Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 24D2211033	**(X3) Date Survey Completed** 11/09/2021
Name of Provider or Supplier Biolife Plasma Services Lp	**Street Address, City, State** 2101 Old Hudson Rd, Saint Paul, MN	
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**
D2005	ENROLLMENT CFR(s): 493.801(a)(4) Authorize the proficiency testing program to release to HHS all data required to-- (i) Determine the laboratory's compliance with this subpart; and (ii) Make PT results available to the public as required in section 353(f)(3)(F) of the Public Health Service Act. This STANDARD is not met as evidenced by: . Based on laboratory document review and Centers for Medicare and Medicaid Services (CMS) report review, the laboratory failed to ensure proficiency testing results for the sole regulated analyte being tested were released to CMS as required. Findings are as follows: 1. The laboratory performed Total Protein testing as confirmed by the Center Manager (CM) during a tour of the laboratory at 10:10 a.m. on 11/09/21. Total Protein testing was implemented on 03/20/21 as indicated by the CM and supported in laboratory records. 2. The laboratory participated in proficiency testing (PT) using the American Association of Bioanalys (AAB) provider. AAB PT result documents from the Chemistry Q2 2021 event were reviewed on date of survey. Testing for this event was completed on 05/26/21 and the Laboratory Director reviewed the AAB results on 06/25/21. 3. Total Protein results from the AAB Chemistry Q2 2021 event were not found during CMS database review completed on 11/08/21. The CLIA 116 - Inquiry report from the database showing PT enrollment with AAB but no reported results was provided to the laboratory for review on 11/09 /21. 4. In an interview at 11:20 a.m. on 11/09/21, the CM and the Technical Consultant confirmed the above finding.