

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 06D2117010	(X3) Date Survey Completed 08/21/2018
Name of Provider or Supplier Biolife Plasma Services, Lp	Street Address, City, State 6310 Source Center Point, Colorado Springs, CO	
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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review proficiency testing procedures and documentation as well as staff confirmation, the laboratory director failed to follow the laboratory's written procedures for one of three chemistry proficiency testing modules in 2017. Findings include: 1. BioLife Plasma Services Standard of Operating Procedures, page 5, section 7.4 states "The Center Manager and Laboratory Director must review, sign and date the Testing Analyst proficiency test results returned from the Proficiency testing service (this includes the performance reports as well as the CMS Scoring Report from reporting cumulative scores for the calendar year) with 30 days of receipt." 2. Review of the Chemistry Q1 2017, T. Protein proficiency testing module revealed the results were received 03/07/2017 and not reviewed by the laboratory director until 05 /11/2017. 3. In an interview conducted 08/21/2018 at 1130 AM, the technical consultant confirmed the Chemistry Q1 2017, T. Protein results were not reviewed according to laboratory policy. The technical consultant also confirmed the Chemistry Q1 2017, T. Protein documentation stated "late review Dr 5/11/2017".</p>