Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2184406	11/23/2022
Name of Provider or Supplier	**Street Address, City, State**	
Biolife Plasma Services Lp	11620 Coursey Blvd, Baton Rouge, LA	

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 Certification survey was performed on November 23, 2022 at BioLife Plasma Services L.P., CLIA ID # 19D2184406. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and interview with personnel, the laboratory failed to establish a complete policy and procedure manual. Findings: 1. Review of the laboratory's policies revealed the laboratory did not have written policies and procedures that included the following: a) Performance specification: detailed procedures for performing accuracy and precision (day-to-day, run-to-run, and within-run, as well as, operator variance), reportable and reference range studies, and actions to take when data from the studies fail to meet acceptability criteria 2. In interview on November 23, 2022 at 12:17 pm, the Quality Manager confirmed the laboratory did not include the identified polices and procedures.
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 policies and interview with personnel, the laboratory failed to establish complete quality control (QC) policies for total protein testing. Findings: 1. Review of the laboratory's "Donor Screening" and "TS Meter-DSP Quick Reference Guide" policies revealed the laboratory did not include the number and levels of controls, as well as written statement related to performance prior to patient testing. The "Donor Screening" policy, which included instructions for total protein testing, did not include frequency of QC performance. 2. In interview on November 23, 2022 at 12:17 pm, the Quality Manager confirmed the laboratory's policies did not include the identified information.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and interview with personnel, the laboratory failed to have the policies related to complaints and record retention approved and signed by the Laboratory Director. Findings: 1. Review of the laboratory's policies revealed the policies were maintained electronically. The following policies did not include the Laboratory Director's approval/signature: Complaints Record retention 2. In interview on November 23, 2022 at 3:50 pm the Training Supervisor stated the SOP's related to duties of the Laboratory Director are reviewed, which does not encompass all policies such as the ones identified. The Training Supervisor confirmed the Laboratory Director did not approve/sign the identified policies.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory

	director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Findings: 1. The laboratory failed to establish a complete policy and procedure manual. Refer to D5401. 2. The laboratory failed to establish complete quality control (QC) policies for total protein testing. Refer to D5403. 3. The laboratory failed to have the policies related to complaints and record retention approved and signed by the Laboratory Director. Refer to D5407.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Consultants failed to provide technical and scientific oversight to the laboratory. Findings: 1. The laboratory failed to establish a complete policy and procedure manual. Refer to D5401. 2. The laboratory failed to establish complete quality control (QC) policies for total protein testing. Refer to D5403. 3. The laboratory failed to have the policies related to complaints and record retention approved and signed by the Laboratory Director. Refer to D5407.