Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2137290	06/04/2019
Name of Provider or Supplier	**Street Address, City, State**	
Biolife Plasma Services Lp	13320 Richmond Avenue, Houston, 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	Noted deficiencies and plans of correction were discussed with the laboratory representative at the entrance and exit conferences. The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, 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.
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 laboratory's submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation performing competency assessments for 1 of 1 technical consultants. The findings were: 1. A review of the laboratory's submitted Form CMS 209 revealed the laboratory identified 1 technical consultant. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of performing a competency assessment of the technical consultant. 3. The laboratory was asked to provide documentation of performing a competency assessment on the technical consultant. No documentation was provided. 4. An interview with the

	quality manager on 06/04/2019 at 1230 hours in the conference room revealed the laboratory did not assess the competency of the technical consultant. This 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 the laboratory's verification studies, review of patient test records, and staff interview, it was revealed the laboratory failed to have documentation of verifying its normal range for total protein. The findings were: 1. A review of the laboratory's verification records revealed the laboratory performed studies in October 2017 on 8 Reichert refractometers for performing total protein testing. They were identified as: 10893-617 10895-617 10897-617 10898-617 10901-617 10902-617 10904-617 2. A review of the laboratory's patient test records revealed the laboratory identified the patient normal range for total protein to be 6 - 9. 3. The laboratory was asked to provide documentation of verifying this normal range was reflective of their population. No documentation was provided. 4. An interview with the quality manager on 06/04/2019 at 1055 hours in the conference room revealed the laboratory did not verify the patient normal range for total protein. This 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 the laboratory's quality control records from 2018 and 2019 (as of the day of the survey) and staff interview, it was revealed the laboratory failed to have documentation of monitoring quality control values over time to detect shifts and trends. The findings were: 1. A review of the laboratory's quality control records from January 2018 to June 2019 (as of the day of the survey) revealed the laboratory failed to have documentation of monitoring its total protein quality control values over time to detect shifts and trends. 2. The laboratory was asked to provide documentation of

	monitoring quality control over time. No documentation was provided. 3. An interview with the quality manager on 06/04/2019 at 1115 hours in the conference room revealed the laboratory assessed quality control values daily, but did not monitor the daily values over time. This confirmed the findings.