

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  46D2297526	<b>(X3) Date Survey Completed</b>  10/23/2025
<b>Name of Provider or Supplier</b>  Biolife Plasma Services Lp	<b>Street Address, City, State</b>  168 East University Parkway, Orem, UT	
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>D5421</b>	<p><b>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE</b> CFR(s): 493.1253(b)(1)</p> <p>(b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by:            _ Based on record review, procedure review, and interview with the Center Manager, the laboratory failed to ensure verification of performance specifications of three of nine Reichert digital refractometers before reporting patient test results. _ Findings include: 1. Record review on 10/23/2025 failed to produce the verification of performance specifications for three of nine Reichert digital refractometers with the following identification numbers: 176781-0822, 16429-0522, and 13816-0120. 2. Review of the standard operating procedure, SOP-232554 "Refractometer Calibration Verification, Variability Analysis, Precision and Specification Testing", found it stated under section 17.0 "This step only applies to new centers or centers converting to a new refractometer, completing precision testing on ALL in house refractometers." 3. Interview with the Center Manager on 10/23/2025 at approximately 2:18 PM, confirmed the laboratory failed to ensure verification of performance specifications of three of nine Reichert digital refractometers before reporting patient test results because they were put into service after the center had been opened and was no longer a new center. 4. The laboratory performed approximately 43,166 total protein tests annually.</p>