

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION							
DISTRICT ADDRESS AND PHONE NUMBER 11155 Dolfield Boulevard, Suite 117 Owings Mills, MD 21117 (410) 779-5455 Fax: (410) 779-5707		DATE(S) OF INSPECTION 8/19/2025-8/20/2025 FEI NUMBER 1270168					
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Garren E. Averett, Laboratory Manager							
FIRM NAME Collaborative Laboratory Services, LLC- Saint Francis Campus		STREET ADDRESS 114 Woodland St					
CITY, STATE, ZIP CODE, COUNTRY Hartford, CT 06105-1208		TYPE ESTABLISHMENT INSPECTED Blood Bank and Transfusion Services					
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 Records including signature by the physician requesting the procedure are not maintained of all emergency transfusions. Specifically, Upon review of your firm's SOP Emergency/Special Issue of Blood Products Number: 3.7.4 on 8/19/2025. I observed that the (b) (4) signed the emergency/special release of blood products form instead of the (b) (4) as stated in your SOP. The following units of blood/blood products are examples of your firm's (b) (4) emergency transfusion orders since 2023 that were issued without documenting the signature of the (b) (4) before or after release: 1. Donor Units (b) (4), (b) (6), (b) (7)(C) issued on 9/4/2023, lacks a (b) (4) signature. 2. Donor Units (b) (4), (b) (6), (b) (7)(C) issued on 5/9/2024, lacks a (b) (4) signature. 3. Donor Units (b) (4), (b) (6), (b) (7)(C) issued on 2/18/2025, lacks a (b) (4) signature.							
SEE REVERSE OF THIS PAGE		<table border="0" style="width: 100%;"> <tr> <td style="width: 60%; vertical-align: top;"> EMPLOYEE(S) SIGNATURE Victoria V Bot, Investigator </td> <td style="width: 40%; vertical-align: top; text-align: center;"> DATE ISSUED 8/20/2025 </td> </tr> <tr> <td style="vertical-align: bottom; text-align: right;"> Victoria V Bot Investigator Signed By: 2003624715 Date Signed: 08/20/2025 12:34:51 X _____ </td> <td></td> </tr> </table>		EMPLOYEE(S) SIGNATURE Victoria V Bot, Investigator	DATE ISSUED 8/20/2025	Victoria V Bot Investigator Signed By: 2003624715 Date Signed: 08/20/2025 12:34:51 X _____	
EMPLOYEE(S) SIGNATURE Victoria V Bot, Investigator	DATE ISSUED 8/20/2025						
Victoria V Bot Investigator Signed By: 2003624715 Date Signed: 08/20/2025 12:34:51 X _____							

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."