DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	12/10/2024-12/17/2024* FEI NUMBER 1047303

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Sallie-Anne Wright, Pathology Operations, Director

FIRM NAME	STREET ADDRESS
Jackson Memorial Hospital Transfusion Medicine Services	Holtz Center, 1611 Nw 12th Ave Rm 2014
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Miami, FL 33136-1005	Hospital 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

Equipment used in the compatibility testing and storage and distribution of blood and blood components is not observed and standardized on a regularly scheduled basis as prescribed in the SOP Manual.

Specifically,

A. You did not perform QA assurance reviews of (b)(4) calibrations and storage temperature (b)(4) alarm checks per your SOP. Your SOP titled "Equipment and Instrument Maintenance" (Laboratory Policy No. (b)(4)) states "records are reviewed and assessed at least (b)(4) by the laboratory director or designee."

- The functional calibration of (b)(4) is performed (b)(4) and for (b)(4) calibration records, all performed in (b)(4) 2024. there was no quality assurance review. These (b)(4) are mainly used for (b)(4).

- In addition, the (b)(4) alarm checks for (b)(4) (b)(4) (b)(4) were not reviewed for quality assurance. The (b)(4) alarm checks are performed to identify potential temperature alarm issues with your storage equipment: refrigerators, freezers, and (b)(4).

B. You have failed to provide documentation of your verification of the newly implemented (b)(4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Sergio E Delgado, Investigator	X Sergio E Delgado Investigator Signed By: 2003066147 Date Signed: 12-17-2024 15:53:56	12/17/2024

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
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(b)(4) temperature monitoring system (b)(4). This is software that (b)(4) the device (b)(4) records of storage temperature readings. The storage equipment is used store blood products and reagents. You installed (b)(4) Environmental Monitoring system on March 25, 2024.

OBSERVATION 2

Records are not concurrently maintained with the performance of each significant step in the storage of each unit of blood and blood components so that all steps can be clearly traced.

Specifically,

You failed to document the relocation of inventory between storage devices to track and ensure accountability so that all steps can be clearly traced. On 9/14/2023, temperature issues with freezer - caused relocation of inventory to freezer - On 3/28/2024, temperature issues with refrigerator - caused relocation of inventory to Bank - Your freezers and refrigerators are mainly used to store blood products.

***DATES OF INSPECTION**

12/10/2024(Tue), 12/11/2024(Wed), 12/12/2024(Thu), 12/17/2024(Tue)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Sergio E Delgado, Investigator X Sergio E Delgado Investigator Signed By: 2003066147 Date Signed: 12-17-2024 15:53:58	12/17/2024

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."