Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2132488	04/10/2023
Name of Provider or Supplier	**Street Address, City, State**	
Biolife Plasma Services, Lp	1511 Sw Wilshire Blvd, Burleson, 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.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on direct observation and confirmed in interview, the laboratory failed to ensure 1 of 1 lot of expired HemataChek control was not available for use in patient testing. Findings included: 1. During a tour of the laboratory warehouse on 04/10 /2023 at 1:25 pm, the surveyor observed the following on a shelf: 1 box of HemataChek control; Lot #SFI--576; expiration date 02/28/2023 2. During an interview on 04/10/2023 at 1:32 pm, the Quality Manager confirmed the HemataChek control was expired.
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 (May, November). 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: 05/01/2022 Refractometer Serial Numbers: 10573-0317, 10542-0317, 10574-0317, 10568-0317, 10564-0317, 10561-0317, 10576-0317 Only the raw data was documented on the form. The laboratory failed to document if the results were within acceptable range, as written in their policy. Calibration date: 11/14 /2022 Refractometer Serial Numbers: 10573-0317, 10542-0317, 10574-0317, 10568-0317, 10564-0317, 10561-0317, 10576-0317, 10574-0317 Only the raw data was documented on the form. The laboratory failed to document if the results were within acceptable range, as written in their policy. 3. During an interview on 04/10/2023 at 12:28 pm, the Quality Manager and Center Manager after review of records, confirmed the findings.
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 3 of 3 QC lots reviewed (random review November 2022, March 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 November 2022 and March through April 2023 revealed no documentation of monitoring QC over time: Low control: Lot#K305442, expiration date: 07/2024; date in use: 07/07/2022 High control: Lot# K305446-01, expiration date: 10/31/2024; date in use: 05/22/2022 Low control: Lot# K305933, expiration date: 07/31/2025; date in use: 02/17/2023 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 75955 tests performed. 4

	During an interview on 04/10/2023 at 1:03 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.