Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2255335	03/28/2024
Name of Provider or Supplier	**Street Address, City, State**	
Biolife Plasma Services Lp	1076a W Mercury Blvd, Hampton, VA	

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 announced CLIA recertification survey was conducted at Biolife Plasma Services, LP (Hampton) on March 28, 2024 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiency cited is as follows:
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 a review of procedures, tour, calibration verification records, lack of

	documentation, and interviews, the laboratory failed to perform calibration verification studies every six (6) months per their policy for eight (8) of 8 Reichert Refractometer chemistry instruments utilized for client total protein analysis in calendar year 2023. Findings include: 1. Review of the laboratory's procedures revealed a policy (titled: Refractometer Calibration Verification Policy Number 013808) that outlined calibration verification to be performed every six months using KOVA Refractrol SP controls to ensure recovery of assigned values of protein concentration for the laboratory's clinical refractometers. 2. During a tour of the facility on 3/28/24 at 11:00 AM, the inspector noted and verified the following 8 Reichert Refractometers in use: 15423, 15424, 15425, 15426, 15427, 15428, 15429, 15430. 3. Review of the laboratory calibration verification records of the 8 meters outlined above revealed one record in calendar year 2023 (date performed 7/23/23). The inspector requested to review additional calibration verification records for the 8 instruments in 2023. No additional calibration verification documentation was available. The site manager stated on 3/28/24 at 12:00 PM, "Our policy is to verify the calibration verification of the meters every six months. The calibration verification was missed in April 2023." 4. An exit interview with the site manager, assistant manager, and quality assurance manager on 3/28/24 at 1:00 PM confirmed the above findings.