Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2268514	07/21/2026
Name of Provider or Supplier	**Street Address, City, State**	
Biolife Plasma Services Lp	1011 S Pond Dr, Webster, TX	

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 routine recertification onsite survey was completed on 07/21/2026. The laboratory was found out of compliance with the CLIA regulations. The condition not met was: D6063 - 42 C.F.R. 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel;
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on the review of the laboratory's policy, refractometer SN list, method verification records, QC records, and confirmed in an interview, the laboratory failed to document verification of accuracy for 1 of 2 new Reichert's refractometers implemented in 2025. The findings were: 1. Review of the laboratory's policy titled "Refractometer Calibration Verification, Variability Analysis, Precision and Specification Testing" revealed "10.2 Complete precision and specification testing after the daily control verification of the refractometer has been completed. Daily control verification must be completed each day that precision testing is completed." Note: Control verification means QC. 2. Review of the refractometer SN list, provided by the laboratory on 07/21/2026, revealed there were 2 new refractometers implemented in 2025. Refractometers SN implemented in 2025 00817-0425 In-service on July 2025 as backup 00818-0425 In-service on July 2025. Out of service on 02/13/2026. 3. Review of the laboratory's method verification records for the 2

	refractometers revealed the laboratory failed to document verification of accuracy for 1 of 2 new Reichert's refractometers implemented in 2025. 00818-0425 4. Review of the laboratory's daily QC records from July to August 2025 revealed no daily QC records for 1 of 2 new Reichert's refractometers implemented in 2025. 00818-0425 5. In an interview on 07/21/2026 at 13:47 pm in a conference room, the Technical Consultant (as indicated on CMS 209 form) confirmed the above findings. Key: QC=Quality Control CMS=Center for Medicare and Medicaid Services
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (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 review of laboratory's calibration verification records, policies/procedures, and confirmed in an interview, the laboratory failed to document calibration verification for 2 of 2 calibration verification events for 8 of 8 refractometers in 2025. The findings were: 1. Review of the laboratory's policy titled "Refractometer Calibration Verification, Variability Analysis, Precision and Specification Testing" revealed "1.5.1 Complete calibration verifictication for all in-service and back up refractometers semi-annually on the first business day of the semi-annual period + ten (10) calendar days." 2. Review of the laboratory calibration verification records from 2025 to 2026 revealed there was no calibration verification documentation for 2 of 2 calibration verification records for 8 of 8 refractometers in 2025. 15465-1021 15469-1021 15473-1021 15474-1021 15475-1021 15477-1021 16408-0522 16410-0522 3. In an interview on 07/21/2026 at 12:53 pm in a conference room, the Center Quality Manager (as indicated on sign-in sheet) confirmed the above findings. Key: SN=Serial Number
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed.

	This CONDITION is not met as evidenced by: Based on the review of the laboratory's submitted CMS 209, testing personnel credential records, and confirmed in an interview, the laboratory failed to have qualifying documentation to qualify 1 of 35 testing personnel (TP) who performed moderate complexity testing. (Refer to 6065).
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; or (b)(2) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology, or nursing from an accredited institution; or (b)(3) Meet the requirements in 493.1405(b)(3)(i)(B), (b)(4)(i)(B), (b)(4)(i)(C) or (b)(5)(i)(B); or (b)(4) Have earned an associate degree in a chemical, biological, clinical or medical laboratory science, or medical laboratory technology or nursing from an accredited institution; or (b)(5) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least a duration of 50 weeks and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(6)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on the review of the laboratory's submitted CMS 209, testing personnel credential records, and confirmed in an interview, the laboratory failed to have qualifying documentation to qualify 1 of 35 testing personnel (TP) who performed moderate complexity testing. The findings were: 1. Review of the laboratory's submitted CMS 209, the Laboratory Personnel Report, signed by the laboratory director on 07/17/2026, revealed the laboratory identified 35 TP who performed moderate complexity testing. 2. Review of the laboratory's TP educational credential records revealed the laboratory failed to have qualifying documentation to qualify 1 of 35 TP who performed moderate complexity testing. TP#20 Hired Date: August 9, 2024 3. In an interview on 07/21/2026 at 12:31 pm in a conference room, the technical consultant (as indicated on CMS 209 form) confirmed the above findings. Key: CMS=Center of Medicare and Medicaid Services TP=Testing personnel