Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2162093	03/23/2021
Name of Provider or Supplier	**Street Address, City, State**	
Biolife Plasma Services Lp	867 Good Homes Rd, Orlando, 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	A recertification survey was conducted on March 23, 2021. Biolife Plasma Services LP clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to perform calibrations within the laboratory's stated performance specifications for 3 (serial numbers 12287-1118, 12278-1118, 12295-1118) of 6 (serial numbers 12291-1118, 12303-1118, 12298-1118, 12287-1118, 12278-1118, 12295-1118) refractometers on 03/25/2020. Findings: Review of the calibration documentation showed that calibrations were performed on 09/13/2019, 03/25/2020 and 10/02/2020. Review of the laboratory's Refractometer Calibration Verification documentation dated 03/2/2020 showed that the Refractrol Low Control Lot #K303250 had an acceptable range of 4.0 to 4.8 g/dL (grams per deciliter). Review of the calibration verification document show that refractometers serial numbers (SN) 12287-1118, 12278-1118, 12295-1118 all reported the low control value of 4.9 g/dL. Review of the policy titled "Refractometer Calibration Verification, Precision and Specification Testing" read "If the result is not within the manufacturer's acceptable range or if a fuzzy image/no sample result is obtained, repeat the calibration using the same vial of protein control in the 1st repeat calibration verification section." There was no documentation that the low control was rerun. Review of the daily controls showed controls for refractometer SN12287-1118 were run on 03/25/2020 to 06/10/2020, and controls for refractometers SN 12278-

	1118 and SN 112295-1118 were run on 03/25/2020 to 10/01/2020. During an interview on 03/23/2021 at 1:10 PM, the Group Quality Manager stated the low level of controls were out of range. During an interview on 03/23/2021 at 1:20 PM, the Group Quality Manager stated controls were run on all instruments where there was the potential for patients to be tested with the refractometer.