

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2162093	(X3) Date Survey Completed 03/16/2023
Name of Provider or Supplier Biolife Plasma Services Lp	Street Address, City, State 867 Good Homes Rd, Orlando, 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	A recertification survey was conducted on March 16, 2023. Biolife Plasma Services LP clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D5437	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (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 (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (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 calibration verification for Total Protein testing on the Reichert TS Meter-DSP refractometers at least semi-annually for four (serial number 12249-1118, 12278-1118, 12287-1118, 12298-1118) of five (serial number 12249-1118, 12278-1118, 12287-1118, 12298-1118, 12303-1118) refractometers currently being used from 10/01/2021 to 03/15 /2023, and failed to perform a calibration verification for one refractometer before putting the refractometer "in service" on 12/02/2022. Findings: Review of the policy titled "Refractometer Calibration Verification, Precision and Specification Testing" read, "Calibration verification will be performed 6 months after precision testing is performed, and semiannually thereafter per applicable steps of SOP" 1. Review of the "Quality Control Record - Refractometer Calibration Verification" record showed</p>

calibrations were performed on 10/01/2021, 06/09/2022 and 03/15/2023, 9 months between each calibration verification for refractometers serial numbers 12249-1118, 12278-1118, 12287-1118 and 12298-1118. On 03/16/2023 at 10:47, the Quality Manager acknowledged the semi-annual calibration verification was performed only once in 2021. 2. Review of the "Equipment Audit Report" refractometer serial numbers of 12303-1118 showed the instrument was put back in service on 12/02/2022 and the last documentation of a validation being performed was 12/16/2021. The "Quality Control Record - Refractometer Calibration Verification" record showed a calibration was performed on 03/15/2023 for refractometer serial numbers of 12303-1118. On 03/16/2023 at 12:05, the Quality Manager stated refractometer serial number 12303-1118 was put back in service on 12/02/2022 and the validation was done on 03/15/2023.