

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2170901	(X3) Date Survey Completed 02/13/2020
Name of Provider or Supplier Biolife Plasma Services	Street Address, City, State 225 W Roosevelt Rd, Villa Park, IL	
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
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (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 review of the laboratory's test menu; equipment; verification records; patients' test records; Laboratory Personnel Report (FORM CMS 209); personnel records; and interview with the center manager, the laboratory failed to demonstrate that it could obtain performance specifications comparable to those established by the manufacturer for accuracy, precision, reportable range, and normal values for its digital refractometers prior to reporting patients' test results. Findings: 1. The laboratory performs Total Protein testing. 2. Test equipment included a total of 8 digital refractometers. 3. Review of verification records revealed that all 8 refractometers were not included in verification performance studies. In a document dated October 16, 2019, titled, "Villa Park Biolife Center Refractometer Control Testing SOP-)13808," it states, "Seven refractometers were tested using High and Low control sample. One refractometry, instrument # 12852-0519 had out of range measurements and was removed from the study." 4. Review of 6 patients' test records show that patients total protein results were reported. 5. There is no documentation to show that testing personnel were included in verification studies for 11 of 14 testing personnel. 6. Verification records show that persons other than those listed on FORM CMS 209 performed verification procedures on the laboratory's refractometers. 7. The Center Manager told the surveyor that verification procedures were performed by</p>

"quality staff" prior to opening the test facility and training of staff. 8. There is no documentation to show that the laboratory's current laboratory director reviewed and approved the results of verification procedures. 9. Review of 8 patients test records show that total protein test results were reported for 8 of 8 test records reviewed. 10. At 1:30 on February 13, 2020, the Center Manager confirmed the surveyor's findings.