Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2275843	10/11/2023
Name of Provider or Supplier	**Street Address, City, State**	
Biolife Plasma Services, Lp	4033 W Airport Fwy, Irving, 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.
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 normal range for 1 of 1 chemistry analytes (Total Protein) was verified by the laboratory's studies in 2023 (February) 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 03/2023. Refractometer Serial Numbers: 16962-0922, 17005-0922, 16993-0922, 16996-0922, 16994-0922, 16590-0722, 16592-0722, 16591-0722 Further review of the verification studies for the refractometers revealed the laboratory did NOT perform a normal range (reference range) study as required. 2. Review of the laboratory's policy titled "Donor Screening Job Aid" revealed normal range for total protein as follows: "Verifiable 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 35,232 tests for the total protein analyte. 4. During an interview on 04/13/2023 at 12:30 pm, the Quality

	Manager and Center Manager confirmed the laboratory failed to perform a normal range verification study.