DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
250 Marquette Ave, Ste. 600 Minneapolis, MN 55401 (612)334-4100 Fax:(612)334-4134	5/5/2025-5/7/2025
	FEI NUMBER 3009166489

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Sarah J. Jefford, Director

FIRM NAME	STREET ADDRESS
Meriter Health Enterprises	36 S Brooks St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Madison, WI 53715-1304	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

Failure to establish scientifically sound and appropriate specifications, standards and test procedures to assure that blood and blood components are safe, pure, potent and effective.

Specifically,
Your standard operating procedure entitled "(b) (4) Exchange Transfusion" gives instructions to prepare (b) (4) (b) (4) products and states that (b) (4) . However, testing methods to ensure prepared (b) (4) are not included in this standard operating procedure and (b) (4) is not tested. For example, (b) (4) (b) (4) unit #W(b) (4), (b) (6), (b) (7)(C) with volume (b) (4) was prepared on (b) (4) for patient with MRN#(b) (4), (b) (6), (b) (7)(C) .

OBSERVATION 2

Failure to maintain quality control and general records.

Specifically,
a) Your standard operating procedure entitled "Information System (b) (4) - Blood Bank" instructs to (b) (4) and (b) (4) . There were no (b) (4) available for review for (b) (4) occurred from March 2022 to May 2025 due to being (b) (4) after data was subsequently (b) (4) to the Blood Bank computer electronic system.
b) Instructions for Use for (b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Irina Gaberman, Investigator	X Irina Gaberman Investigator Signed By: 1300222798 Date Signed: 05-07-2025 07:30:09	5/7/2025

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(b) (4)". There were no records available to ensure removal of the blood product monitoring devices every (b) (4) was performed.

c) Operational Manual for the (b) (4) requires checking and documenting operating temperature and (b) (4) over temperature alert points. Review of preventative maintenance records from March 2022 to May 2025 for your (b) (4) found that their preventative records are documented as "(b) (4)" but do not have documented operating temperature and (b) (4) over temperature alert points for each (b) (4) to ensure they operate according to the manufacturing instructions. There are (b) (4) in your hospital.

d) There are no records documenting operation of (b) (4) and (b) (4) since the medical technologists are not utilizing unique password and username linked to each operator/medical technologist. At least (b) (4) patient specimen were run on (b) (4) and (b) (4) (b) (4) since both instruments were validated on 04/29/2025.

OBSERVATION 3

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 entitled Blood Products BOOK, section Receiving Blood Products states: "(b) (4)". On 05/05/2025, (b) (4) red blood cells unit were observed received and entered into your Blood Bank computer inventory system. Units (b) (4), (b) (6), (b) (7)(C), (b) (4), (b) (6), (b) (7)(C), (b) (4), (b) (6), (b) (7)(C), and (b) (4), (b) (6), (b) (7)(C) were not inspected for abnormal appearance but their visual inspection was entered as passing.

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."