DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Customhouse Rm900 200 Chestnut St Philadelphia, PA 19106 (215)597-4390 Ext:4200 Fax:(215)597-0875	1/28/2026-2/2/2026* FEI NUMBER 3023715801

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Justine Goyne, Center Manager

FIRM NAME	STREET ADDRESS
B Positive National Blood Services - Wyoming, LLC.	Midway Shopping Center, 1054 Wyoming Ave Ste 16
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Wyoming, PA 18644-1331	Source Plasma Donor Center

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 are not made concurrently with the performance of each step in the distribution of products.

Specifically,

on 1/30/2026, during a review of your firm's biohazard waste management program, I observed there were no biohazard pick-up records retained for (b) (4) and (b) (4)

OBSERVATION 2

Written standard operating procedures including all steps to be followed in the collection, processing, storage and distribution of blood and blood components for further manufacturing purposes were not always established.

Specifically,

on 1/30/2026 during the review of your firm's deviations/incidents, your firm has no procedures in place for deviation/issue management for your (b) (4), (b) (6), (b) (7)(C) who performs donor registration, screening, collections, or processing. For instance, incident I254-12017 created on 11/24/2025 by your (b) (4), (b) (6), (b) (7)(C) During my inquiry I asked the (b) (4), (b) (6), (b) (7)(C) what the formal process for the investigation and closure of the deviations/incidents is that (b) (6), (b) (7)(C) creates. The (b) (4), (b) (6), (b) (7)(C) stated there is no written guidance. A SOP, *Issue Management*, A 7.01.10, and the (b) (4), (b) (6), (b) (7)(C) position description does not provide any details on what entity or person reviews the deviations/incidents that are created by the (b) (4), (b) (6), (b) (7)(C)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Michele Gottshall, Investigator	X Michele Gottshall Investigator Signed By: MICHELE GOTTSHALL -S Date Signed: 02-02-2026 12:46:49	2/2/2026

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OBSERVATION 3
Failure to use supplies and reagents in a manner consistent with instructions provided by the manufacturer.

Specifically,

during my walk-through of your firm, I observed approximately 10 boxes of expired large (b) (4) gloves with an expiration date of 1/1/2024. These boxes are set (b) (4) away from the glove inventory and there is no signage to prevent staff from utilizing the gloves.

***DATES OF INSPECTION**
1/28/2026(Wed), 1/29/2026(Thu), 1/30/2026(Fri), 2/02/2026(Mon)

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Michele Gottshall, Investigator

X Michele Gottshall Investigator Signed By: MICHELE GOTTSHALL -S Date Signed: 02-02-2026 12:46:49

DATE ISSUED
2/2/2026

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."