Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D2192461	10/22/2024
Name of Provider or Supplier	**Street Address, City, State**	
Biolife Plasma Services Lp	7801 W Layton Ave, Greenfield, WI	

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
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 surveyor review of laboratory records and interview the quality manager and a technical consultant, staff A and staff B, the laboratory did not perform calibration verification every six months for six of six Reichert refractometers used for patient testing. Finding include: 1. Review of Reichert refractometer calibration verification records showed calibration verification was performed on total protein testing on December 12, 2022, September 12, 2023, April 12, 2024, and October 12, 2024.

	Further review showed no additional calibration verifications between June 12, 2023, and September 12, 2023, and March 12, 2024, and April 12, 2024. 2. Interview with staff A on October 22, 2024, at 11:25 AM stated calibration verification was performed in December 2022 and was due in June of 2023, noting in their quality system it was late and run in September 2023. Further interview confirmed approximately 8000 donor total protein tests were performed each month. 3. Interview with staff B on October 22, 2024, at 11:20 AM stated calibration verification was performed on April 12, 2024, instead of March 12, 2024, and was indeed a month late. Further interview confirmed the laboratory did not perform calibration verification every six months for six of six Reichert refractometers used for patient testing.