Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2249485	02/28/2025
Name of Provider or Supplier	**Street Address, City, State**	
Biolife Plasma Services, Lp	4620 Bryant Irvin Rd Ste 516, Fort Worth, TX	

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	The laboratory was found to be in substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of laboratory policy, American Association of Bioanalysts (AAB) proficiency testing (PT) records, and confirmed in interview, the laboratory failed to attest to the routine integration of proficiency samples into the patient workload for two of three total protein (TP) events in 2024 (Events 2 and 3). Findings included: 1. Review of the laboratory's Proficiency Testing policy stated: " RESPONSIBILITIES AND PROCEDURE ... 6.0 Report results to the testing service (Management) ... 6.3 Complete the analyst's E-Sign through the AAB website. This will cause the printout to include the attestation statement (e.g., The undersigned analyst attests that samples were tested in the same manner as patient samples.) 6.4 Print results once submitted and review the printed results. If errors are found contact the applicable Proficiency Testing Service immediately to correct the results. 6.4.1. The attestation statement should be visible on the report with a designated location for the testing analyst to sign." 2. Review of 2024 AAB PT records (Events 2 and 3) stated: "Attestations The undersigned analyst attests that samples were tested in the same manner as patient samples." 3. Further review of total protein PT records for Events 2 and 3 in 2024 revealed the testing analyst(s) failed to sign the attestation statements. 4. During an interview on 02/28/2025 at 10:45 a.m., the Quality Representative, after a review of records confirmed the laboratory failed to attest to the routine integration of proficiency samples into the patient workload.

D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of laboratory policies, Centers for Medicare and Medicaid Services (CMS) 209 form, testing personnel records, and staff interview, the laboratory director failed to specify in writing the responsibilities and duties for 1 of 26 Testing Persons (TP-20, random review) performing moderate complexity testing. Findings included: 1. Review of the laboratory's policy "Moderate Complexity CLIA Testing Requirements" stated: "RESPONSIBILITIES AND PROCEDURE... 8.0 Ensure that testing personnel are qualified to perform moderate complexity testing and understand their center responsibilities (Lab Director, Management) ... 8.3 Obtain appropriate signatures on Moderate Complexity Testing - Testing Personnel Qualifications and Responsibilities form before testing personnel begin training in the duties for that role." 2. Review of the Centers for Medicare & Medicaid (CMS) 209 form revealed TP-20 as a testing person performing moderately complex laboratory testing in the specialty of chemistry. 3. Review of TP-20's personnel file revealed no documentation of the delegation of responsibilities by the laboratory director. On 02/28/2025 at 10:08 a.m. the laboratory Quality Representative was asked to provide documentation of the delegation of responsibilities by the laboratory director for TP-20. No documentation was provided. 4. During an interview on 02/28/2025 at 10:18 a.m., the Quality Representative stated that there was no documentation of the delegation of responsibilities by the laboratory director for each TP-20, confirming the above findings.