

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 29D2192766	(X3) Date Survey Completed 03/13/2023
Name of Provider or Supplier Biolife Plasma Services Lp	Street Address, City, State 2882 S Maryland Pkwy, Las Vegas, 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	<p>This Statement of Deficiencies was created as a result of an on-site CLIA recertification survey conducted at your facility on March 13, 2023. 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.</p>
D6029	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</p> <p>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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.</p> <p>This STANDARD is not met as evidenced by: Based on a review of laboratory personnel records, and an interview with the technical consultant, the director failed to ensure that all personnel have the appropriate education for the type and complexity of the services offered. Findings include: 1. A review of the laboratory personnel records revealed that there were no record of the highest level of education for one of 26 testing personnel in the performance of the total protein test. 2. There were no records of a minimum of a high school diploma or equivalent for person number 13 listed on the first page of the CMS-209 form. 3. The findings were confirmed during an interview with the Technical Consultant on March 13, 2023 at approximately 11:15 AM. The laboratory performs approximately 71710 routine chemistry tests annually.</p>

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 State of Nevada Division of Public and Behavioral Health records, a review of the CMS-209 form, a review of the laboratory personnel records, and an interview with the Technical Consultant, the director failed to ensure that all testing personnel possessed the appropriate or current personnel certification as required by the State of Nevada. Findings include: 1. Two of 27 personnel listed on the CMS-209 form did not possess the appropriate or current personnel certification required by the State of Nevada. 2. A review of the State of Nevada Division of Public and Behavioral Health records revealed that personnel number 13 listed on page one of the CMS-209 form did not possess a current Office Laboratory Assistant certification. The certification had an expiration date of August 13, 2022. 3. A review of the personnel certification for personnel number 16 listed on page one of the CMS-209 form revealed that the personnel did not possess the appropriate certification for the performance of moderate complexity testing required by the State of Nevada. The personnel possessed certification as a Laboratory Assistant instead of an Office Laboratory Assistant. The State of Nevada prohibits performance of moderate complexity testing by personnel certified as a Laboratory Assistant. 4. The findings were confirmed during an interview with the Technical Consultant on March 13, 2023 at approximately 10:30 AM. The laboratory performs approximately 71710 routine chemistry tests annually.