Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2137288	09/10/2019
Name of Provider or Supplier	**Street Address, City, State**	
Biolife Plasma Services Lp Dba Shire Biolife	12355 Fm 1960 Rd W, 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(s) at the exit conference. The facility representative(s) were 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.
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 a review of the laboratory's verification studies, a 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. Findings include: 1. A review of the laboratory's verification records revealed the laboratory performed studies in October 2017 on 6 Reichert refractometers for performing total protein

	testing. They were identified as: 10689-0417 10683-0417 10694-0417 10698-0417 10699-0417 10700-0417 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 management representative on 9/10/2019 at 11:20 a.m. in the conference room revealed the laboratory did not verify the patient normal range for total protein. This confirmed the above findings.