Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2249485	04/13/2023
Name of Provider or Supplier	**Street Address, City, State**	
Biolife Plasma Services, Lp	4620 Bryant Irvin Rd Ste 516, Fort Worth, 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	The laboratory was found to be in substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the CMS (Center for Medicare and Medicaid Services) 209 form, laboratory policies, personnel records, and confirmed in staff interview, it was revealed the laboratory failed to perform competency assessments for 2 of 2 technical consultants (TC-1, TC-2) in 2022. Findings included: 1. Review of the laboratory's submitted CMS 209 form identified 2 TCs. 2. Review of the laboratory policy titled "Moderate Complexity CLIA Testing Requirements" revealed: "RESPONSIBILITIES AND PROCEDURE ... 13.0 Assess competency of Technical Consultant (Laboratory Director). 13.1 Laboratory Director must assess Technical Consultant competency initially and annually (within 12 months) form the date approved as a Technical Consultant." 3. A random review of personnel records in 2022 revealed there were no documented initial competency assessments per laboratory policy for the duties performed as a TC for the following: TC-1: hire date: 03/2022 TC-2: hire date: 09 /2022 4. During an interview on 04/13/2023 at 10:20 am, the Quality Manager and Center Manager after review of records, confirmed the above findings.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the

	laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of calibration records, and confirmed in interview, the laboratory failed to follow their own written policy to ensure instrument calibrations for 8 of 8 refractometer chemistry analyzers were acceptable for 2 of 2 calibrations performed in 2022 (September) and 2023 (March). Findings included: 1. Review of the laboratory's policy titled "Refractometer Calibration Verification, Precision and Specification Testing" revealed: "PART A - PROCEDURE FOR CALIBRATION VERIFICATION ... 4.0 Review the results of the refractometer calibration verification (Medical Historian other than who performed the calibration verification). 4.1 Review the results of the calibration verification to ensure all information has been documented appropriately and that the results are within acceptable range." 2. Review of the laboratory's refractometer calibration records performed in 2022 revealed the following: Calibration date: 09/14/2022 Refractometer Serial Numbers: 15346-0921, 15461-1021, 15582-1121, 15335-0921, 15349-0921, 15448-1021, 15449-1021, 15453-1021 Only the raw data was documented. The laboratory failed to document if the results were within acceptable range, as written in their policy. Calibration date: 03/14/2023 Refractometer Serial Numbers: 15346-0921, 15461-1021, 15582-1121, 15335-0921, 15349-0921, 15448-1021, 15449-1021, 15453-1021 Only the raw data was documented. The laboratory failed to document if the results were within acceptable range, as written in their policy. 3. During an interview on 04/13/2023 at 11:30 am, the Quality Manager and Center Manager after review of records, confirmed the findings.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (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 review of verification studies for the Reichert refractometer chemistry analyzer, laboratory policies, laboratory records, and confirmed in interview, the laboratory failed to ensure the reportable range and normal range for 1 of 1 chemistry analytes (Total Protein) were verified by the laboratory's studies in 2022 (March) for 8 of 8 refractometers. Findings included: 1. According to verification studies, the laboratory added eight Reichert refractometer chemistry analyzers to their test menu on 03/2022. Refractometer Serial Numbers: 15346-0921, 15461-1021, 15582-1121, 15335-0921, 15349-0921, 15448-1021, 15449-1021, 15453-1021 Further review of the verification studies for the refractometers revealed the laboratory did NOT perform reportable range and normal range studies as required. 2. Review of the laboratory's policy titled "Donor Screening Job Aid" revealed acceptable ranges for total protein as follows: Normal Range: 6.0-9.0 grams/dL Reportable Range: 4.8-10.0

	grams/dL The laboratory was asked to provide the studies used to obtain these acceptable ranges. None were provided. 3. Review of laboratory records revealed an annual test volume of 49,214 tests for the total protein analyte. 4. During an interview on 04/13/2023 at 10:40 am, the Quality Manager and Center Manager confirmed the laboratory failed to perform reportable range and normal range verification studies.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory policies, quality control (QC) records, laboratory records, and confirmed in staff interview, the laboratory failed to monitor the accuracy and precision of KOVA Refractol SP QC material over time for the total protein analyte tested on the refractometer analyzer 6 of 6 QC lots reviewed (random review August through October 2022, February 2023 through April 2023) to ensure accurate and reliable test results. Findings included: 1. Review of laboratory policies revealed the laboratory did not have a procedure for monitoring the accuracy and precision of test performance over time. 2. A random review of the following lots of QC tested in August 2022 through October 2022 and February 2022 through April 2023 revealed no documentation of monitoring QC over time: Low control: Lot# K305442; expiration date:07/31/2024; date in use: 1/31/2023 Low control: Lot #K304831; expiration date:05/31/2023; date in use: 7/23/2022 Low control: Lot# K305933; expiration date: 07/31/2025; date in use: 03/19/2023 High control: Lot# K304833, expiration date: 10/31/2023; date in use: 06/30/2022 High control: Lot# K305446, expiration date: 10/31/2024; date in use: 12/21/2022 High control: Lot# K305932; expiration date:09/30/2025; date in use: 3/30/2023 The laboratory was asked to provide documentation of monitoring QC over time for the total protein analyte tested on the refractometer analyzer using the KOVA Refractol SP QC material. None was provided. 3. Review of laboratory records revealed the laboratory had an annual volume of 49,214 tests performed. 4 During an interview on 04/13/2023 at 12:20 pm, the Quality Manager and Center Manager, confirmed the laboratory failed to monitor the accuracy and precision of KOVA Refractol SP QC material over time to ensure accurate and reliable test results.