Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D1007873	11/12/2025
Name of Provider or Supplier	**Street Address, City, State**	
Biolife Plasma Services Lp	2009 Bluegrass Circle, Cheyenne, WY	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A recertification survey was conducted at BioLife Plasma Services LP, located at 2009 Bluegrass Circle, Cheyenne, WY 82009, on 11/12/25. The laboratory was surveyed under 42 CFR part 493 CLIA requirements. The laboratory was found out of compliance with the following condition: 42 CFR 493.1100 Condition: Facility administration
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) (b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records, policy and procedure review, and staff interview, the laboratory failed to analyze proficiency test samples the same number of times that it routinely tested donor samples for 1 of 7 AAB (American Association of Bioanalysts) proficiency testing events reviewed from 2023 event #3 through 2025 event #3. The findings were: 1. Review of the PT record for AAB 2024 event #3 showed the following concerns: a. Review of the PT documentation showed a submission/attestation statement was signed by TP (testing personnel) #1 and the laboratory director on 9/23/24. The form was submitted to AAB on 9/23/24 at 3:26 PM. Further review of a testing worksheet showed the serial number of the refractometer used for testing was 03859-0510. b. Review of the PT documentation showed a submission/attestation statement was signed by TP #2 and the laboratory director on 9/23/24. The form was submitted to AAB on 9/23/24 at 3:26 PM. Further review of a testing worksheet showed the serial number of the refractometer used for testing was 03363-0409. 2. Interview with the quality management representative (QMR) on 11/12/25 at 2:55 PM revealed the laboratory required testing personnel who did not achieve a score of 100% on a proficiency testing event to participate in the next PT event. Further, the QMR was unable to show evidence the PT samples

	were tested in the same manner and the same number of times as a donor sample. 3. Review of the "Standard Operating Procedure Proficiency Testing" policy and procedure showed..."4.2 Samples must be tested in the same manner as donor specimens by personnel who routinely perform the procedure...4.8 Testing can only be repeated if an error occurred..."
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). This CONDITION is not met as evidenced by: Based on observation, staff interview, review of policy and procedures, and review of professional standards, the laboratory failed to ensure effective infection control and prevention practices were implemented to protect testing personnel and plasma donors during 4 observations of blood sample collection. The laboratory collected 38,585 blood samples per year. Refer to D3011.
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on observation, staff interview, review of policy and procedures, and review of professional standards, the laboratory failed to ensure effective infection control and prevention practices were implemented to protect testing personnel and plasma donors during 4 observations of blood sample collection. The laboratory collected 38,585 blood samples per year. The findings were: 1. Observation on 11/12/25 at 2:08 PM showed TP (testing personnel) #3 had donned gloves, a gown, and a face shield, and performed a finger stick to collect a blood sample on donor #1. After completing the donor screening, TP #3 provided the donor with a card and instructed the donor to go to the plasmapheresis area. At 2:12 PM, without doffing her gloves and performing hand hygiene, TP #3 proceeded to process and collect a finger stick blood sample for donor #2. At 2:17 PM, without doffing her gloves and performing hand hygiene, TP #3 proceeded to process and collect a finger stick blood sample on donor #3. 2. Observation on 11/12/25 at 2:17 PM showed TP #4 had donned gloves, a gown, and a face shield, and performed a finger stick to collect a blood sample on donor #4. As a result of the donor's finger stick two drops of blood were left on the countertop. TP #4 completed processing the donor and then left the processing area to retrieve a spray bottle of Clorox Germicidal Cleaner; sprayed the drops of blood with the cleaner and immediately wiped the counter with a paper cloth. Interview with TP #4 at 2:25 PM revealed she was unaware of how long the cleaner should be left on the blood splatter for it to be effective. 3. Observation on 11/12/25 at 2:27 PM showed TP #5 was wearing gloves, a gown, and a face shield, and had completed the screening process for donor #5. Without doffing her gloves and performing hand hygiene, TP #5

	proceeded to process and collect a finger stick blood sample on donor #6. 4. Interview with the quality management representative (QMR) on 11/12/25 at 4:25 PM confirmed the contaminated blood spot on the counter was not cleaned as per the manufacturer's instructions. In addition, the QMR revealed the plasmapheresis center followed the standard operating procedures as provided by "headquarters" and would need to contact "headquarters" for more information regarding glove use during the donor screening process. 5. Review of the "Blood-OPIM [other potentially infectious diseases] Disinfecting Guide" showed to clean contaminated surfaces Clorox Healthcare Bleach Germicidal Cleaner was to be used. The directions for use showed "Spray on area, wipe clean, spray on area again, wait 1 minute, wipe clean. Wipe area with water." 6. Review of the "Exposure Control Plan" policy and procedure showed "...2.7.1.2 Hand hygiene and a new pair of gloves donned prior to each donor procedure to include: 2.7.1.2.1 Phlebotomy: Venipuncture, Venipuncture adjustment, Whole blood draws (e.g., SPE [serum protein electrophoresis])." 7. Review of universal precautions for the prevention of potentially infectious diseases retrieved from https://www.cdc.gov/mmwr/preview/mmwrhtml/00000039.htm on 11/14/25 showed: "The following general guidelines are recommended: ...Change gloves between patient contacts..." 8. Review of "Clinical Safety: Hand Hygiene for Healthcare Workers" retrieved from https://www.cdc.gov/clean-hands/hcp/clinical-safety/index.html on 11/14/25 showed "When to change gloves and clean hands...If moving from care on one patient to another patient..." THIS IS A REPEAT DEFICIENCY, last cited on 9/25/23.