DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Harbor Bay Parkway Alameda, CA 94502-7070 (510)337-6700 Fax:(510)337-6702	4/21/2026-4/22/2026
	FEI NUMBER 3025527098

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Ashley K. Dickinson, Quality Management Representative

FIRM NAME	STREET ADDRESS
BioLife Plasma Services, L.P.	9080 W Sahara Ave
CITY, STATE, ZIP CODE, COUNTRY Las Vegas, NV 89117	TYPE ESTABLISHMENT INSPECTED Plasmapheresis 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 maintain equipment used in the collection of blood and blood products in a clean and orderly manner and so as to facilitate cleaning and maintenance.

This requirement ensures that automated equipment, including plasmapheresis machines, is adequately maintained to ensure proper performance.

Specifically, I determined that the (b) (4), used in the collection of Source Plasma, was not maintained in accordance with the manufacturer's recommendations. During the inspection, I reviewed preventive maintenance (PM) records for all (b) (4) (b) (4) apheresis devices covering the period from (b) (4). I reviewed preventive maintenance (PM) records and found that the required maintenance for the apheresis devices had not been performed as specified in the device Operator's Manual (**Exhibit 4**), which states, "(b) (4) (b) (4) (b) (4)." The affected devices are listed below (**Exhibit 5**):

Device SN #	(b) (4)
(b) (4)	

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Paul M Chefor, Investigator	X	4/22/2026

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Las Vegas, NV 89117	Plasmapheresis Center

(b) (4)

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	Paul M Chefor, Investigator	X	4/22/2026

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."