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	3/10/2026-3/20/2026* FEI NUMBER 3023831018

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Christopher S. Foote, District Quality Manager

FIRM NAME	STREET ADDRESS
BioLife Plasma Services L.P.	2800 Marconi Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Sacramento, CA 95821-5206	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 determine the eligibility of a donor of blood or blood components before collection.

The establishment failed to ensure donors are in good health prior to donation.

Specifically, donors are not systematically evaluated for pulse regularity at each donation. During the inspection, review of the following revealed this deficiency:

- Your firm's procedures include provisions for consulting the medical staff when an irregular pulse is identified; however, operations have not been designed to systematically evaluate pulse regularity that would trigger such consultation.
- On March 11, 2026, direct observation of (b)(4) donor pre-donation physical examinations showed screening staff used the (b) (4) to screen pulse, blood pressure, and temperature, but did not manually palpate the donor's pulse at the wrist, neck, or auscultate heart sounds to assess pulse regularity.
- Review of the (b) (4) (b)(4) confirmed the device is not FDA cleared to detect pulse rhythm irregularities.
- Procedures that include steps to evaluate a donor for an irregular pulse are not being followed. Specifically, Standard Operating Procedure TOOL-219398, "Donor Screening Job Aid," Version 8.0, states pulse regularity should be checked after being referred to the center medical personnel

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	Shelley H Beausoleil, Investigator	X Shelley H Beausoleil Investigator Signed By: Shelley H. Beausoleil - S Date Signed: 03-20-2026 11:19:48	3/20/2026

when initial pulse readings are out of range.

Review of donation records for 8 out of 8 donors with out-of-range pulse readings who were referred to the center's physician substitute showed that the (b) (4) re-take of the donor's pulse was not performed by the MSS, which would indicate these donors were not screened for an irregular pulse. In one case, Donor (b) (6), (b) (7)(C) was found to have an out-of-range pulse on (b) (6), (b) (7)(C) of (b) (6), (b) (7)(C) visits and was referred to the physician substitute. This donor's pulse was never taken a third time by medical staff. In all cases, donors were not allowed to donate because the pulse was found to be out of range.

Your firm collected Source Plasma from (b) (4) donors in 2024, (b) (4) donors in 2025, and (b) (4) donors in 2026 (year-to-date).

OBSERVATION 2

The standard operating procedure fails to include written descriptions of methods for performing donor qualifying tests and measurements, including minimum and maximum values for a test or procedure when a factor in determining acceptability.

Your establishment's standard operating procedures fail to include adequate written descriptions of methods for performing donor qualifying tests and measurements related to evaluating pulse regularity for donor suitability.

Specifically, Standard Operating Procedures SOP-240019, "Donor Screening," Version 11.0, effective August 18, 2025, SOP-243783, "MSS Evaluation of Donor Screening Criteria," Version 7.0, and SOP TOOL-219398, "Donor Screening Job Aid", Version 8.0, do not include:

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CITY, STATE, ZIP CODE, COUNTRY Sacramento, CA 95821-5206	TYPE ESTABLISHMENT INSPECTED Source Plasma Establishment

- Instructions or methods for systematically assessing pulse regularity at each donation during the pre-donation physical examination
- Criteria for determining pulse regularity acceptability
- Clear procedures for what to do when an irregular pulse is found
- Standard Operating Procedure SOP-243783, "MSS Evaluation of Donor Screening Criteria," Version 7.0, conflicts with TOOL-219398, "Donor Screening Job Aid," Version 8.0, in that TOOL-219398 states the MSS must take the (b) (4) pulse measurement (b) (4) but SOP-243783 states this is optional.

Your establishment's standard operating procedures fail to include adequate written descriptions to ensure Source Plasma not collected in accordance with your procedures for protecting the health of the donor are found unsuitable.

Specifically, Standard Operating Procedure TOOL-220247, "BioLife Deviation and CAPA Process," Version 8.0, effective February 16, 2026, classifies units over nomogram due to weight entry errors as "low risk" deviations and allows Quality Assurance to release these units for further manufacturing. This procedure fails to recognize that units collected in excess of volume limits violate donor safety requirements and should be determined unsuitable and quarantined, not released.

OBSERVATION 3

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Sacramento, CA 95821-5206	Source Plasma Establishment

The responsible physician improperly delegated activities related to the collection of blood and blood components.

Your establishment improperly delegated determinations that must be made by a responsible physician.

Specifically, Standard Operating Procedure SOP-243783, "MSS Evaluation of Donor Screening Criteria," Version 7.0, effective August 18, 2025, delegates the evaluation of irregular pulse to a Medical Support Specialist (MSS), who functions as a physician substitute at your firm

OBSERVATION 4

Failure to prevent the release of unsuitable blood and blood components for further manufacturing.

Your establishment failed to prevent the release of unsuitable Source Plasma for further manufacturing. Your firm does not always determine a donation unsuitable when it is established that procedures designed to ensure the donation would not adversely affect the health of the donor were not followed.

Specifically, on (b) (6), (b) (7)(C) Donor ID (b) (6), (b) (7)(C) had a unit over nomogram (UON) of (b) (6), (b) (7)(C) (b) (6), (b) (7)(C) due to incorrect weight entry. Your firm detected this UON and Quality Assurance released the unit for further manufacturing on October 19, 2024, per deviation PR #4590750.

OBSERVATION 5

Failure to make reasonable attempts to notify a donor who has been determined not be to eligible as a donor based on eligibility criteria.

Your establishment failed to notify deferred donors within 8 weeks of the deferral determination.

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Specifically, your firm's standard operating procedure on donor notification does not include steps to notify donors who are deferred following adverse reactions where the center determines Source Plasma donations may affect the health of the donor. Donors who were permanently deferred following severe adverse reactions were not notified of their deferral status and the reason for deferral. Examples include:

- Donor (b) (6), (b) (7)(C) experienced a severe hypotensive event during plasma donation on (b) (6), (b) (7)(C) (b) (6), (b) (7)(C) including chills, warm/hot sensation, pallor, and lightheadedness, where symptoms did not resolve and emergency medical services were contacted, and the donor was transported. The Center Physician permanently deferred the donor due to the severity of the adverse event on May 14, 2024. The donor was not contacted within 8 weeks to notify them which blood products they should not donate and the reason for the deferral.

- Donor (b) (6), (b) (7)(C) experienced a severe adverse reaction during the donation of Source Plasma on (b) (6), (b) (7)(C) including a hypotensive/vasovagal reaction with chest pain requiring emergency medical services transport. The donor was permanently deferred on November 30, 2023, due to the severity of the reaction. The donor was not contacted within 8 weeks to notify them which blood products they should not donate and the reason for the deferral.

- Donor (b) (6), (b) (7)(C) experienced a seizure/convulsions and a head injury at pre-donation. The donor was determined to be unsuitable to donate plasma and was permanently deferred by the Center Physician on May 10, 2023. The donor was not contacted within 8 weeks to notify them which blood products they should not donate and the reason for the deferral.

There were 22 severe adverse reactions at this center from January 1, 2025, through present day.

***DATES OF INSPECTION**

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3/10/2026(Tue), 3/11/2026(Wed), 3/12/2026(Thu), 3/13/2026(Fri), 3/17/2026(Tue), 3/18/2026(Wed), 3/19/2026(Thu), 3/20/2026(Fri)

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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."