Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2136816	04/20/2021
Name of Provider or Supplier	**Street Address, City, State**	
Biolife Plasma Services Lp	1385 State Road 436, Casselberry, 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 April 20, 2021. Biolife Plasma Services LP clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to perform calibration on the Reichert Refractometer total protein instrument at least once every 6 months from

	04/22/19 to 04/22/2020 for 1 of 8 refractometers (serial #10935-0817). Findings: Review of the procedure titled Refractometer Calibration Verification, Precision, and Specification Testing noted "Complete calibration verification for all in service and back-up refractometers semi-annually...." Review of the laboratory's Quality Control Record - Refractometer Calibration Verification records showed the laboratory performed calibrations on 04/22/2019, 10/26/2019, and 04/22/2020. The Calibration Verification records showed that the calibration for refractometer serial #10935-0817 was not performed on 10/26/2019. Review of the Refractometer Details Report showed that patient specimens were tested on refractometer serial #10935-0817 from 10/26/2019 to 4/26/2020. On 04/20/2021 at 10:27 AM, the Quality Management Representative stated the calibration on refractometer serial #10935-0817 was missed on 10/26/2019.