Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2258512	12/18/2023
Name of Provider or Supplier	**Street Address, City, State**	
Biolife Plasma Services Lp	1685 Apalachee Pkwy, Tallahassee, FL	

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	An onsite announced CLIA recertification survey was conducted at Biolife Plasma Services LP, a laboratory in Tallahassee, FL, on 12/18/2023. The laboratory is not in compliance with Code of Federal Regulations (CFR) 42, Part 493, Laboratory Requirements.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on the review of American Association of Bioanalysts (AAB) proficiency testing results and staff interview, the laboratory failed to review proficiency test (PT) results for 4 out of 4 testing events reviewed. (3rd testing event 2022 and 1st, 2nd, and 3rd testing events for 2023) The findings include: During a review of AAB proficiency testing results performed on 12/18/23, it was discovered that no reviews were done for the 3rd testing event in 2022, as well as the 1st, 2nd, and 3rd testing events for 2023 for Total Protein proficiency testing. An interview was completed on 12/18/2023 at 12:00 PM with the Center Manager, who confirmed that there was no documentation that the PT results were reviewed.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number

	and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and staff interview, quality control (QC) was not performed on 1 out of 6 Reichert Total Protein chemistry analyzers reviewed on 01/29/2023 with 67 Patients reported. (serial number 15368-0921) The findings include: A review of daily QC for January 2023 for 6 Reichert Total Protein chemistry analyzers revealed that, on 01/29/2023, the laboratory did not perform the high and low levels of QC on instrument 15368-0921 prior to performing 67 Patient tests. An interview was completed on 12/18/23 at 1:10 PM with the Center Manager, who confirmed that QC had not been performed on instrument 15368-0921 on 01/29/23. The laboratory's policy entitled "Control Verification of Refractometer" confirms that a high and low control must be ran on refractometers before patient testing.