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

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 19701 Fairchild<br>Irvine, CA 92612-2445<br>(949)608-2900 Fax:(949)608-4417 | 4/27/2026-4/29/2026 |
| | FEI NUMBER<br>2077856 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Dr Aaron Sassoon , M.D, Laboratory Medical Director

| FIRM NAME | STREET ADDRESS |
|---|---|
| Children's Hospital of Orange County | Blood Bank - Transfusion Services, 1201 W La Veta Ave |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| Orange, CA 92868-4203 | 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 present educational material to the donor.

Specifically, your firm has failed to provide donor education material to donor (b) (4), (b) (6), (b) (7)(C) who was interviewed by (b) (5), (b) (7)(C) on 4/28/2026. You failed to follow SOP "Donor Identification and Donation Process," Number BB232v4, effective date 01/29/2024, states on page 3:

Give education material to donor. Ensure donor understands the following:
a. Blood donation eligibility is confidential and depends on thoughtful, honest answers to keep the blood supply safe.
b. Donors should have enough privacy to answer history questions confidentially.
c. If the donor is unable to read the material or is not comfortable answering questions on the computer, we can provide translators and/or assistance.

(b) (4)

## OBSERVATION 2

Failure to obtain from the donor on the day of donation a postal address where the donor may be contacted for 8 weeks after donation.

Specifically, your firm has failed to obtain confirmation from donors on the day of donation regarding whether

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | | DATE ISSUED |
|---|---|---|---|
| | Maurine Fadlalla, Investigator | X Maurine Fadlalla Investigator Signed By: MAURINE FADLALLA -S Date Signed: 04-29-2026 09:56:59 | 4/29/2026 |

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they will be at their current address 8 weeks after donation. On (b) (6), (b) (7)(C) during donor screening, staff member (b) (6), (b) (7)(C) and (b) (6), (b) (7)(C) failed to ask donors (b) (4), (b) (6), (b) (7)(C) and (b) (4), (b) (6), (b) (7)(C) if they would be at their current address for the next 8 weeks after donation. Neither your blood donor registration card, your one-on-one donor screening, nor your Medical Questionnaire review, conducted by the donor center staff, addressed verification of a postal address where the prospective donor may be contacted for 8 weeks after the donation in all donor registrations observed. In addition, SOP "Donor Identification and Donation Process" version BB232v4, effective date 01/29/2024, fails to state the requirement of the 8-week postal address verification.

Since (b) (4) your firm has collected approximately (b) (4) units.

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**SEE REVERSE OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Maurine Fadlalla, Investigator

X Maurine Fadlalla
Investigator
Signed By: MAURINE FADLALLA
-S
Date Signed: 04-29-2026
09:56:59

DATE ISSUED
4/29/2026

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."