

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2192122	(X3) Date Survey Completed 01/23/2025
Name of Provider or Supplier Biolife Plasma Services Lp	Street Address, City, State 8702 Staples Mill Road, Richmond, 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 on January 23, 2025 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiency cited is as follows:
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of standard operating procedures (SOP), instrument logs, calibration verification records, lack of documentation, and interviews, the laboratory failed to perform calibration verification studies semi-annually per their policy for three (3) of eight (8) Reichert Refractometer chemistry instruments utilized for client</p>

total protein analysis in calendar year 2023. Findings include: 1. Review of the laboratory's SOP's revealed a policy (titled: Refractometer Calibration Verification Policy Number 232554) that outlined calibration verification, "Complete calibration verification for all in-service and back up refractometers semi-annually on the first business day of the semi-annual period up to 10 plus calendar days". 2. Review of the instrument test logs revealed the facility utilized 8 Reichert Refractometer chemistry instruments for client total protein analysis during the review timeframe of 3/8/23 to 1/23/25. 3. Review of the Reichert Refractometers calibration verification records for calendar year 2023 revealed that the facility performed calibration verification once (dated as performed on 11/3/23) for the following 3 instrument serial numbers (SN): 14200, 14160, and 14161. The inspector requested to review additional calibration verification records for the 3 SN instruments outlined above performed in 2023. No additional calibration verification documentation was available. 4. An exit interview with the site manager and quality manager on 11/23/24 at 12:30 PM confirmed the above findings.