

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D2170881	(X3) Date Survey Completed 06/23/2023
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 06/23/2023. The laboratory was found in compliance with a standard-level deficiency cited. The findings were reviewed with the group operations manager, quality manager, and the quality manager for Broken Arrow during an exit conference performed at the conclusion of the survey.
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with the group operations manager,</p>

quality manager, and the quality manager for Broken Arrow, the laboratory failed to perform calibration verification procedures at least once every 6 months for the refractometer total protein testing performed on 5 Reichert refractometers. Findings include: (1) On 06/23/2023 at 11:55 am, the group operations manager stated the laboratory performed total protein testing on 5 Reichert refractometers. (Serial#'s 12531-0219, 12546-0319, 12535-0219, 12653-0319, and 12534-0219); (2) A review of records from August of 2021 through the current time identified no evidence calibration verification procedures had been performed at least once every six months between 4/08/2022 and 03/20/2023; (3) Interview with the group operations manager, quality manager, and the quality manager for Broken Arrow on 06/23/2023 at 11:55 am confirmed the laboratory had not performed calibration verification at least once every six months between 06/23/2023 and 03/20/2023.