

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 60 Eighth Street NE Atlanta, GA 30309 (404) 253-1161 Fax: (404) 253-1202	DATE(S) OF INSPECTION 5/22/2025-5/27/2025*
	FEI NUMBER 3014286287

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Kayla N. Erculiani, Manager of Technical Services

FIRM NAME Blood Connection, Inc. (The)	STREET ADDRESS 101 Kitty Hawk Dr
CITY, STATE, ZIP CODE, COUNTRY Morrisville, NC 27560-8511	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 WE OBSERVED:

OBSERVATION 1

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

Specifically, Standard Operating Procedures for handling returned units were not always followed. According to your SOP, (b) (4).4220, products which are returned for reasons deemed as unsuitable or outdated must be handled by placing (b) (4) (as appropriate).

1. Your firm submitted BPDR #863812, discovered on 08/23/23. According to that submission blood units were (b) (4) returned to your facility. These units were not (b) (4), and were instead (b) (4).
2. Your firm submitted BPDR #877401, discovered on 5/1/24. (b) (4) blood units were impacted. According to that submission, products were received by a (b) (4) with the (b) (4) being found unacceptable. Products were returned to your facility and were not (b) (4). Units were then (b) (4).
3. According to (b) (4), which occurred on 9/20/24, (b) (4) was returned to your facility due to a (b) (4) discrepancy. (b) (4) was not (b) (4). Before your firm had the opportunity to (b) (4) and evaluate, (b) (4).

OBSERVATION 2

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Marla A Cassidy, Investigator David E Lowe, Investigator	<div> David E Lowe Investigator Signed By: 2000397489 Date Signed: 05-27-2025 14:16:16 </div> X	DATE ISSUED 5/27/2025

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TYPE ESTABLISHMENT INSPECTED

Blood Bank

Failure to perform a thorough investigation of an unexplained discrepancy.

Specifically, (b) (4) shows (b) (4) units of platelets returned from a customer on (b) (4). In the comments section, the customer wrote (b) (4). According to your internal investigation, (b) (4), (b) (4) unit was expired and discarded. The other (b) (4) units passed (b) (4) inspections and were returned to inventory. However, your staff did not contact the customer to inquire about the comments regarding contamination.

***DATES OF INSPECTION**

5/22/2025(Thu), 5/23/2025(Fri), 5/27/2025(Tue)

Marla A Cassidy
Investigator
Signed By: 2000537862
Date Signed: 05-27-2025 14:17:16

X

**SEE REVERSE
OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Marla A Cassidy, Investigator
David E Lowe, Investigator

David E Lowe
Investigator
Signed By: 2000397489
Date Signed: 05-27-2025
14:16:16

X

DATE ISSUED

5/27/2025

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."