

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 29D2183452	(X3) Date Survey Completed 11/21/2024
Name of Provider or Supplier Biolife Plasma Services Lp	Street Address, City, State 1711 W Craig Rd, N 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	This Statement of Deficiencies was created as a result of an on-site CLIA recertification survey conducted at your facility on November 21, 2024. 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.
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the 2023 and 2024 American Association of Bioanalysts-Medical Laboratory Evaluation (AAB-MLE) proficiency testing (PT) records, and an interview with the Center Manager, the Assistant Manager and the Quality Manager, the laboratory failed to maintain all of the records for the 2023 Chemistry test event number one. Findings include: 1. A review of the 2023 AAB-MLE PT records revealed that the laboratory failed to maintain a copy of the proficiency testing report forms and the attestation statement provided by the PT program and signed by the laboratory director and signed by the analyst who performed the testing for the event.</p>

2. The findings were confirmed during an interview conducted on November 21, 2024 at approximately 11:45 AM. The laboratory performs approximately 63,428 chemistry tests annually.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(11)

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.

This STANDARD is not met as evidenced by:

Based on a review of a completed CMS-209 form, a review of the laboratory training and competency assessment records, and an interview with the Center Manager, Assistant Manager, and Quality Manager, the director failed to ensure that all personnel received the appropriate training and demonstrated that they can perform all testing reliably to provide and report accurate results. Findings include: 1. A review of a completed CMS-209 form and a review of the laboratory training and competency assessment records revealed that there were no records of initial training and competency assessment for one of 31 testing personnel in the performance of the total protein test. 2. The Center Manager, Assistant Manager and Quality Manager confirmed the finding during an interview conducted on November 21, 2024 at approximately 11:00 AM. The laboratory performs approximately 63,428 chemistry tests annually.

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 completed CMS-209 form listing the moderate complexity testing personnel, the laboratory employee records of personnel certification and training and competency assessments, a review of the Division of Public and Behavioral Health (DPBH, the Division), and an interview with the Center Manager, Assistant Manager, and Quality Manager, the laboratory failed to ensure that the testing personnel maintained the Office Laboratory Assistant certification required by the State of Nevada to perform patient testing. Findings include: 1. A review of the completed CMS-209 form and the laboratory employee records revealed that five of 31 testing personnel failed to apply for or maintain their personnel certification as an Office Laboratory Assistant as required by the State of Nevada as follows: A. The Office Laboratory Assistant certification for personnel number 11 on the CMS-209 form expired on July 9, 2024. At the end of a 30-day grace period, the certification was expired by the Division on August 9, 2024. The personnel applied for a new certification as an Office Laboratory Assistant on August 23, 2024. The new

certification was issued on August 26, 2024. The personnel continued to perform donor testing for total protein between August 9, 2024 and August 26, 2024. B. The Office Laboratory Assistant certification for personnel number 13 on the CMS-209 form expired on May 23, 2024. At the end of a 30-day grace period, the certification was expired by the Division on June 25, 2024. The personnel applied for a new certification as an Office Laboratory Assistant on August 30, 2024. The new certification was issued on August 30, 2024. The personnel continued to perform donor testing for total protein between June 25, 2024 and August 30, 2024. C. The Office Laboratory Assistant certification for personnel number 19 on the CMS-209 form expired on November 11, 2023. At the end of a 30-day grace period, the certification was expired by the Division on December 12, 2023. The personnel applied to reinstate the certification as an Office Laboratory Assistant on January 25, 2024. The certification was reinstated on March 11, 2024. The personnel continued to perform donor testing for total protein between December 12, 2023 and March 11, 2024. D. The Office Laboratory Assistant certification for personnel number 27 on the CMS-209 form expired on March 17, 2024. At the end of a 30-day grace period, the certification was expired by the Division on April 23, 2024. The personnel applied for a new certification as an Office Laboratory Assistant on May 9, 2024. The new certification for the application dated May 9, 2024 was issued on May 10, 2024. The personnel continued to perform donor testing for total protein between April 23, 2024 and May 10, 2024. E. A review of the training and competency assessment for personnel number 30 on the CMS-209 form and a review of the Office Laboratory Certification, and the Division records revealed that the personnel failed to submit an application for certification as an Office Laboratory Assistant prior to performing donor testing for total protein. The documentation of training and competency assessment revealed that the personnel had performed donor screening on September 24, 2024. The Division records revealed that the personnel failed to submit an application for certification as an Office Laboratory assistant until October 24, 2024.

2. The findings were confirmed during an interview with the Center Manager, the Assistant Manager and the Quality Manager conducted on November 21, 2024 at approximately 11:15 AM. The laboratory performs approximately 63,428 chemistry tests annually.