

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2170479	(X3) Date Survey Completed 12/17/2025
Name of Provider or Supplier Biolife Plasma Services Lp	Street Address, City, State 1301 E Osceola Pkwy, Kissimmee, 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 Services LP on December 17, 2025. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. Standard deficiencies cited are as follows:
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on interview, review of the procedure manual, and the American Association of Bioanalysts / Medical Laboratory Evaluation (AAB/MLE) proficiency testing (PT) records, the Laboratory Director failed to sign the attestation form for one (2025 1st) PT event of six (2025 1st, 2nd, 3rd, 2024 1st, 2nd, 3rd) PT events for the specialty of Chemistry. Findings: 1. Review of the procedure titled, Proficiency Testing in section 7.0 Complete Attestations on the Printout of Submitted Results noted, "The Laboratory Director must sign and date the Printout timely, recommended at next visit." 2. Review of the AAB/MLE PT records showed attestation statement for 2025 1st event was not signed by the Laboratory Director. 3. On 12/17/2025 at 10:33 AM, the Center Manager acknowledged the attestation was not signed by the Laboratory Director.</p>
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</p>

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.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to perform calibration verification for Total Protein testing on the Reichert TS Meter-DSP refractometers at least semi-annually for 2 (serial number 12670-0319, 12681-0419) of eight (serial numbers 12668-0319, 12669-0319, 12670-0319, 12672-0419, 12673-0419, 12679-0419, 12681-0419, 12691-0419) refractometers from 08/10/2024 to 08/07/2025.

Findings: 1. Review of the policy titled, "Refractometer Calibration Verification, Precision and Specification Testing" noted, "Calibration verification will be performed 6 months after precision testing is performed, and semiannually thereafter per applicable steps of SOP" (Standard Operating Procedure). 2. Review of the "Quality Control Record - Refractometer Calibration Verification," record showed calibrations were performed on all eight refractometers on 08/09/2024 and 08/08/2025. 3. Review of the "Quality Control Record - Refractometer Calibration Verification" record showed calibrations were performed on five (serial number 12668-0319, 12669-0319, 12672-0419, 12673-0419, 12679-0419) refractometers on 02/05/2025. 4. Review of the "Quality Control Record - Refractometer Calibration Verification" record showed calibrations were performed on (serial number 12672-0419, 12691-0419) refractometers on 02/06/2025. 5. Review of the "Equipment Audit Report" refractometer serial numbers of 12670-0319 showed the instrument was taken out of service on 02/02/2025 and put back in service on 03/11/2025. No documents of calibration verification for this instrument between 08/09/2024 to 08/08/2025 could be found. 6. Review of the "Equipment Audit Report" refractometer serial numbers of 12681-0419 showed the instrument was taken out of service on 01/18/2025 and put back in service on 02/07/2025. No documents of calibration verification for this instrument between 08/09/2024 to 08/08/2025 could be found. 7. On 12/17/2023 at 11:15 AM, the Center Manager stated refractometer serial number 12670-0319 was out of service on 02/02/2025 and to back in service on 03/11/2025. 8. On 12/17/2023 at 12:30 AM, the Center Manager stated refractometer serial number 12681-0419 was out of service on 01/18/2025 and back in service on 02/07/2025 9. On 12/17/2023 at 12:10 PM, the Center Manager stated they were unable to locate the missing calibrations.