

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  29D2192766	<b>(X3) Date Survey Completed</b>  11/25/2024
<b>Name of Provider or Supplier</b>  Biolife Plasma Services Lp	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	<p>This Statement of Deficiencies was created as a result of an on-site CLIA recertification survey conducted at your facility on November 25, 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.</p>
<b>D6064</b>	<p><b>TESTING PERSONNEL QUALIFICATIONS</b> CFR(s): 493.1423(a)</p> <p>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.</p> <p>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 two of 32 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 21 on the CMS-209 form expired on February 22, 2023. At the end of a 30-day grace period, the certification was expired by the Division on March 17, 2023. The personnel applied to reinstate the certification on March 20, 2023. The new certification was issued on March 30, 2023. The personnel continued to perform donor testing for total protein between March 20, 2023 and March 30, 2023. B. A review of the training and</p>

competency assessment for personnel number 26 on the CMS-209 form and a review of the Office Laboratory Assistant certification, and the Division records revealed that the initial application for the Office Laboratory Assistant certification submitted on August 7, 2021 was denied on April 19, 2023. The personnel reapplied for certification on November 28, 2023. The certification was issued on November 29, 2023. A review of the documentation of training and competency assessment revealed that the personnel had performed donor screening on September 13, 2023, prior to reapplication for certification. 2. The findings were confirmed during an interview with the Center Manager and the Quality Manager conducted on November 21, 2024 at approximately 11:15 AM. The laboratory performs approximately 71,710 chemistry tests annually.