

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 29D2169398	(X3) Date Survey Completed 04/11/2023
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 generated as a result of the onsite CLIA recertification survey conducted at your facility on 4/11/2023. 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.
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of American Association of Bioanalysts (AAB) Proficiency Testing (PT) event Q3 of 2021 and AAB PT events Q2 and Q3 of 2022, review of the director approved Proficiency Testing policy, and an interview with the testing personnel responsible for entering the PT results, the laboratory director failed to sign the attestation form to affirm that the proficiency testing samples were integrated into the routine workload using the laboratory's routine methods. Findings include: 1. Review of the attestation forms from AAB PT event Q3 of 2021 and AAB PT events Q2 and Q3 of 2022 revealed that the laboratory director failed to sign the attestation forms for these events. 2. Review of the director approved laboratory policy titled, "Proficiency Testing" found that Section 5.6 states that the "Laboratory Director must sign the back of Reporting Form timely, recommended at next visit." 3. In an interview, on April 11, 2023, at approximately 10:30 AM, the testing personnel identified as number 5 on the CMS-209 form confirmed these findings. This testing personnel was responsible for entering and submitting the PT results to AAB. The laboratory performs approximately 101,862 chemistry tests per year.</p>