DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303)236-3000 Fax:(303)236-3100	6/2/2025-6/5/2025
	FEI NUMBER 1000065349

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mark S. Wright, Associate Chief Operating Officer

FIRM NAME	STREET ADDRESS
Denver Health Medical Center	777 Bannock St
CITY, STATE, ZIP CODE, COUNTRY Denver, CO 80204-4507	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

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

Specifically, your firm failed to adequately validate the input and output of your new (b)(4) (b)(4), which includes following:

1. The interface between the (b)(4) and the electronic testing (b)(4)
2. The bench quality control testing that is entered into the (b)(4) (b)(4), which is required for patient and product testing.
3. A performance qualification including an initial summary of expectations for the system output was not documented for the new (b)(4)
4. A final review and approval for use of the new (b)(4) was not documented.

Your firm relies on your (b)(4) to automate the receipt and distribution of blood products, store blood units and patient test results, assign and crossmatch units to patients, and document quality control of reagents.

OBSERVATION 2

Records including signature by the physician requesting the procedure are not maintained of all emergency transfusions.

Specifically, while reviewing the emergency release documents for blood units emergency released in --,

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: 06-05-2025 09:59:18	6/5/2025

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Denver, CO 80204-4507	Blood Bank

(b)(4), it was noted that:

1. The requesting physician's signature was not always documented when units were removed from your (b)(4) room refrigerator.
2. The signatures on the "(b)(4)" rev May 2021 were not legible and it is unclear if a physician signed the form.
3. At least one example of a non-physician signing the "(b)(4) (b)(4)" rev May 2021.

Since (b)(4), your firm has emergency released approximately (b)(4) units of red blood cells (RBCs).

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: 06-05-2025 09:59:18	6/5/2025

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."