

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D2242431	<b>(X3) Date Survey Completed</b>  10/23/2025
<b>Name of Provider or Supplier</b>  Biolife Plasma Services Lp	<b>Street Address, City, State</b>  1960 Hacienda Dr, Vista, CA	
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>D2087</b>	<p>ROUTINE CHEMISTRY CFR(s): 493.841(a)</p> <p>(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's review of the American Proficiency Institute (API) proficiency testing (PT) records and interviews with the operations manager (OM), quality management representative (QMR), and district quality manager (DQM); it was determined that the laboratory failed to attain at least 80 percent of the acceptable score in Routine Chemistry for the Total Protein analyte. The findings include: 1. The surveyor reviewed the PT records wherein API reported an unsatisfactory score of 40% for the Total Protein analyte during the first event of 2025 (Q1-2025). 2. The OM, QMR, and DQM affirmed by interviews on October 23, 2025, at approximately 9:00 a.m. that the laboratory obtained the unsatisfactory PT score mentioned in statement #1. 3. The accuracy and reliability of patient test reported cannot be determined. 4. According to the laboratory's testing declaration form (Lab-144) submitted on the day of the survey, the laboratory performed approximately 62,276 patient test samples annually for Total Protein analyte including the time the laboratory received an unsatisfactory proficiency testing score of 40% for Q1-2025. .</p>
<b>D3039</b>	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(5)</p> <p>(a)(5) Quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years.</p>

This STANDARD is not met as evidenced by:  
 Based on the surveyor's review of the laboratory's policy and procedure, lack quality assessment records, interviews operations manager (OM), quality management representative (QMR), and district quality manager (DQM), and email communication with the region quality lead; it was determined that the laboratory failed to retain quality system assessment records for at least 2 years. The findings include: 1. The laboratory's practice included performing an annual review of the eye wash inspection records every month of July and retained records for 12 months. 2. The surveyor's review of the inspection log documentation for the eye wash for the years 2023, 2024 and 2025 showed that there was no evidence of a review in July 2024, and the records for 2023 were unavailable at the time of the survey on October 23, 2025. 3. The lack of records was confirmed by an email received on October 28, 2025, from the region quality lead, which stated that the laboratory could not retrieve the 2023 records as they were only kept for 12 months. 4. The safety of patients and laboratory personnel cannot be assured. 5. According to the annual testing declaration volume submitted on October 23, 2025, the laboratory performed and reported 62,276 patient samples during the time when quality system assessment records were not properly retained.

**D6016**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
 CFR(s): 493.1407(e)(4)(i)

(e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:  
 Based on the surveyor's review of the proficiency testing documentation for the first event of 2025 and interviews with the operations manager, quality management representative and district quality manager; this deficiency is herein cited for the laboratory director due to failure to ensure that proficiency testing samples were tested as required under Subpart H of this part. See D2087.

**D6020**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
 CFR(s): 493.1407(e)(5)

(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

This STANDARD is not met as evidenced by:  
 Based on the surveyor's review of the laboratory's policy and procedures, interviews and email communication with the staff; the laboratory director is herein cited for failure to ensure the quality assessment records were properly maintained to ensure safety and compliance. See D3039.