**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)<br>Denver, CO 80225-0087<br>(303)236-3000 Fax:(303)236-3100 | 4/21/2025-4/24/2025 |
| | FEI NUMBER<br>3029463597 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Ambyr L. Spencer, Clinical Excellence Operations Manager

| FIRM NAME | STREET ADDRESS |
|---|---|
| Primary Children's Hospital - Miller Campus | 2250 N Miller Campus Dr |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| Lehi, UT 84043-7233 | 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 of equipment to perform in the manner for which it was designed so as to assure compliance with the official requirements prescribed in 21 CFR 606.

Specifically,

1. Your firm's validation for your X-ray Irradiator was performed on 01/30/2024 and approved for use on 02/12/2024. However, the following was noted in the validation:
   a. The Film used in the dosimetry during the validation had an expiration date of 4/27/2023.
   b. The Film reader calibration date was 9/13/2022.
   c. The third party dosimetry report was reported on 02/15/2024. The results stated that four (4) out of six (6) of the measurements failed and were above the acceptable (b) (4) limit.

2. Your firm's Instrument/Equipment Qualification for the blood product and reagent storage refrigerators (s/n (b) (4), s/n (b) (4) and s/n (b) (4)) did not contain documentation explaining the reason for the repeated Temperature Mapping Chart. The refrigerators are used to store blood products and reagents and were approved for use on 02/12/2024.

Since 02/12/2024, your firm has irradiated approximately (b) (4) units of red blood cells (RBCs).

## OBSERVATION 2

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | | DATE ISSUED |
|---|---|---|---|
| | Emily B Camire, Investigator | X Emily B Camire<br>Inves igator<br>Signed By: EMILY B. CAMIRE -S<br>Date Signed: 04-24-2025<br>10:02:41 | 4/24/2025 |

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The product is capable of bearing a full label, but the label does not include the name, address, and license number of the manufacturer.

Specifically, your firm's labeling post manufacturing and/or modification:1. Does not contain the address of your firm 2. Does not contain the unique facility identifier and 3. Contains the license number of your blood product supplier.

Since February 2024, your firm has irradiated approximately (b) (4) units of red blood cell (RBC), aliquoted approximately (b) (4) neonate aliquots, and thawed approximately (b) (4) blood products.

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**OBSERVATION 3**
Failure to submit a biological product deviation report.

Specifically, your firm failed to submit the following reportable deviation: On 04/01/2024, a whole unit of blood was issued to the caregiver instead of the half unit that was ordered.

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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."