS
Long Island Jewish Medical Center	27005 76th Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
New Hyde Park, NY 11040-1402	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 storage and distribution of blood and blood components for allogeneic transfusion, autologous transfusion and further manufacturing purposes were not always established, maintained and followed.

Specifically,

a) Your standard operating procedure #SYS-3722 01 entitled "Receiving, Handling, and Inspection of Blood and Blood Components" section entitled "Visual Inspection of Red Cell Units" requires inspecting of Red Blood Cell units for any evidence of discoloration or clotting, and documenting visual inspection in LIS [Laboratory Information System, (b)(4) On (b)(4) Red Blood Cells units were received from the distributor in your Blood Bank. There was no visual inspection performed for discoloration or clotting prior to scanning units into your LIS system.

b) Your standard operating procedure #703918-220 entitled "Verification of Patient and Issuance of Blood Products for Transfusion" section #20 states: "Inspect blood product for the following (b)(4) release for transfusion: Visual inspection of blood product for hemolysis, presence of clots, discoloration, foaming or bubbles in components". On (b)(6) (b)(7)(C) Red Blood Cells unit (b)(4) (b)(6) (b)(7)(C) and unit (b)(4) (b)(6) (b)(7)(C) were issued to patient with MRN# (b)(6) (b)(7)(C) without visual inspection performed (b)(4) crossmatched (b)(4) to the back of the units.

c) On (b)(6) (b)(7)(C), during accessioning, blood specimen received with MRN# (b)(6) (b)(7)(C) was labeled with MRN# (b)(6) (b)(7)(C) in your Blood Bank. You do not have a standard operating procedure that includes the steps to follow when the specimen received for testing is mislabeled during accessioning.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Irina Gaberman, Investigator	X Irina Gaberman Investigator Signed By: 1300222798 Date Signed: 05-01-2026 08:16:30	5/1/2026

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Mathew Foley, MD, VP & Chief Medical Officer

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Long Island Jewish Medical Center	27005 76th Ave
CITY, STATE, ZIP CODE, COUNTRY New Hyde Park, NY 11040-1402	TYPE ESTABLISHMENT INSPECTED Blood Bank

OBSERVATION 2

Failure to maintain processing, quality control and general records.

Specifically,

a) On (b)(6) (b)(7)(C), during accessioning, blood specimen received with MRN# (b)(6) (b)(7)(C) was labeled with MRN# (b)(6) (b)(7)(C) in your Blood Bank. The mislabeled specimen was put on (b)(4), (b)(4). However, your investigation does not include records from the (b)(4) showing that the run with mislabeled specimen was aborted and/or the results were invalidated. In addition, source data records from the (b)(4) were not available for review.

b) Your standard operating procedure #703918 entitled "Reconstitution of Whole Blood (Exchange Transfusion)" describes the steps of reconstituting whole blood. However:

i) There are no records of whole blood reconstitution performed for reconstituted unit (b)(4) (b)(6) (b)(7)(C) prepared on (b)(6) (b)(7)(C) and documented in your Blood Bank Electronic Computer System. The records would include the weight of the unit and calculation of the volume of fresh frozen plasma to be added.

ii) (b)(4) calculations documented for reconstituted whole blood unit (b)(4) (b)(6) (b)(7)(C) show subtraction of (b)(4) of the weight of the bag from the total weight of the Red Blood Cells bag instead of (b)(4) as instructed in the standard operating procedure without any explanation.

c) There is no documentation of the (b)(4) cycles performed at your Blood Bank including the names of the individuals performing (b)(4), unit numbers of blood products that were (b)(4) per cycle and completion of the (b)(4) cycle.

***DATES OF INSPECTION**

4/27/2026(Mon), 4/28/2026(Tue), 4/29/2026(Wed), 5/01/2026(Fri)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Irina Gaberman, Investigator X Irina Gaberman Investigator Signed By: 1300222798 Date Signed: 05-01-2026 08:16:30	5/1/2026

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."