

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2083684	(X3) Date Survey Completed 03/12/2025
Name of Provider or Supplier Biolife Plasma Services Lp	Street Address, City, State 3026 Chapel Hill Rd, Douglasville, GA	
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 Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on March 12, 2025. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on observation and staff interview, the laboratory failed to ensure Vacuette tubes are not in use after their expiration date. Findings include: 1. Observation during the laboratory tour on 3/12/25 at 11:20 a.m. revealed 69 blue top Vacuette tubes (lot #B231136Q) in a bin, in the processing area of the laboratory, had expired on 03/02/25. 2. Interview with testing personnel #3 (CMS 209), on 03/12/25, at 11:20 p.m., in the processing area confirmed the above finding.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on review of the standard operations procedures (SOP), observation during the labortory tour, and interview with testing personnel (TP), the lab failed to perform the</p>

eyewash maintenance per the policy. Findings include: 1. Observation during the lab tour revealed the eyewash stations were not maintained since May 3, 2024. 2. Review of SOP policy number SOP-242151 stated the eyewash stations shall be maintained weekly - the eyewash stations are to be activated for 1 minute to ensure: the fluid flows correctly, ensure the fluid runs clear, and the fluid temperature is between 60°F - 100°F. The annual maintenance must include: flow is 1.5 liter/minute, running for 15 minutes, and the temperature of the fluid is between 60°F - 100°F. Both maintenance procedures should be documented on the Weekly and Annual Eyewash Inspection form. 3. Interview with TP #3 (CMS 209 form) on 03/12/25 in the conference room at 1230 PM, confirmed the findings above.