

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  52D2098027	<b>(X3) Date Survey Completed</b>  10/07/2021
<b>Name of Provider or Supplier</b>  Biolife Plasma Services Lp	<b>Street Address, City, State</b>  226901 Rib Mountain Dr, Wausau, WI	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5401</b>	<p><b>PROCEDURE MANUAL</b> 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 surveyor review of American Association of Bioanalysts (AAB) proficiency testing (PT), laboratory procedures, and interview with two technical consultants, staff A and staff B, testing personnel did not follow the procedure for "Proficiency Testing" for five of five samples in the second event in 2020. Findings include: 1. Review of the "Proficiency Testing" procedure stated: "2.0 Receive two sets of proficiency testing samples (All Staff) 2.1 Designate one set of samples to be used by the testing analyst. 2.2 Designate the second set of samples to be used for remaining staff for in-house proficiency testing." Further review of the procedure stated: "6.2 Wait until the day after the Testing Services cut-off date for submission of test results before remaining personnel perform testing." 2. Review of AAB PT chemistry records for 2020 revealed the online submission date and time for the "Second Quadrimester Shipment 2020" was May 21, 2020 at 10:00 PM Central Standard Time (CST). Further reviewed revealed five of five total protein samples were tested on by five testing personnel, one on May 15, 2020 and four on May 21, 2020. 3. Interview with staff A and staff B on October 7, 2021 at 1:45 PM confirmed the testing personnel did not follow the procedure for "Proficiency Testing" for five of five samples in the second event in 2020.</p>