

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER

Food and Drug Administration
Center for Biologics Evaluation and Research - Document Control Center
10903 New Hampshire Avenue, WO71 - G112
Silver Spring, MD 20993-0002

240-402-8360

Industry Information: www.fda.gov/oc/industry

DATE(S) OF INSPECTION

November 5-7, 2024

FEI NUMBER

3030553177

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: William Earley, Assistant Director of Quality Assurance

FIRM NAME

B Positive National Blood Services

STREET ADDRESS

841 South 25th Street, Unit 15

CITY, STATE AND ZIP CODE

Easton, Pennsylvania 18045

TYPE OF ESTABLISHMENT INSPECTED

Source Plasma Collection Facility

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) (WE) OBSERVED:

Observation 1: The firm did not recalibrate the (b)(4) (Traceable Certificate Number: (b)(4)) used to perform (b)(4) QC checks of the (b)(4) device according to the schedule in the (b)(4) and as recommended by the (b)(4) laboratory that performs calibration of equipment for the firm. The recalibration was due on March 30, 2024. The firm put the (b)(4) into service on (b)(4), in order to implement the use of the new (b)(4). The firm used weight ID 00003 for daily QC checks of the collection devices from (b)(4). The requirement for a schedule is significant because recalibration of the (b)(4) shows, on an (b)(4) bases, that the (b)(4) device meets the specifications in the Operators Manual. The accuracy of the (b)(4) is important because it determines whether the correct volume of plasma and anticoagulant is collected. During that period, (b)(4) Source Plasma units were collected.

Observation 2: The firm did not conduct a Performance Qualification (PQ) study of the (b)(4) Thermo (b)(4) Freezers, prior to use, to determine the (b)(4) for units of Source Plasma placed into the (b)(4) Freezers. The freezers have been used to initially (b)(4) Source Plasma units collected since the center opened on February 20, 2024 without completing the (b)(4) freezer qualification to demonstrate this equipment performs as it was designed, to ensure compliance with manufacturing requirements for Source Plasma.

Michelle D. Gutierrez - S
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Add Continuation Page

Dionne Cook - S
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SEE
REVERSE
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PAGE

EMPLOYEE(S) NAME AND TITLE (Print or Type)

Michelle Gutierrez, Lead CSO, CBER/OBRR/DBCD
Dionne Cook, CSO, CBER/OBRR/DBCD

DATE ISSUED

11-7-2024

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 judgement, 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."