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	1/6/2025-1/7/2025 FEI NUMBER 1072749

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Amy T. Fisher, Blood Services Manager

FIRM NAME	STREET ADDRESS
Cumberland County Hospital System, Inc.	3357 Village Dr Ste 150
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Fayetteville, NC 28304-4549	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

Written reports of investigations of adverse reactions, including conclusions and follow up, are not prepared and maintained.

Specifically,

all donation-related donor adverse reactions are not being documented. Donor Center staff stated they are not recording or documenting minor or "[redacted]" donor reactions in either the donor management software or on the [redacted] *Blood Donor Reaction Form.* Only moderate or severe reactions are being captured on the [redacted], *Blood Donor Reaction Form.* When asked for records documenting reactions over the [redacted], the center only produced one [redacted], *Blood Donor Reaction Form.*

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	David E Lowe, Investigator X David E Lowe Investigator Signed By: 2000397489 Date Signed: 01-07-2025 13:07:33	1/7/2025

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."