DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 Main Street, Ste 4-930 Cincinnati, OH 45202 (513)322-0700 Fax:(513)679-2772	4/8/2025-4/14/2025* FEI NUMBER 1577551

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Michael R. Frayser, 88 MDG Commander	
FIRM NAME Department of Defense - Air Force	STREET ADDRESS 4881 Sugar Maple Dr
CITY, STATE, ZIP CODE, COUNTRY Dayton, OH 45433-5529	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

Failure to make reasonable attempts to notify the donor within 8 weeks after determining that the donor was deferred or determined not to be eligible for donation.

Specifically,

1. Donor (b) (4), (b) (6), (b) (7)(C) donated a unit of blood on (b) (6), (b) (7)(C) ((b) (4), (b) (6), (b) (7)(C)). This donation was positive for Syphilis on (b) (6), (b) (7)(C). The donor notification to notify this donor of a reactive test result was not sent.

2. Donor (b) (4), (b) (6), (b) (7)(C) donated a unit of blood on (b) (6), (b) (7)(C) ((b) (4), (b) (6), (b) (7)(C)). This donor had a previous HBc positive result on (b) (6), (b) (7)(C). This was the second positive HBc result for this donor. The donor notification was sent on 11/07/2024. This notification was not within the required 8 week time period.

---

*DATES OF INSPECTION

4/08/2025(Tue), 4/09/2025(Wed), 4/10/2025(Thu), 4/14/2025(Mon)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jennifer L Sheehan, Investigator	X Jennifer L Sheehan Investigator Signed By: Jennifer L. Sheehan - S Date Signed: 04-14-2025 08:13:30	4/14/2025

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."