

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 29D2169398	(X3) Date Survey Completed 08/03/2021
Name of Provider or Supplier Biolife Plasma Services Lp	Street Address, City, State 2255 N Green Valley Pkwy, Henderson, NV	
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	This Statement of Deficiencies was created as a result of an on-site CLIA recertification survey conducted at your facility on August 3, 2021. The findings and conclusions of any investigation by the Division of Public and Behavioral Health shall not be construed as prohibiting any criminal or civil investigations, actions or other claims for relief that may be available to any party under applicable federal, state, or local laws.
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 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)</p>

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 a review of the laboratory personnel records for personnel licensure and highest level of education for the technical consultants, and an interview with the Center Quality Manager, and the Center Manager, the laboratory failed to ensure that one of two technical consultants possessed a laboratory personnel license issued by the State of Nevada. Findings include: 1. One of two personnel fulfilling the role of the technical consultant for the laboratory, did not possess a State of Nevada Office Laboratory Assistant license as required. 2. The finding was confirmed by the Center Quality Manager, and the Center Manager during an interview conducted on August 3, 2021 at approximately 9:45 AM.

D6064

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1423(a)

Each individual performing moderate complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required.

This STANDARD is not met as evidenced by:
Based on a review of the laboratory personnel records for personnel licensure and the highest level of education for the testing personnel, and an interview with the Center Quality Manager, and the Center Manager, the laboratory failed to ensure that the testing personnel possessed a current laboratory personnel license issued by the State of Nevada. Findings include: 1. One of 36 testing personnel did not possess an active State of Nevada Office Laboratory Assistant license as required. The personnel license for the personnel expired on June 1, 2021. 2. The finding was confirmed by the Center Quality Manager, and the Center Manager during an interview conducted on August 3, 2021 at approximately 9:45 AM.