Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 53D1007874	(X3) Date Survey Completed 11/13/2025
Name of Provider or Supplier Biolife Plasma Services Lp	**Street Address, City, State** 1122 Adams Street, Laramie, 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
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 3 of 4 observations of blood sample collection during the donor screening process. The laboratory collected 20,312 blood samples per year. The findings were: 1. Observation on 11/13/25 at 10:53 AM showed TP (testing personnel) #1 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 #1 provided the donor with a card and instructed the donor to go to the plasmapheresis area. TP #1 sprayed the counter with a disinfectant; however, TP #1 did not remove her gloves and perform hand hygiene before performing a finger stick to obtain a blood sample to screen donor #2. At 11:05 AM TP #1, without doffing her gloves and performing hand hygiene, performed a finger stick to obtain a blood sample for donor #3. Interview with TP #1 at 11:11 AM revealed there was no need to change gloves between donors if the gloves had not been visibly soiled. In addition, TP #1 stated gloves were changed between donors in the plasmapheresis section of the facility; however, it was not required in the screening area. 2. Interview with the center manager on 11/13/25 at 11:12 PM revealed staff members followed the standard operating procedure provided by the corporation. 3. Interview with the quality manager on 11/13/25 at 11:49 AM revealed the Environmental Health and Safety (EHS) officer for the corporation had informed him guidance provided by CDC only pertained to healthcare facilities and since BioLife was not a healthcare facility the

	same standards did not apply. In addition, the quality manager stated the EHS officer was going to refer the question to the corporations's medical team. 4. 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])." 5. 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..." 6. 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..."