

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D2192409	(X3) Date Survey Completed 07/21/2026
Name of Provider or Supplier Biolife Plasma Services Lp	Street Address, City, State 813 Bethel Rd, Ste C-100, Columbus, OH	
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	An off-site revisit survey was completed on 08/05/2026 for all previous deficiencies cited on 07/21/2026. All deficiencies have been corrected, and no new noncompliance was found. The facility is in compliance with 42 CFR Part 493, Requirements for Laboratories.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of the policy and procedure titled "Proficiency Testing" and an interview with the Quality Manager (QM), the laboratory failed to follow its policy and procedure for proficiency testing (PT). This deficient practice had the potential to affect six out of six proficiency testing events from 08/13/2024 through 07/21/2026. Findings Include: 1. Review of the policy and procedure titled "Proficiency Testing", approved via signature and date by the LD on 02/16/2026, and provided the date of the inspection, found the following statement: "4.2 Samples must be tested in the same manner as donor specimens by personnel who routinely perform the procedure." 2. During an interview on 07/21/2026 at 10:30 AM, the QM stated, "The PT samples are performed in a nurse's office or empty exam room with a manager present. If the manager notices an error being made, they will immediately stop the testing and correct the error if possible." The QM further stated, "This was not how donor specimens are tested." 3. Review of laboratory records revealed 42,735 donors were tested from 08/13/2024 through 07/21/2026.