DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax:(313)393-8139	2/10/2026-2/20/2026* FEI NUMBER 3004582762

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Hannah C. Kays, Center Operations Manager

FIRM NAME	STREET ADDRESS
BioLife Plasma Services L.P.	111 E Alto Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Kokomo, IN 46902-3602	Source Plasma Establishment

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 perform a thorough investigation of an unexplained discrepancy.

Specifically,

The quality control unit failed to perform a thorough investigation of staff failing to (b) (4) soft goods (b) (4) to phlebotomy and (b) (4) during venipuncture into the firm's Blood Establishment Computer System (BECS), Donor Information System (DIS).

For example, since January 1, 2025, to present, the quality control unit has identified (b) (4) events with (b) (4) staff failing to (b) (4) soft goods and (b) (4) used during venipuncture.

Year	Month	# of MNC errors (Scanning Omissions)
2025	January	(b) (4)
2025	February	(b) (4)
2025	March	(b) (4)
2025	April	(b) (4)
2025	May	(b) (4)
2025	June	(b) (4)
2025	July	(b) (4)
2025	August	(b) (4)

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EMPLOYEE(S) SIGNATURE
Lesley Mae P Lutao, Investigator

X Lesley Mae P Lutao
Investigator
Signed By: Lesley Mae P. Lutao - S
Date Signed: 02-20-2026 13:58:34

DATE ISSUED
2/20/2026

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2025	September	(b) (4)
2025	October	(b) (4)
2025	November	(b) (4)
2025	December	(b) (4)
2026	January	(b) (4)
2026	February	(b) (4)

These events were classified as (b) (4). The only correction performed has been to (b) (4) plasmapheresis machine, where staff will (b) (4) soft goods.

No thorough investigation was performed, nor a corrective action plan was taken to prevent recurrence of the explained discrepancies.

According to the firm's procedure, SOP-001634, "Error Management, Tracking and Trending", version 7.0 and version 8.0 effective August 29, 2025, (b) (4)

These soft goods (needle, saline, anticoagulant, collection container, plasmapheresis disposable set, harness, and bowl) are used for source plasma collection using the (b) (4) apheresis machines. No deviation record was initiated from January 1, 2025, to February 14, 2026, based on the trending events.

OBSERVATION 2

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Records are not concurrently maintained with the performance of each significant step in the collection of each unit of blood and blood components so that all steps can be clearly traced.

Specifically,

You failed to concurrently (b) (4) soft goods used during collection including needle, saline, anticoagulant, collection container, plasmapheresis kit (disposable set, harness, and (b) (4) used during plasmapheresis procedure for each donor.

For example, (b) (4) events were identified of staff failing to (b) (4) soft goods and (b) (4) (b) (4) were since January 1, 2025 to present (see **OBSERVATION 1**).

OBSERVATION 3
Failure to submit a supplement at least 30 days prior to distributing product made using the change.

Specifically,

You failed to submit a supplement at least 30 days prior to distribution of the source plasma product when you changed your automated apheresis machine equipment (b) (4) (b) (4).

The change in automated apheresis machine equipment involves the following:

1. Collection volume (b) (4).
2. Collection container change (b) (4).
3. (b) (4) changes to determine collection (b) (4) (b) (4) (b) (4) (b) (4).

Since June 18, 2025, you collected and distributed (b) (4) units of plasma using the (b) (4) (b) (4) apheresis machines for further manufacture.

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*DATES OF INSPECTION

2/10/2026(Tue), 2/11/2026(Wed), 2/12/2026(Thu), 2/18/2026(Wed), 2/19/2026(Thu), 2/20/2026(Fri)

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Lesley Mae P Lutao, Investigator

X Lesley Mae P Lutao
Investigator
Signed By: Lesley Mae P. Lutao - S
Date Signed: 02-20-2026 13:58:34

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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."