**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
FOOD AND DRUG ADMINISTRATION

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 1201 Harbor Bay Parkway<br>Alameda, CA 94502-7070<br>(510)337-6700 Fax:(510)337-6702 | 3/24/2025-3/27/2025 |
| | FEI NUMBER<br>1000161288 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Matthew D. Uy, DO, Maj, USAF, MC, FS

| FIRM NAME | STREET ADDRESS |
|---|---|
| Department of Defense - Air Force, 99th Medical Group | 4700 Las Vegas Blvd |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| Nellis AFB, NV 89191-6600 | 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

Input to and output from the computer are not checked for accuracy.

Specifically, your firm failed to adequately test the input and output of your new (b)(4) (b)(4) related to the following:

1. The (b)(4) between the electronic (b)(4) and the (b)(4) (b)(4)
2. Not addressing the 38 issue investigations from the operational qualification prior to going live with the new (b)(4)

Your firm relies on your (b)(4) to automate the (b)(4) (b)(4)

## OBSERVATION 2

Failure to submit a biological product deviation report within 45 days from the date you acquired information suggesting that a reportable event occurred.

Specifically, your firm failed to submit the following reportable deviations:

1. On 01/18/2024, it was discovered that the reagents used for the (b)(4) machine had passed their (b)(4). The reagents were placed on the machine on (b)(4) should have been replaced on (b)(4) and were not. Four blood products (W041023172261-*, W041023182010-5, W041023181906-F, W202023822926-6) were issued to patients during

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | | DATE ISSUED |
|---|---|---|---|
| | Emily B Camire, Investigator | X Emily B Camire Investigator Signed By: EMILY B. CAMIRE -S Date Signed: 03-27-2025 12:38:14 | 3/27/2025 |

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the time the reagents were past the [redacted].

2. On 03/29/2024, a nurse discovered that a unit in the [redacted] was expired and returned it to the blood bank. Upon receipt back to the blood bank it was discovered that the incorrect unit tag had been placed on the unit.

**OBSERVATION 3**

Failure to perform a thorough investigation of an unexplained discrepancy and a failure of a lot or unit to meet any of its specifications.

Specifically, your firm failed to completely document the investigation performed related to the following deviations:

1. Variance-2024-0021: On [redacted] a shipment of [redacted] red blood cells (RBCs) was delivered a day late. When the box arrived, the temperature was [redacted] the 1-10 C acceptance. The deviation does not contain the units that were impacted or the discard information.
2. Variance-2024-0026: On 07/22/2024, the refrigerator storing blood products was left open and started to alarm. Once the alarm had been addressed, the refrigerator had been out of temperature for [redacted] with a reading of [redacted]. The units were compromised. The deviation does not state how many units were compromised, the unit numbers, how the units were quarantined, and when they were discarded.
3. Variance-2024-0030: On [redacted], a shipment of blood was received with a unit that had broken and contaminated the other units in the shipment. The deviation does not contain the units that were in the shipment, how many were contaminated, what units were destroyed, and if any units were accepted into inventory.

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| | Emily B Camire, Investigator | X Emily B Camire Investigator Signed By: EMILY B. CAMIRE -S Date Signed: 03-27-2025 12:38:14 | 3/27/2025 |

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."