

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D2170881	(X3) Date Survey Completed 05/20/2025
Name of Provider or Supplier Biolife Plasma Services, Lp	Street Address, City, State 4275 Nw 63rd St, Oklahoma City, OK	
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	The recertification survey was performed on 05/21/2025). The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the center manager, quality manager, and technical consultant at the conclusion of the survey.
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records, written policies, and interview with the center manager, the laboratory failed to follow their written policy to assess the competency of the technical consultant, based on the position responsibilities as listed in Subpart M, for one of one person. Findings include: (1) A review of the laboratory policy titled, "Moderate Complexity CLIA Testing Requirements" stated the following in Section 13.1 "Laboratory Director must evaluate the Technical Consultant initially for approval and assess for competency annually (within 12 months) from the date approved as a Technical Consultant"; (2) A review of the Form CMS-209 (Laboratory Personnel Report) and personnel records for competency assessments performed during the review period of July 2023 through the current date identified competencies, based on job responsibilities, had not been performed after 07/14/2023 for one of one individual listed as the technical consultant on Form CMS-209; (3) The findings were reviewed with the center manager who stated on 05/20/2025 at 01:30 pm, the policy had not been followed.</p>
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</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.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the center manager, the laboratory failed to perform calibration verification procedures at least once every six months for seven Reichert T5 Digital Refractometers used during the review period of July 2023 through the current date. Findings include: (1) On 05/20/2025 at 11:00 am, the center manager stated Total Protein testing was performed using seven Reichert T5 Digital Refractometers (Serial Numbers 12531-0219, 12546-0319, 12535-0219, 12653-0319, 12534-0219, 12654-0319, and 125454-0319); (2) A review of records from July 2023 through the current date identified no evidence calibration verification had been performed at least once every six months for each of the Refractometers listed above between 09/22/2023 and 02/12/2025; (3) The records were reviewed with the center manager who stated on 05/20/2025 at 12:20 pm, calibration verification procedures had not been performed every six months as stated above.