DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Harbor Bay Parkway Alameda, CA 94502-7070 (510)337-6700 Fax:(510)337-6702	8/25/2025-8/29/2025
	FEI NUMBER 2970324

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jessica (nmi) Mancilla, Quality Assurance Director

FIRM NAME	STREET ADDRESS
Central California Blood Center	4343 W Herndon Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Fresno, CA 93722-3794	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

The phlebotomy site is not prepared by a method that gives maximum assurance of a sterile container of blood.

During observations of collection procedures, (b) (4) (b) (4) Specialists were individually observed preparing venipuncture sites for (b) (4) separate donors. The following deficiencies were observed:

A. The venipuncture sites were prepared using (b) (4) and (b) (4) (b) (4) that are labeled as "Non-sterile Solution."

B. After preparing the venipuncture sites with the (b) (4) and (b) (4) (b) (4), the (b) (4) Specialists were observed placing (b) (4) directly onto the venipuncture sites while the solution was still drying.

Additionally, on 8/28/2025, a (b) (4) Specialist was also observed preparing a donor's venipuncture site without utilizing (b) (4) as directed by the manufacturer. The manufacturer's instructions for use specify: " (b) (4) (b) (4)

OBSERVATION 2

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Amy A Johnson, Investigator X Amy A Johnson Investigator Signed By: 2001751346 Date Signed: 08-29-2025 15:00:55	8/29/2025

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Central California Blood Center	4343 W Herndon Ave
CITY, STATE, ZIP CODE, COUNTRY Fresno, CA 93722-3794	TYPE ESTABLISHMENT INSPECTED Blood Bank

Failure to perform a thorough investigation and make a record of the conclusions and follow-up of an unexplained discrepancy.

Specifically,

Your firm's (b) (4) system generated multiple warning messages indicating invalidated samples during (b) (4) assay testing. On 8/3/2023, five messages were reported and on 12/19/2023 four warning messages were reported. In both instances, your firm failed to initiate an investigation to determine the root cause of the invalidated runs.

OBSERVATION 3
Written standard operating procedures including all steps to be followed in the collection and processing of blood and blood components for allogeneic transfusion and further manufacturing purposes were not always established and maintained.

Specifically,

A. Your firm does not have written procedures governing donor follow-up activities for donors who experienced adverse reactions during the donation process.

B. Your firm's current procedure titled, "Anti- Hepatitis C Virus (b) (4) System" (Version 1.0, Effective date: 1/19/2021), does not contain detailed instructions for performing testing operations. Instead, your procedure instructs personnel to reference the (b) (4) System Operations Manual.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Amy A Johnson, Investigator X Amy A Johnson Investigator Signed By: 2001751346 Date Signed: 08-29-2025 15:00:55	8/29/2025

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."