

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2132488	(X3) Date Survey Completed 06/09/2025
Name of Provider or Supplier Biolife Plasma Services, Lp	Street Address, City, State 1511 Sw Wilshire Blvd, Burleson, TX	
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
D0000	The facility was found to be out of compliance with CLIA regulations 42 CFR Part 493. CONDITION LEVEL DEFICIENCIES were found to be out of compliance: 493.1409 Technical Consultant 493.1412 Testing Personnel, moderate complexity
D6033	<p>TECHNICAL CONSULTANT-MODERATE COMPLEXITY CFR(s): 493.1409</p> <p>The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services (CMS) 209 form, personnel records, and in interview with staff, the laboratory failed to have one of two technical consultants who met the qualification requirements of 493.1411 of this subpart. The laboratory failed to ensure one of two individuals employed met the minimum requirements of two years of laboratory training or experience to qualify as a technical consultant in the specialty of chemistry. Refer to D6035.</p>
D6035	<p>TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411</p> <p>(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State</p>

in which the laboratory is located; AND (b)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i)(A) Hold an earned doctoral or master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(3)(i)(B) Meet either requirements in 493.1405(b)(3)(i)(B) or (b)(4)(i)(B) or (C); AND (b)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(4)(i)(B) Meet 493.1405(b)(5)(i)(B); and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(5)(i) Have earned an associate degree in medical laboratory technology, medical laboratory science, or clinical laboratory science; and (b)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. (b)(6) For blood gas analysis, the individual must- (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3) or (4) of this section; or (b)(6)(ii)(A) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (b)(6)(ii)(B) Have at least 2 years of laboratory training or experience, or both, in blood gas analysis; or (b)(7) Notwithstanding any other provision of this section, an individual is considered qualified as a technical consultant under this section if they were qualified and serving as a technical consultant for moderate complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024.

This STANDARD is not met as evidenced by:
 Based on review of the Centers for Medicare and Medicaid Services (CMS) 209 form, personnel records, and in interview with staff, the laboratory failed to employ one or more individuals who were qualified to provide technical consultation for each of the specialties of service in which the laboratory performs moderate complexity tests. The laboratory failed to ensure one of two individuals employed met the minimum requirements of two years of laboratory training or experience to qualify as a technical consultant in the specialty of chemistry. Findings included: 1. Review of the CMS-209 listed the two technical consultants. 2. Review of personnel documents for Technical Consultant-1 (TC-1) revealed he did not meet the requirements to qualify as a technical consultant for moderate complexity testing (chemistry specialty). TC-1 did not meet requirements, as stated in CFR 493.1411 (D6035). 3. During an interview on 06/09/2025 at 12:07 p.m., the laboratory representatives after a review of findings confirmed the above findings. The laboratory failed to employ one or more individuals who were qualified to provide technical consultation for each of the specialties of service in which the laboratory performs moderate complexity tests.

D6063

LABORATORY TESTING PERSONNEL
 CFR(s): 493.1421

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.

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 34 testing persons (TP-17 random review) met the qualifications required to perform moderate complexity testing prior to performing patient testing. Refer to D6065.

D6065

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(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 (b)(2) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology, or nursing from an accredited institution; or (b)(3) Meet the requirements in 493.1405(b)(3)(i)(B), (b)(4)(i)(B), (b)(4)(i)(C) or (b)(5)(i)(B); or (b)(4) Have earned an associate degree in a chemical, biological, clinical or medical laboratory science, or medical laboratory technology or nursing from an accredited institution; or (b)(5) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least a duration of 50 weeks and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(6)(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 34 testing persons (TP-17 random review) met the qualifications required to perform moderate complexity testing prior to performing patient testing. Findings included: 1. Review of the CMS-209 form included TP-1 through TP-34 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 CLIA acceptable proof of education documents on file in the center. Proof of education is CLIA 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-17; educational documents provided were from a foreign institution. The educational documents were NOT evaluated for a United States equivalency. 4.

During an interview on 06/09/2025 at 10:56 a.m., the laboratory representatives were asked to provide educational documentation for TP-17. No documentation was provided. This confirmed the above findings.