DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
11155 Dolfield Boulevard, Suite 117 Owings Mills, MD 21117 (410)779-5455 Fax:(410)779-5707	10/29/2024-10/30/2024
	FEI NUMBER 1073936

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Martin J. Spalding, Medical Director

FIRM NAME	STREET ADDRESS
Lexington Medical Center	2720 Sunset Blvd
CITY, STATE, ZIP CODE, COUNTRY West Columbia, SC 29169-4810	TYPE ESTABLISHMENT INSPECTED 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 WE OBSERVED:

OBSERVATION 1

Records including signature by the physician requesting the procedure are not maintained of all emergency transfusions.

Specifically,

The following units of blood/blood products were issued as emergency transfusion orders without documenting the signature of the requesting physician before or after release:

1. Donor Units W205023563563 and W201723078778, dated 7/31/2023, lacks a physician signature.
2. Donor Units W202322135319, W203222114356, W201723747094, W201223247692, W201723744519, and W201222216897, dated 1/20/2023, lacks a physician signature.
3. Donor Unit W202023334052, dated 10/3/2023, lacks a physician signature.
4. Donor Units W202023241377 and W203623545757, dated 10/9/2023, lacks a physician signature.
5. Donor Units W203223274093, W201223326049, W201223311083, and W201223341732, dated 7/31/2023, lacks a physician signature.

OBSERVATION 2

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

Specifically,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Kenneth L Smalls, Investigator Danielle R Rainey, Investigator	X Kenneth L Smalls Investigator Signed By: Kenneth L Smalls -S Date Signed: 10-30-2024 14:28:29	10/30/2024

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West Columbia, SC 29169-4810	Hospital Blood Bank

Your firm failed to follow your procedure titled "Quality Control [redacted]" documenting the quality control log for each cycle for the following [redacted] units:

1) Cycle Number [redacted] for Unit Number W1822240877200, dated 6/6/2024 at the time of 10:26:11 and Cycle Number [redacted] for Unit Numbers W18172406410100 and W18172407077500 dated 6/6/2024 at the time of 09:39:00. The QC Log was documented for [redacted] cycle; however, it does not indicate the specific cycle number.
2) Cycle Number [redacted] for Unit Numbers W18622401087400 and W18622403448600 dated 6/8/2024 at the time of 23:28:41. There was [redacted] cycle documentation on the Quality Control Log.
3) Cycle Number: [redacted] for Unit Number W18092409551600, dated 6/26/2024 at the time of 13:38:12 and Cycle Number [redacted] for Unit Numbers W18172408046900 and W18172407559300 dated 6/26/2024 at the time of 12:00:18. The QC Log was documented for [redacted] cycle; however, it does not indicate the specific cycle number.
4) Cycle Number [redacted] for Unit Number W18032408894300, dated 7/9/2024 at the time of 19:46:26 and Cycle Number [redacted] for Unit Numbers W18122405966000 and W18622406056900 dated 7/9/2024 at the time of 08:02:31. The QC Log was documented for [redacted] cycle; however, it does not indicate the specific cycle number.
5) Cycle Number [redacted] for Unit Numbers W18412402553000 and W18122407642100 dated 7/23/2024 at the time of 09:15:16. The QC Log was documented for [redacted] cycles, it does not indicate the specific cycle number [redacted], and there was no irradiator log containing a [redacted] cycle number.

X Danielle R Rainey
Investigator
Signed By: Danielle Rainey -S
Date Signed: 10-30-2024 14:29:00

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	Kenneth L Smalls, Investigator Danielle R Rainey, Investigator	X Kenneth L Smalls Investigator Signed By: Kenneth L Smalls -S Date Signed: 10-30-2024 14:28:29	10/30/2024

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."