

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  19D2184406	<b>(X3) Date Survey Completed</b>  03/09/2021
<b>Name of Provider or Supplier</b>  Biolife Plasma Services Lp	<b>Street Address, City, State</b>  11620 Coursey Blvd, Baton Rouge, LA	
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>D0000</b>	An Initial Survey was performed at BioLife Plasma Services, L.P., CLIA ID # 19D2184406 on March 9, 2021. BioLife Plasma Services, L.P. was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1403 CONDITION: Laboratories Performing Moderate Complexity Testing; Laboratory Director 42 CFR 493.1407 CONDITION: Laboratories Performing Moderate Complexity Testing; Technical Consultant
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by:</p> <p>I. Based on record review and interview with personnel, the laboratory failed to ensure written policies and procedures to address competency for Technical Consultant were complete. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not include competency assessment criteria and frequency of performance for personnel serving as Technical Consultant. 2. Review of the laboratory's CMS 209 form (Laboratory Personnel Report) revealed the following personnel serves as Technical Consultants: a) Personnel 2 b) Personnel 3 3. Review of personnel records revealed the Laboratory Director did not perform a competency assessment for the duties as Technical Consultant for the following personnel: a) Personnel 2 b) Personnel 3 4. In interview on March 9, 2021 at 3:20 pm, the Quality Manager confirmed the laboratory did not have a competency assessment policy for the duties of Technical Consultant and that the Laboratory Director did not perform a competency assessment for the above personnel serving as Technical Consultants. II. Based on record review and interview with personnel, the laboratory failed to ensure initial competency assessments were performed and documented by</p>

the Laboratory Director for nine (9) of eleven (11) personnel reviewed. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory performs initial competency assessments for all new testing personnel. 2. Review of personnel records revealed the Laboratory Director did not perform and document the initial competency assessment for the following nine (9) of eleven (11) personnel: a) Personnel 5 b) Personnel 6 c) Personnel 7 d) Personnel 8 e) Personnel 9 f) Personnel 10 g) Personnel 14 h) Personnel 15 i) Personnel 21 3. In interview on March 9, 2021 at 3:20 pm, the Quality Manager confirmed the initial competency assessments for the above personnel were not performed by the Laboratory Director. III. Based on record review and interview with personnel , the laboratory failed to ensure the 6 month competency assessments were performed and documented by a qualified Technical Consultant for eight (8) of eight (8) personnel. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory performs a 6 month competency assessment for testing personnel. 2. Review of laboratory's CMS 209 (Laboratory Personnel Report) form revealed the laboratory employs two (2) Technical Consultants; however, both Technical Consultants did not have a Louisiana state License. 3. Review of personnel records revealed the 6 month competency assessments were performed by the Technical Consultants for the following eight (8) of eight (8) testing personnel: a) Personnel 4 b) Personnel 5 c) Personnel 6 d) Personnel 9 e) Personnel 10 f) Personnel 11 g) Personnel 15 h) Personnel 21 4. In interview on March 9, 2021 at 3:20 pm, the Quality Manager confirmed the 6 month assessments were performed by the Technical Consultants who did not meet moderate testing qualifications.

**D6000**

**MODERATE COMPLEXITY LABORATORY DIRECTOR**  
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:  
Based on observation, record review, and interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director failed to ensure the laboratory employed a Technical Consultant that met the qualifications for a moderate complexity testing laboratory. Refer to D6028. 2. The Laboratory Director failed to ensure policies and procedures for assessing personnel competency were established and maintained. Refer to D6030.

**D6028**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(10)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart;

This STANDARD is not met as evidenced by:  
Based on record review and interview with personnel, the Laboratory Director failed to ensure the laboratory employed a Technical Consultant that met the qualifications for a moderate complexity testing laboratory. Refer to D6035.

**D6030**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(12)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:  
Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were established and maintained. Findings: 1. The laboratory failed to ensure written policies and procedures to address competency for Technical Consultant were complete. Refer to D5209 I. 2. The laboratory failed to ensure initial competency assessments were performed and documented by the Laboratory Director for nine (9) of eleven (11) personnel reviewed. Refer to D5209 II. 3. The laboratory failed to ensure the 6 month competency assessments were performed and documented by a qualified Technical Consultant for eight (8) of eight (8) personnel. Refer to D5209 III.

**D6033**

**TECHNICAL CONSULTANT-MODERATE COMPEXITY**  
CFR(s): 493.1409

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.

This CONDITION is not met as evidenced by:  
Based on record review and interview with personnel, the Technical Consultant failed to provide technical oversight of the laboratory for moderate complexity testing. Refer to D6035.

**D6035**

**TECHNICAL CONSULTANT QUALIFICATIONS**  
CFR(s): 493.1411

(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 possess qualifications that are equivalent to those required for such certification; 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 in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived 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) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

This STANDARD is not met as evidenced by:

Based on review of personnel records and interview with personnel, the Technical Consultant failed to meet the qualifications for personnel serving as Technical Consultant of a moderate complexity testing laboratory. Findings: 1. Review of the laboratory's CMS 209 (Laboratory Personnel Report) form revealed the following personnel serving as Technical Consultants: a) Personnel 2 b) Personnel 3 2. Review of personnel records revealed the following Technical Consultants did not possess a current Louisiana state license: a) Personnel 2 b) Personnel 3 3. In interview on March 9, 2021, at 1:55 pm, the Quality Manager confirmed she was unaware that the Technical Consultants needed a state license to serve in this position.