DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax:(404)253-1202	5/13/2025-5/15/2025
	FEI NUMBER 1000140351

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mitchell E. Ferguson, Vice President of Operations

FIRM NAME	STREET ADDRESS
Mission Hospitals Transfusion Service	509 Biltmore Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Asheville, NC 28801-4601	Hospital Transfusion Service

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

Written standard operating procedures including all steps to be followed in the processing and distribution of blood and blood components for allogeneic transfusion were not always followed.

Specifically, your firm failed to follow the written procedure entitled Neonatal Transfusion, (b)(4) .0511.00 that indicates the aliquot (b)(4) preparation and must not used. My review of randomly selected (b)(4) products from the (b)(4) log revealed that an RBC neonatal aliquot (W12162498549800) was documented as being (b)(4) on (b)(4) at (b)(4). During my review of the complete product history in (b)(4), I found the (b)(4) unit wasn't modified and crossmatched in the system until (b)(4) and was dispensed for transfusion at (b)(4). The aliquot was issued and transfused more than - (b)(4) preparation.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Randy L Clarida, Investigator X Randy L Clarida Investigator Signed By: Randy L. Clarida -S Date Signed: 05-15-2025 08:59:13	5/15/2025

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."