

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2229786	(X3) Date Survey Completed 03/22/2023
Name of Provider or Supplier Biolife Plasma Services, Lp	Street Address, City, State 8061 S Hampton Rd, Dallas, 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 deficiency and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions in the CLIA program, and recertification is recommended.
D5441	<p>CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control records from September 2021 to March 2023, and staff interview, it was revealed the laboratory failed to have documentation of monitoring quality control values over time. The findings include: 1. A review of the laboratory's quality control records for total protein testing from September 2021 to March 2023 revealed the laboratory utilized the following quality control lot numbers: a) Low Control Lot: K304831 Lot: K305933 b) High Control Lot: K304716 Lot: K305446 2. The laboratory was asked to provide documentation of monitoring the accuracy and precision of the quality control material over time to detect shifts and trends. No documentation was provided. 3. An interview with the</p>

technical consultant number 2 (as listed on Form CMS 209) on 03/22/2023 at 1154 hours in the conference room confirmed the facility did not monitor quality control values over time.