Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2132488	09/10/2019
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	Entrance and exit conferences were held with laboratory representatives. The survey process was discussed, and survey forms were provided. An opportunity for questions and comments was given. Noted deficiency and plans of correction were discussed with the laboratory representatives at the entrance and exit conferences. The facility representatives were given an opportunity to provide evidence of compliance with the noted deficiency, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider /supplier, the State Survey Agency (SA) should be notified immediately.
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 the laboratory's verification studies, laboratory policies, and staff interview, it was revealed the laboratory failed to have documentation of verifying its reportable range for total protein. Findings included: 1. A review of the laboratory's

	verification records revealed the laboratory performed studies in July 2017 on 8 Reichert refractometers for performing total protein testing. They were identified as: 10572-0317 10574-0317 10561-0317 10568-0317 10564-0317 10576-0317 10573-0317 10542-0317 2. The laboratory policy titled "Donor Requirement-Microhematocrit and Total Protein" stated, "3.8.2 If the Total Protein value is outside of the verifiable reportable range for the digital refractometer of 4.4 grams/dL and 10.5 grams/dL, enter 'E' in the TP field for 'exceeded range' and defer the donor for the day." 3. The laboratory was asked to provide documentation of verifying its reportable range for total protein. No documentation was provided. 4. During an interview with Technical Consultant #1 on 09/10/2019 at 1030 hours in the conference room, the Quality Management Representative contacted the corporate Calibration/Maintenance (C/M) department. The representative from the C/M department stated the accuracy/precision verification study utilized 4 different control materials with values from 4 to 10.7 and used water for a 0 value. Technical Consultant #1 was asked to provide documentation of a statistical evaluation of these control materials to verify each refractometer's reportable range. No documentation was provided. This confirmed the above findings.