

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  53D1007873	<b>(X3) Date Survey Completed</b>  09/25/2023
<b>Name of Provider or Supplier</b>  Biolife Plasma Services Lp	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D3011</b>	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on observation, staff interview, and review of policy and procedures, the laboratory failed to ensure effective infection control and prevention practices were implemented during 2 of 2 observations of blood sample collection. The laboratory collected 41,956 blood samples per year. The findings were: 1. Observation on 9/25 /23 at 10:09 AM showed testing personnel (TP) #1 had donned gloves and performed a fingerstick to collect a blood sample on donor #1 soiling his gloves with visible blood. TP #1 removed his gloves and without performing hand hygiene donned new gloves and finished processing the donor. TP #1 doffed his gloves and without performing hand hygiene retrieved a card from a rack, to indicate which section of the facility the donor was to have the plasmapheresis performed, and handed the card to the patient. TP #1 returned to his station and without performing hand hygiene donned new gloves and proceeded to performed a fingerstick to obtain a blood sample for donor #2. Upon completing the procedure TP #1 doffed his gloves and went to a counter, located outside of the donor screening area, and used hand sanitizer to perform hand hygiene. There was no hand sanitizer available at the blood collection station. 2. Observation on 9/25/23 at 10:22 AM showed TP #2 had collected a blood sample via fingerstick on donor #3. Upon completing the procedure TP #2 doffed her gloves and without performing hand hygiene assisted the donor to a computer station at the front of the building. TP #2 came back to the donor screening area and with her unclean hands used the mouse and the keyboard of the manager's computer. TP #2 entered an exam room and obtained some hand sanitizer to perform hand hygiene. There was no hand sanitizer available at the blood collection station. Interview with</p>

TP #2, at that time, revealed there had been a change in the standard operating procedures and it was no longer required to perform hand hygiene or change gloves between donors. 3. Interview with the assistant manager on 9/25/23 at 10:58 AM revealed the laboratory had removed the extra precautions that were in place during the public health emergency; however, no changes had been made to the standard operating procedure. 4. Review of the "Exposure Control Plan" policy and procedure with an effective date of 9/12/23 showed "...Workplace Hygiene...2.5.4 Hands must be washed immediately with soap and water: ...b) after removing or changing gloves that have been worn as PPE for the tasks listed in 2.7.1.1, whether or not gloves are visibly contaminated...2.7.1.1 Gloves are required to be worn while performing the following tasks due to the risk of an unexpected release of blood/OPIM [other potentially infectious materials] during normal operations, reacting to an emergency situation (e.g. line break,), and as a good hygiene practice: Performing fingerstick tasks (i.e. Hct [hematocrit], T.P. [total protein])" In addition the policy showed "2.7.1.2 Hand hygiene and a new pair of gloves donned prior to each donor procedure to include: 2.7.2.3.1 Phlebotomy...Whole blood draws (e.g., SPE [serum protein electrophoresis]" and "2.7.1.3 Gloves shall be immediately removed and hands washed with soap and water when: contaminated with blood or OPIM or when there is reasonable suspicion that the gloves were contaminated with blood or OPIM...prior to leaving the production areas to enter a non-production area."