DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615)366-7801 Fax:(615)366-7802	4/8/2025-4/14/2025* FEI NUMBER 3000203326

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Sharon Carter, District Director

FIRM NAME	STREET ADDRESS
Lifesouth Community Blood Centers - Montgomery Region	4139 Carmichael Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Montgomery, AL 36106-2803	Community 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

The phlebotomy site is not prepared by a method that gives maximum assurance of a sterile container of Whole Blood.

Specifically,

On 4/9/25 while at a mobile drive, I observed Phlebotomist [redacted] marking the venipuncture site of two donors ([redacted] unit W1151 25 053072 and [redacted] unit W1151 25 053075) using a [redacted] on the [redacted] ([redacted] of the vein) with the intention of surrounding the needle insertion site. After completing the [redacted], phlebotomist [redacted] proceeded to stick the needle [redacted] the intended insertion site.

According to firm's SOP [redacted], **Prepare the Venipuncture Site, page 1 section 1.3.1.4**, "*If necessary, use a [redacted] the venipuncture area, [redacted] insertion site) [redacted] performing the [redacted].*"

Furthermore, per manufacturer's specifications, the [redacted] used to [redacted] on the donor's [redacted] are "[redacted]." Phlebotomist [redacted] used the [redacted] of both donors.

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	Fabian N Chaparro-Rodriguez, Investigator X Fabian N Chaparro-Rodriguez Investigator Signed By: Fabian N. Chaparro-rodriguez -S Date Signed: 04-14-2025 13:40:14	4/14/2025

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OBSERVATION 2
Failure to perform a thorough investigation and make a record of the conclusions and follow-up of an unexplained discrepancy.

Specifically,

Since (b)(4), your firm performed approximately - ABO blood grouping tests (b)(4) at fixed donor collection sites and mobile donor collection sites that failed to match the results performed by your contract laboratory ABO blood grouping test results.

Your firm failed to perform a thorough investigation or make a record of the conclusions and follow-up of these unexplained discrepancies.

OBSERVATION 3
Failure to use supplies and reagents in a manner consistent with instructions provided by the manufacturer.

Specifically,

A)

According to manufacturer's recommendations for the (b)(4) used by Phlebotomists to [redacted] the venipuncture site on donor's [redacted]; these [redacted] are "(b)(4)".

Your firm failed to use these [redacted] as recommended by the manufacturer. On [redacted], while at the firm's donor floor, I observed phlebotomist [redacted] (b)(4) of the venipuncture site of two different donors with the same [redacted]. On [redacted], while at a mobile drive, I observed phlebotomist [redacted] (b)(4) the [redacted] of the venipuncture site of two different donors with the same [redacted].

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On 4/11/25, during conversation with management discussing this issue, it was stated by the Regional Director that since the firm started using these [redacted], one single [redacted] is used multiple times on multiple donors during preparation of the phlebotomy site.

B)

According to ABO blood grouping reagent (Anti-A and Anti-B) instructions for use, "Quality control of reagents is essential and should be performed on [redacted] and in accordance with local, state and federal regulations." According to ABO blood grouping reagent (Anti-A and Anti-B) instructions for use, "The reagent should be stored at [redacted]."

Since [redacted], your firm performed approximately [redacted] ABO blood grouping [redacted] ABO types at your fixed donor center and mobile donor center sites. Your firm has failed to perform quality control testing in accordance with federal regulations on [redacted] of use.

Since 06/11/2024, your firm has failed to document the temperature ABO blood grouping reagents are stored.

OBSERVATION 4

Representative samples of each lot of Blood grouping reagents are not tested on a regularly scheduled basis as described in the SOP Manual to determine their capacity to perform as required by the regulations.

Specifically,

According to ABO blood grouping reagent (Anti-A and Anti-B) instructions for use, "Quality control of

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reagents is essential and should be performed on [redacted] of use and in accordance with local, state and federal regulations."

Since [redacted], your firm performed approximately [redacted] ABO blood grouping [redacted] ABO types at your fixed donor center and mobile donor center sites. Your firm has failed to perform quality control testing in accordance with federal regulations on [redacted] of use.

Your firm currently does not have a standard operating procedure addressing the regularly scheduled testing of ABO blood grouping reagents to determine their capacity to perform as required by regulations.

OBSERVATION 5

The standard operating procedure fails to include a written description of the quality control procedures for supplies and reagents employed in.

Specifically,

According to ABO blood grouping reagent (Anti-A and Anti-B) instructions for use, "Quality control of reagents is essential and should be performed on [redacted] of use and in accordance with local, state and federal regulations." According to ABO blood grouping reagent (Anti-A and Anti-B) instructions for use, "The reagent should be stored at [redacted]."

Since [redacted], your firm performed approximately [redacted] ABO blood grouping [redacted] technique ABO types at your fixed donor center and mobile donor center sites. Your firm has failed to perform quality control testing in accordance with federal regulations on [redacted] of use.

Your firm currently does not have a standard operating procedure addressing the [redacted] scheduled

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testing of ABO blood grouping reagents to determine their capacity to perform as required by regulations.

Your firm utilizes standard operating procedure [b)(4)], titled Document Daily Quality Control, version 4.0, implemented 06/11/2024, your firm no longer instructs employees to document the lot number of ABO reagents and the ABO reagent storage temperature at the time of removal.

***DATES OF INSPECTION**
4/08/2025(Tue), 4/09/2025(Wed), 4/11/2025(Fri), 4/14/2025(Mon)

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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."