Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2145340	11/07/2023
Name of Provider or Supplier	**Street Address, City, State**	
Biolife Plasma Services, Lp	16480 N 59th Ave, Glendale, AZ	

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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(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 proficiency testing (PT) records from 2021, 2022, and 2023 and interview with facility personnel, the laboratory director and testing personnel failed to sign the PT attestation statements. Findings include: 1. The laboratory performs testing in the speciality of Chemistry with an annual test volume of 92,338. 2. The PT attestation statements presented for review for the first, second and third events of 2021 and first, second and third events of 2022 lacked the signatures of the laboratory director and testing personnel. 3. The PT attestation statement presented for review for the first event of 2023 lacked the testing personnel's signature. 4. The facility personnel interviewed on 11/07/23 at 10:00 AM confirmed that the PT attestation statements indicated above were not signed by the laboratory director and testing personnel.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two

	years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on lack of proficiency testing (PT) attestation statements for review from 2023 and interview with the facility personnel, the laboratory failed to provide evidence of the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens. Findings include: 1. The laboratory performs testing in the speciality of Chemistry with an annual test volume of 92,338. 2. The laboratory participates in three PT events annually for Total Protein. 3. During the survey on 11/07/23, the laboratory failed to provide evidence of the signed PT attestation statements for the second and third PT events of 2023. 4. The facility personnel interviewed on 11/07/23 at 10:05 AM confirmed the attestation statements indicated above were not available for review at the time of the survey.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's established test procedure for Donor Screening, review of patient test reports and interview with the facility personnel, the laboratory failed to follow the established Donor Screening test procedure regarding the course of action to take if a test system becomes inoperable. Findings include: 1. The laboratory performs testing in the speciality of Chemistry with an annual test volume of 92,338. 2. The laboratory's established test procedure, Donor Screening (SOP-240019), states, " Complete the Manual Data Collection for Donor Screening form up to the point DIS becomes available or starts saving vitals...Scan and upload the Manual Data Collection for Donor Screening form into the documents section of the applicable donor in DIS." 3. No evidence was presented for review during the survey to indicate the laboratory scanned the Manual Data Collection for Donor Screening form for patient (PDN#) A26516681 from 7/03/23 into DIS. 4. The facility personnel

	interviewed on 11/07/23 at 11:10 AM confirmed the laboratory failed to follow the course of action to take if a test system becomes inoperable as instructed in the established test procedure referenced above.