

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2183403	(X3) Date Survey Completed 01/07/2026
Name of Provider or Supplier Biolife Plasma Services L.P.	Street Address, City, State 9312 Arlington Expy, Jacksonville, FL	
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 Center on 1/7/2026. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D5437	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p> <p>(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (a)(1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (a)(2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (a)(2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (a)(2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (a)(3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to perform and document calibration procedures at least every six months for 3 of 3 refractometers reviewed (Meters 13084, 13096, and 13246). The findings include: Review of the calibration logs on January 7, 2026, revealed the following gaps in required six-month calibration: a. Meter 13084: Calibrated on 7/2024, 1/2025, and 9/2025. The interval between the January 2025 and September 2025 calibrations was eight months. b. Meter 13096: Calibrated on 7/2024, 1/2025, and 9/2025. The interval between the January 2025 and September 2025 calibrations was eight months. c. Meter 13246: Calibrated on 10/2024 and 1/2025. As of 1/7/2026, the meter had not been calibrated for one year. During an interview on January 7, 2026, at 10:30 am, the Quality</p>

Manager confirmed the laboratory had not performed or documented the calibrations for the three meters at the frequency required by the manufacturer. The facility policy titled "Refractometer Calibration Verification, Variability Analysis, Precision and Specification Testing" 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." .