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	12/6/2024-12/11/2024* FEI NUMBER 3022480823

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jessica NMI Mancilla, Quality Assurance Director

FIRM NAME	STREET ADDRESS
Central California Blood Center/ Clovis Donor Center	645 W Herndon Ave, Ste 200
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Clovis, CA 93612-0297	Donor Center

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 provide adequate space for the orderly storage of blood and blood components to prevent contamination.

Specifically,

Your storage room fails to provide proper storage space and is unable to be satisfactory cleaned. Material used for preparation of your product, such as your "[redacted]" are stored [redacted] on [redacted] and unable to be cleaned underneath. The current storage configuration places [redacted] in a manner that limits accessibility and prevents adequate cleaning of the area [redacted] them. The current configuration poses a challenge for your employees to ensure minimal contamination.

OBSERVATION 2

Written standard operating procedures including all steps to be followed in the collection of blood and blood components for further manufacturing purposes were not always followed.

Specifically,

I observed multiple phlebotomists failing to invert the sample tubes sufficiently after they were collected. As stated in your SOP "Collection and Preparation of Whole Blood" (rev. 12/12/22), the collection of sample tubes must include the inversion of each tube to be [redacted]. For a blood sample collected on 12/6/2024, I observed that the tubes were only inverted [redacted]. For another blood sample collected on 12/6/2024, I observed your phlebotomist putting a tube in her hand, inverting

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Conor J Mccarron, Investigator	X Conor J Mccarron Investigator Signed By: 2004153102 Date Signed: 12-11-2024 14:27:37	12/11/2024

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[redacted] then adding another tube into her same hand and inverting [redacted] and doing this till all tubes were a hand, making it so some samples were adequately mixed and others were not.

***DATES OF INSPECTION**

12/06/2024(Fri), 12/07/2024(Sat), 12/09/2024(Mon), 12/10/2024(Tue), 12/11/2024(Wed)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Conor J Mccarron, Investigator X Conor J Mccarron Investigator Signed By: 2004153102 Date Signed: 12-11-2024 14:27:37	12/11/2024

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."