

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 4/21/2025-4/29/2025* FEI NUMBER 2472396					
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Raven C. Carter, AVP of Operations							
FIRM NAME Montefiore Medical Center		STREET ADDRESS 111 E 210th St					
CITY, STATE, ZIP CODE, COUNTRY Bronx, NY 10467-2401		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 Records are not maintained in a manner which allows steps in the manufacture and distribution of product to be traced. Specifically, a) Review of blood product quarantine report generated by your blood bank computer electronic system found that blood products listed on the report could not be always located in quarantine storage in your blood bank. For example, Red Blood Cells unit # (b) (4), (b) (6), (b) (7)(C) put in quarantine on (b) (6), (b) (7)(C) Red Blood Cells unit # (b) (4), (b) (6), (b) (7)(C) put in quarantine on (b) (6), (b) (7)(C), Red Blood Cells unit # (b) (4), (b) (6), (b) (7)(C) put in quarantine on (b) (6), (b) (7)(C) were not physically located in your Blood Bank. b) Irradiation time for your blood products is (b) (4) (~ (b) (4) Review of irradiation records from June 2023 to April 2025 found that on 12/05/2024, (b) (4) platelet products were irradiated at (b) (4) followed by irradiation of another (b) (4) units of platelets at (b) (4) ((b) (4) from the previous irradiation); Red Blood Cells Unit # (b) (4), (b) (6), (b) (7)(C) was irradiated at (b) (4) on 12/06/2024 (b) (4) minutes after the Red Blood Cells unit # (b) (4), (b) (6), (b) (7)(C) that was irradiated at (b) (4) on 12/06/2024 as documented on the (b) (4) Irradiation Log reviewed by Manager/Supervisor on 12/06/2024 and 12/07/2024 respectively. c) Your Blood Bank distributes (b) (4) batches of blood products to a refrigerator located at the transfusion center for scheduled transfusions. Time when blood products are removed and/or returned to the transfusion center refrigerator and inspection are not documented. For example, (b) (4) Red Blood Cells products were issued to transfusion center on (b) (6), (b) (7)(C) at (b) (4) to patient with MRN# (b) (4), (b) (6), (b) (7)(C) as documented in the Blood Bank computer electronic system. Transfusion start time documented in the progress notes was (b) (4). Time and inspection of the Red Blood Cells removed							
SEE REVERSE OF THIS PAGE		<table style="width: 100%; border: none;"> <tr> <td style="width: 60%; border: none;"> EMPLOYEE(S) SIGNATURE Irina Gaberman, Investigator </td> <td style="width: 40%; border: none; text-align: center;"> DATE ISSUED 4/29/2025 </td> </tr> <tr> <td style="border: none;"> Irina Gaberman Investigator Signed By: 1300222798 Date Signed: 04-29-2025 08:02:26 X _____ </td> <td style="border: none;"></td> </tr> </table>		EMPLOYEE(S) SIGNATURE Irina Gaberman, Investigator	DATE ISSUED 4/29/2025	Irina Gaberman Investigator Signed By: 1300222798 Date Signed: 04-29-2025 08:02:26 X _____	
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from transfusion center refrigerator were not documented and could not be traced. OBSERVATION 2 Failure to maintain quality control and general records. Specifically, a) Your standard operating procedure 2.10 entitled "Reconstituted Whole Blood for Exchange Transfusions" includes formula to calculate volume of plasma to be added to red blood cells to achieve a desired final hematocrit count. Review of reconstituted whole blood records for unit # (b) (4), (b) (6), (b) (7)(C) found that there were no calculations documented based on the initial hematocrit count, the weight of the bag and the volume of the red blood cells. On (b) (6), (b) (7)(C), reconstituted whole blood unit # (b) (4), (b) (6), (b) (7)(C) was issued to patient with MRN# (b) (4), (b) (6), (b) (7)(C), Order # (b) (4), (b) (6), (b) (7)(C) This unit was transfused. b) Your standard operating procedure entitled "Blood Bank Computer Downtime Procedure" states: "All patient results and product issues shall be documented on manual log sheets". Review of issued products during downtime from June 2023 to present found that issuance of blood products is not always documented on the log sheet. For example, during scheduled downtime on (b) (6), (b) (7)(C), 13 blood products were issued to the patients. Issuance of these blood products was not documented on the log. There was no visual inspection documented for any of the 13 blood products issued. For example: platelet unit # (b) (4), (b) (6), (b) (7)(C) issued on (b) (6), (b) (7)(C) to patient with MRN# (b) (4), (b) (6), (b) (7)(C), platelet unit # (b) (4), (b) (6), (b) (7)(C) issued to patient with MRN# (b) (4), (b) (6), (b) (7)(C) Red Blood Cells unit # (b) (4), (b) (6), (b) (7)(C) issued to patient with MRN# (b) (4), (b) (6), (b) (7)(C), all three units were tran (b) (4). c) Your (b) (4) automatic blood specimen (b) (4) analyzers require (b) (4) (b) (4) temperature and (b) (4) humidity (non-condensing) op (b) (4) tions. (b) (4) zes require (b) (4) humidity (non-condensing) at (b) (4) operating conditions. There are no records that document operating conditions for any o ecimen analyzers. OBSERVATION 3			
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Written standard operating procedures including all steps to be followed in the distribution of blood and blood components for allogeneic transfusion were not always followed. Specifically, Your standard operating procedure #3.12 entitled "Issuing Products" section Blood Product Issue, part 9, states: "Perform Visual Inspection". On 04/21/2025, one unit of platelets, (b) (4), (b) (6), (b) (7)(C) was observed being issued to patient with MRN (b) (4), (b) (6), (b) (7)(C). There was no visual inspection performed of this unit. Visual inspection was documented as performed in Blood Bank computer electronic system.			
*DATES OF INSPECTION 4/21/2025(Mon), 4/22/2025(Tue), 4/29/2025(Tue)			
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FORM FDA 483 (09/08)		PREVIOUS EDITION OBSOLETE	INSPECTIONAL OBSERVATIONS PAGE 3 of 3 PAGES

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."