

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION					
DISTRICT ADDRESS AND PHONE NUMBER 555 Winderley Place, Suite 200 Maitland, FL 32751 (407) 475-4700 Fax: (407) 475-4768		DATE(S) OF INSPECTION 8/12/2025-8/18/2025*			
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Lorrie A. Woods, District Director		FEI NUMBER 1076458			
FIRM NAME LifeSouth Community Blood Centers, Inc.		STREET ADDRESS 1221 NW 13th St			
CITY, STATE, ZIP CODE, COUNTRY Gainesville, FL 32601-4111		TYPE ESTABLISHMENT INSPECTED 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 Failure to use supplies and reagents in a manner consistent with instructions provided by the manufacturer. Specifically, According to ABO blood grouping reagent (Anti-A and Anti-B) instructions for use, (b) (4) (b) (4) According to ABO blood grouping reagent (Anti-A and Anti-B) instructions for use, (b) (4) Your firm has failed to perform quality control testing and failed to document temperature ABO grouping reagents are stored in accordance with federal regulations on each day of use.					
*DATES OF INSPECTION 8/12/2025(Tue), 8/13/2025(Wed), 8/14/2025(Thu), 8/18/2025(Mon)					
SEE REVERSE OF THIS PAGE		<table border="0" style="width: 100%;"> <tr> <td style="width: 60%; vertical-align: top;"> EMPLOYEE(S) SIGNATURE Laura E Garcia, Investigator </td> <td style="width: 40%; vertical-align: top;"> Laura E Garcia Investigator Signed By: Laura E. Garcia-S Date Signed: 08-18-2025 13:45:54 X </td> </tr> </table>		EMPLOYEE(S) SIGNATURE Laura E Garcia, Investigator	Laura E Garcia Investigator Signed By: Laura E. Garcia-S Date Signed: 08-18-2025 13:45:54 X
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DATE ISSUED 8/18/2025					

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."