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	6/23/2025-6/24/2025
	FEI NUMBER 1000389954

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Sarah Dolley, Laboratory Director, (MLS)

FIRM NAME	STREET ADDRESS
Aurora St. Luke's Medical Center	2900 W Oklahoma Ave
CITY, STATE, ZIP CODE, COUNTRY Milwaukee, WI 53215-4330	TYPE ESTABLISHMENT INSPECTED Hospital Blood Bank - Transfusion Services

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 distribution of blood and blood components for allogeneic transfusion were not always established.

Specifically,

Your firm failed to notify nursing staff that requested blood products were ready for release or had been dispatched via your (b) (4) system. As a result, the units remained unattended in your (b) (4) system without confirmation of delivery. In both cases, the blood units were subsequently transfused to patients. Furthermore, your firm failed to initiate investigations into Incident Number SE-25-0170072, dated 6/11/2025, and Incident Number SE-25-0180103, dated 6/21/2025, both of which involved nurses discovering the units in the (b) (4) system without prior notification. In each case, the blood products were transfused to patients.

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Kenneth L Smalls, Investigator

X Kenneth L Smalls
Investigator
Signed By: Kenneth L. Smalls -S
Date Signed: 06-24-2025
10:37:35

DATE ISSUED
6/24/2025

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."