

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D2282345	(X3) Date Survey Completed 02/13/2024
Name of Provider or Supplier Biolife Plasma Services Lp	Street Address, City, State 2000 Silvernail Rd, Pewaukee, WI	
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
D5301	<p>TEST REQUEST CFR(s): 493.1241(a)</p> <p>The laboratory must have a written or electronic request for patient testing from an authorized person.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory documents and interview with the Center Manager (Staff A) and District Quality Manager (Staff B), the laboratory does not have a request from an authorized person for 41,000 of the 41,000 estimated total protein tests performed annually at this laboratory. Findings include: 1. Review of documents provided by the laboratory and the district quality manager showed no evidence the laboratory director or other authorized person had approved an order for total protein testing. In e-mail correspondence on February 20, 2024, at 2:10 PM, Staff B provided "Regulatory Affairs Memorandum, number 18.01". The memo stated 21 CFR 630.15(b)(4) requires performance of a total protein test on every donor and that, "The Laboratory Director cannot deviate from this requirement". The memo further stated, "The Lab Director approves this requirement and procedure through his /her signature on form VV-00705129, "CLIA Laboratory Director Acknowledgement". In e-mail correspondence on February 22, 2024, at 1:46 PM, Staff B provided SOP-240019, "Donor Screening" and the "CLIA Laboratory Director Acknowledgement" signed by the laboratory director on February 7, 2024. The CLIA Laboratory Director Acknowledgement form did not reference an order for laboratory testing and did not show approval of a standing order for testing performed in the laboratory. 2. Review of the "Application for Certification" CMS (Centers for Medicare and Medicaid Services) Form 116 signed by the laboratory director on February 7, 2024, showed the laboratory performed approximately 41,000 chemistry tests annually. 3. Interview with Staff A on February 13, 2024, at 9:15 AM confirmed the only chemistry testing the laboratory performed was total protein testing by refractometer. Further interview at 11:10 AM revealed they were unaware of a</p>

separate standing order for the total protein testing performed on donors in the laboratory.