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	4/30/2026-5/1/2026
	FEI NUMBER 2174458

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Dr. Thomas D. Brucker, Associate Chief Pathologist

FIRM NAME	STREET ADDRESS
Zablocki, Clement J., Veterans Affairs Medical Center	5000 W National Ave
CITY, STATE, ZIP CODE, COUNTRY Milwaukee, WI 53295-0001	TYPE ESTABLISHMENT INSPECTED Hospital Transfusion Center

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 of blood and blood components for allogeneic transfusion were not always followed.

Specifically,

Your firm failed to maintain concurrent and accurate records of receiving temperatures for incoming blood and blood components prior to storage into your inventory. Additionally, your written procedure titled, "Incoming Shipments - Inspection and Storage" (Effective: 7/11/2025, version 3.2), instructs your technologists to sign and verify that the blood products received at that date and time satisfied the appropriate shipping condition requirements (i.e. temperature).

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Amy A Johnson, Investigator	Amy Johnson X	5/1/2026 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."