

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D2166113	(X3) Date Survey Completed 08/14/2025
Name of Provider or Supplier Biolife Plasma Services Lp	Street Address, City, State 3131 E Greenway Rd, Phoenix, AZ	
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	<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 lack of semi-annual calibration verification documentation for eight Reichart refractometers and interview with the Technical Consultant (TC-1), the laboratory failed to perform and document calibration verification procedures on 1 out of 8 refractometers in July 2024, 8 out at 8 refractometers in January 2025, and 3 out of 8 refractometers in June 2025. Findings include: 1. The laboratory utilizes 8 Reichart refractometers to perform Total Protein testing in the subspecialty of Routine Chemistry, with a reported annual test volume of 100,208. 2. Refractometer serial numbers include: 12720-0419, 12722-0419, 12753-0419, 12751-0419, 12716-0419, 12657-0419, 12718-0419 and 12719-0419. 3. Laboratory policy (SOP-232554, 1.5.1)</p>

states, "Complete calibration verification for all in-service and back up refractometers semi-annually on the first business day of the semi-annual period + ten (10) calendar days." 4. No documentation was presented for review to indicate the laboratory performed calibration verification procedures on 1 out of 8 refractometers (12657-0419) in July 2024. 5. No documentation was presented for review to indicate the laboratory performed calibration verification procedures on 8 out of 8 refractometers in January 2025 (serial numbers 12720-0419, 12722-0419, 12753-0419, 12751-0419, 12716-0419, 12657-0419, 12718-0419 and 12719-0419). 6. No documentation was presented for review to indicate the laboratory performed calibration verification procedures on 3 out of 8 refractometers (12657-0419, 12718-0419 and 12719-0419) in June 2025. 7. The TC-1 interviewed on August 14, 2025 at 11:15 AM confirmed the laboratory failed to perform calibration verification procedures on each refractometer as indicated above.

D5775

COMPARISON OF TEST RESULTS
CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites.

This STANDARD is not met as evidenced by:
Based on lack of semi-annual instrument comparison (variability) documentation for eight Reichart refractometers and interview with the Technical Consultant (TC-1), the laboratory failed to perform and document instrument comparison procedures on 2 out of 8 refractometers in February 2024, 2 out at 8 refractometers in October 2024, and 3 out of 8 refractometers in June 2025. Findings include: 1. The laboratory utilizes 8 Reichart refractometers to perform Total Protein testing in the subspecialty of Routine Chemistry, with a reported annual test volume of 100,208. 2. Refractometer serial numbers include: 12720-0419, 12722-0419, 12753-0419, 12751-0419, 12716-0419, 12657-0419, 12718-0419 and 12719-0419. 3. Laboratory policy (SOP-232554, 1.5.1 and 6.0) states, "Complete calibration verification for all in-service and back up refractometers semi-annually on the first business day of the semi-annual period + ten (10) calendar days. Complete Variability Analysis using Calibration Verification results. Within 3 calendar days of completion of Calibration Verification complete Variability Analysis." 4. No documentation was presented for review to indicate the laboratory performed instrument variability procedures on 2 out of 8 refractometers (12716-0419 and 12718-0419) in February 2024. 5. No documentation was presented for review to indicate the laboratory performed instrument variability procedures on 2 out of 8 refractometers (12657-0419 and 12718-0419) in October 2024. 6. No documentation was presented for review to indicate the laboratory performed instrument variability procedures on 3 out of 8 refractometers (12657-0419, 12718-0419 and 12719-0419) in June 2025. 7. The TC-1 interviewed on August 14, 2025 at 11:43 AM confirmed the laboratory failed to perform instrument comparison (variability) procedures on each refractometer as indicated above.