DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	6/3/2025-6/6/2025 FEI NUMBER 1070196

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Rebecca L. Thornton, Director QA and Regulatory Affairs

FIRM NAME	STREET ADDRESS
OneBlood, Inc.	10100 Dr Martin Luther King Jr St N
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
St Petersburg, FL 33716-3806	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

Failure to submit a biological product deviation report within 45 days from the date you acquired information suggesting that a reportable event occurred.

Specifically,

Our review of Biological Product Deviation reports from 12/2021 – 06/2025, disclosed that 23 out of 282 reports were found to be reported (b) (4) 45-calendar days from the date that a reportable event has been discovered. The following table summarizes the 23 Biological Product Deviation reports submitted after the required timeframe:

BPD #	Blood Unit #	Reporting Days
11333 (890408)	(b) (4), (b) (6), (b) (7)(C)	(b) (4)
11322 (888508)	(b) (4), (b) (6), (b) (7)(C)	(b) (4)
11318 (887327)	(b) (4), (b) (6), (b) (7)(C)	(b) (4)
11310 (887230)	(b) (4), (b) (6), (b) (7)(C)	(b) (4)
11309 (885621)	(b) (4), (b) (6), (b) (7)(C)	(b) (4)
11308 (885371)	(b) (4), (b) (6), (b) (7)(C)	(b) (4)
11304 (885880)	(b) (4), (b) (6), (b) (7)(C)	(b) (4)
11302 (884921)	(b) (4), (b) (6), (b) (7)(C)	(b) (4)
11296 (882504)	(b) (4), (b) (6), (b) (7)(C)	(b) (4)
11280 (875311)	(b) (4), (b) (6), (b) (7)(C)	(b) (4)

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Laura E Garcia, Investigator
Steen N Graham, Investigator
Annette Melendez, Investigator

X Annette Melendez Investigator Signed By: Annette Melendez -S Date Signed: 06-06-2025 13:34:58

DATE ISSUED
6/6/2025

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	6/3/2025-6/6/2025
	FEI NUMBER 1070196

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Rebecca L. Thornton, Director QA and Regulatory Affairs

FIRM NAME	STREET ADDRESS
OneBlood, Inc.	10100 Dr Martin Luther King Jr St N
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
St Petersburg, FL 33716-3806	Blood Bank

11260 (870399)	(b) (4), (b) (6), (b) (7)(C)	(b) (4)	
11259 (870543)	(b) (4), (b) (6), (b) (7)(C)	(b) (4)	
11239 (864309)	(b) (4), (b) (6), (b) (7)(C)	(b) (4)	
11181 (852509)	(b) (4), (b) (6), (b) (7)(C)	(b) (4)	
11176 (849853)	(b) (4), (b) (6), (b) (7)(C)	(b) (4)	
11155 (844632)	(b) (4), (b) (6), (b) (7)(C)	(b) (4)	
11135 (841678)	(b) (4), (b) (6), (b) (7)(C)	(b) (4)	
11113 (840826)	(b) (4), (b) (6), (b) (7)(C)	(b) (4)	
11104 (839003)	(b) (4), (b) (6), (b) (7)(C)	(b) (4)	
11094 (838449)	(b) (4), (b) (6), (b) (7)(C)	(b) (4)	
11084 (836536)	(b) (4), (b) (6), (b) (7)(C)	(b) (4)	
11055 (832226)	(b) (4), (b) (6), (b) (7)(C)	(b) (4)	

This is a recurrent observation from previous inspection.

X Steen N Graham
Investigator
Signed By: Steen N. Graham -S
Date Signed: 06-06-2025 13:35:28

X Laura E Garcia
Investigator
Signed By: Laura E. Garcia -S
Date Signed: 06-06-2025 13:36:00

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Laura E Garcia, Investigator
Steen N Graham, Investigator
Annette Melendez, Investigator

X Annette Melendez
Investigator
Signed By: Annette Melendez -S
Date Signed: 06-06-2025 13:34:58

DATE ISSUED
6/6/2025

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."