Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2244634	11/14/2023
Name of Provider or Supplier	**Street Address, City, State**	
Biolife Plasma Services Lp	6701 Black Horse Pike, Egg Harbor Twp, NJ	

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
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 surveyor review of the Electronic Procedures (EP), the Performance Specification records (PS) and Reichert Technologies TS Meter-DSP User's Guide (UG) and interview with the Quality Manager (QM), the laboratory failed to have all applicable procedures in the EP and PS for Total Protein testing performed on the Reichert Technologies TS Meter-DSP from 12/3/21 to the date of the survey. The findings include. 1. The laboratory failed to provide a Total Protein established reportable range and instructions on how to report patient results beyond that range in the EP. 2. The QM confirmed on 11/14/23 at 11:45 am that the laboratory did not

	perform linearity as part of their PS and therefore they did not provide established reportable ranges and how to report patient results beyond that range in the EP.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on surveyor review of the Performance Specification records (PS) for the eight Reichert Technologies TS Meter-DSP's used for Total Protein testing and the Reichert Technologies TS Meter-DSP User's Guide (UG) and interview with the Quality Manager (QM), the laboratory failed to perform all PS requirements for Total Protein testing performed on the Reichert Technologies TS Meter-DSP's from 12/3/21 to the date of the survey. The findings include: 1. There was no evidence that the laboratory performed linearity on all eight Reichert Technologies TS Meter-DSP's to establish the strictest Total Protein reportable range between the eight meter's and the manufacturer's reportable/measuring range. 2. There was no evidence that the laboratory placed an established reportable range into use through either written documentation and/or their electronic medical record (EMR) to ensure that patient results beyond that range would not be reported. 3. There was no evidence that the laboratory verified the reference/acceptable range for Total protein. 4. The QM confirmed on 11/14/23 at 12:00 pm that the laboratory failed to perform all PS requirements for Total Protein testing.