

<p><b>Statement of Deficiencies</b></p>	<p><b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D2177640</p>	<p><b>(X3) Date Survey Completed</b>  08/30/2023</p>
<p><b>Name of Provider or Supplier</b>  Biolife Plasma Services, Lp</p>	<p><b>Street Address, City, State</b>  6246 Rufe Snow Dr Suite A, North Richland Hills, TX</p>	
<p>For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.</p>		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<p><b>D0000</b></p>	<p>The facility was found to be out of compliance with CLIA regulations 42 CFR Part 493. The following CONDITION LEVEL DEFICIENCIES were found to be out of compliance: 493.1412 Laboratories performing moderate complexity testing; testing personnel</p>
<p><b>D6063</b></p>	<p>LABORATORY TESTING PERSONNEL CFR(s): 493.1421</p> <p>The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.</p> <p>This CONDITION is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services (CMS) 209 form, laboratory policy, personnel records, and confirmed in interview, the laboratory failed to have documentation that 1 of 44 testing persons (TP-11 random review) met the qualifications required to perform moderate complexity testing prior to performing patient testing. Refer to D6065.</p>
<p><b>D6065</b></p>	<p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i)</p> <p>(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have</p>

successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on review of the Centers for Medicare and Medicaid (CMS) 209 form, laboratory policy, personnel records, and confirmed in interview, the laboratory failed to have documentation that 1 of 44 testing persons (TP-11 random review) met the qualifications required to perform moderate complexity testing prior to performing patient testing. Findings: 1. Review of the CMS-209 form included TP-1 through TP-44 listed to perform moderate complexity testing. 2. Review of the laboratory's policy titled "Moderate Complexity CLIA Testing Requirements" revealed:

"RESPONSIBILITIES AND PROCEDURE ... 4.0 Obtain proof of education for all employees (Management or designee). 4.1 File CLIA acceptable proof of education for all employees, including those not certified to perform moderate complexity training, in the center CLIA binder. 4.1.1 All staff members must have CUA acceptable proof of education documents on file in the center. Proof of education is CUA acceptable if and only if it meets one of the following criteria in Figure 1 below ... 4.1.4 Employees with foreign proof of education must have them evaluated and translated to English, if applicable, for U.S. education equivalency by Biolife Human Resources (HR). 4.1.4.1 Proof of education sent to Biolife HR for evaluation must meet CLIA requirements per previous steps of this SOP. 4.1.4.2 A foreign proof of education verification report must be received from HR and retained in the center prior to employee performing moderate complexity testing." 3. A random review of personnel records revealed the laboratory did NOT have documentation to ensure the following testing person was qualified to perform moderate complexity testing: TP-11; educational documents provided were from a foreign institution with an English translation. The educational documents were NOT evaluated for a United States equivalency. 4. During an interview on 08/30/2023 at 10:53 am, the Center Manager, District Quality Manager, and Quality Representative confirmed the above findings.