

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		
<small>DISTRICT ADDRESS AND PHONE NUMBER</small> 404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615) 366-7801 Fax: (615) 366-7802	<small>DATE(S) OF INSPECTION</small> 3/26/2025-3/26/2025 <hr/> <small>FEI NUMBER</small> 1000524796	
<small>NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED</small> Sharon P. Carpenter, District Director		
<small>FIRM NAME</small> Lifesouth Community Blood Centers Inc. - East Alabama Region	<small>STREET ADDRESS</small> 505 E Thomason Cir	
<small>CITY, STATE, ZIP CODE, COUNTRY</small> Opelika, AL 36801-5431	<small>TYPE ESTABLISHMENT INSPECTED</small> Donor Center	
<p>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.</p>		
<p>DURING AN INSPECTION OF YOUR FIRM I OBSERVED: OBSERVATION 1 Failure to perform a thorough investigation and make a record of the conclusions and follow-up of an unexplained discrepancy.</p> <p>Specifically,</p> <p>Since 01/01/2024, your firm performed approximately (b)(4) ABO blood grouping tests (b)(4) at fixed donor collection sites and mobile donor collection sites that failed to match the results perform by your contract laboratory ABO blood grouping test results.</p> <p>Your firm failed to perform a thorough investigation or make a record of the conclusions and follow-up of these unexplained discrepancies.</p>		
<p>OBSERVATION 2 Failure to use supplies and reagents in a manner consistent with instructions provided by the manufacturer.</p> <p>Specifically,</p> <p>According to ABO blood grouping reagent (Anti-A and Anti-B) instructions for use, (b)(4)</p>		
SEE REVERSE OF THIS PAGE	<small>EMPLOYEE(S) SIGNATURE</small> Cody D Rickman, Investigator <div style="text-align: right; margin-top: 20px;">X _____</div>	<small>DATE ISSUED</small> 3/26/2025
<small>FORM FDA 483 (09/08)</small> <div style="display: inline-block; width: 30%; text-align: center;"><small>PREVIOUS EDITION OBSOLETE</small></div> <div style="display: inline-block; width: 40%; text-align: center;">INSPECTIONAL OBSERVATIONS</div>		

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Donor Center

(b) (4) According to ABO blood grouping reagent (Anti-A and Anti-B) instructions for use, (b) (4)

Since 07/17/2019, your firm performed approximately (b) (4) ABO blood grouping (b) (4) 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 each day of use.

Since 06/13/2024, your firm has failed to document the temperature ABO blood grouping reagents are stored.

OBSERVATION 3

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, (b) (4)

Since 07/17/2019, your firm performed approximately (b) (4) ABO blood grouping (b) (4) 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 each day 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

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EMPLOYEE(S) SIGNATURE

Cody D Rickman, Investigator

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<p>regulations.</p> <hr/> <p>OBSERVATION 4</p> <p>The standard operating procedure fails to include a written description of the quality control procedures for supplies and reagents employed in blood collection.</p> <p>Specifically,</p> <p>According to ABO blood grouping reagent (Anti-A and Anti-B) instructions for use, (b) (4)</p> <p>(b) (4) According to ABO blood grouping reagent (Anti-A and Anti-B) instructions for use, (b) (4)</p> <p>Since 07/17/2019, your firm performed approximately (b) (4) ABO blood grouping (b) (4) 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 each day of use.</p> <p>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.</p> <p>Your firm utilizes standard operating procedure (b) (4).8.1, 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.</p>		
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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."