

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		
DISTRICT ADDRESS AND PHONE NUMBER 1201 Main Street, Suite 7200 Dallas, TX 75202 (214) 253-5200 Fax: (214) 253-5314	DATE(S) OF INSPECTION 11/19/2024-11/22/2024 FEI NUMBER 3017393622	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Erin M. Kaguai, District Quality Manager		
FIRM NAME BioLife Plasma Services L.P.	STREET ADDRESS 1455 W Arbrook Blvd	
CITY, STATE, ZIP CODE, COUNTRY Arlington, TX 76015-4104	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 donor, quality control and general records. Specifically, You did not label your standard with an open date or expiration date. During observation of Daily Refractometer Control QC testing on 11/20/24, I observed that the (b)(4) (b)(4) vial under LOT (b)(4) used to perform daily QC on the (b)(4) Refractometers in the center did not have the date opened, open vial expiration date, nor the employee initial and date documented on the label. You stated that the vial was opened on 11/20/2024. I observed the vial being used for (b)(4) QC for (b)(4) of the (b)(4) Refractometers prior to documentation of the open date on the label. You did not document the previously stated information concurrently. Per your SOP-243891, "Control Verification of Refractometer", under step "4.0 Verify Refractometer (Medical Historian)" and step 4.2.4, it reads that (b)(4) (b)(4) ----- You stated that the fingerprint scanner used to obtain the consent for Donor (b)(4) (b)(6) (b)(7)(C) was not working, and you were not able to provide me the donor's printed signature for Consent of		
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Michelle Paxon, Investigator Michelle Paxon Investigator Signed By: 2003996263 Date Signed: 11-22-2024 16:12:25 X _____	DATE ISSUED 11/22/2024

DISTRICT ADDRESS AND PHONE NUMBER

DATE(S) OF INSPECTION

FEI NUMBER

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

FIRM NAME

STREET ADDRESS

CITY, STATE, ZIP CODE, COUNTRY

TYPE ESTABLISHMENT INSPECTED

(b)(4)

(b)(6)

(b)(7)(C)

(b)(4) (b)(6) (b)(7)(C)

(b)(6)

(b)(7)(C)

(b)(4)

It also reads that

(b)(4)

EMPLOYEE(S) SIGNATURE _____

Michelle Paxon
Investigator
Signed By: 2003998263
Date Signed: 11-22-2024
16:12:25

X

DATE ISSUED _____

FORM FDA 483 (09/08)

PREVIOUS EDITION OBSOLETE

INSPECTIONAL OBSERVATIONS

PAGE 2 of 2 PAGES

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."