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	4/23/2026-4/24/2026
	FEI NUMBER 3015522052

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Cindy C. Grigoryan, Quality Director

FIRM NAME	STREET ADDRESS
Central Pennsylvania Blood Bank	475 W Governor Rd Ste 4
CITY, STATE, ZIP CODE, COUNTRY Hershey, PA 17033-2217	TYPE ESTABLISHMENT INSPECTED Blood 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

Failure to weigh a donor at each donation.

Specifically, your firm collected plasma by plasmapheresis from (b)(4) donors since the previous inspection on 5/6/2022. Donor weight is used in the (b) (4) to calculate the quantity of platelets and plasma that can be safely collected from the donor. Your written procedures do not require weighing apheresis donors. Two staff members stated that donors provide their weights verbally, and they are not weighed (b) (4) apheresis procedures. During the inspection, there was no scale for measuring bodyweight on the premises.

OBSERVATION 2

Medical history assessment failed to include factors that make the donor ineligible to donate because of an increased risk for, or evidence of, a relevant transfusion-transmitted infection such as behaviors associated with a relevant transfusion-transmitted infection and intimate contact with risk for a relevant transfusion-transmitted infection.

Specifically, collections staff administer the donor medical history interview verbally and record the donor's responses on the (b) (4) While conducting donor screening on (b) (6), (b) (7)(C) (b) (4) collecting whole blood unit (b) (4), (b) (6), (b) (7)(C) phlebotomist (b) (6), (b) (7)(C) asked about a history of ever having had a (b) (6), (b) (7)(C) for the (b) (6), (b) (7)(C) instead of "for (b) (6), (b) (7)(C) " as written on the (b) (4). On (b) (6), (b) (7)(C) (b) (4) collecting unit (b) (4), (b) (6), (b) (7)(C), she asked whether the donor had had sexual contact with anyone who has ever had a (b) (6), (b) (7)(C) test "for the (b) (6), (b) (7)(C) instead of "for (b) (6), (b) (7)(C)," as written on the (b) (4). Both donors responded (b) (6), (b) (7)(C) to these questions.

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Emily A Walters, Investigator

X Emily A Walters
Investigator
Signed By: EMILY A. WALTERS - S
Date Signed: 04-24-2026 13:51:39

DATE ISSUED
4/24/2026

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EMPLOYEE(S) SIGNATURE
Emily A Walters, Investigator

X Emily A Walters
Investigator
Signed By: EMILY A. WALTERS -S
Date Signed: 04-24-2026 13:51:39

DATE ISSUED
4/24/2026

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."