

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  03D2145340	<b>(X3) Date Survey Completed</b>  04/08/2025
<b>Name of Provider or Supplier</b>  Biolife Plasma Services, Lp	<b>Street Address, City, State</b>  16480 N 59th Ave, Glendale, AZ	
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>D3031</b>	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following:</p> <p>This STANDARD is not met as evidenced by: Based on review of calibration verification records on April 8, 2025, lack of the manufacturer's package insert for calibration verification material and interview with the facility personnel, the laboratory failed to retain the manufacturer's assay sheets for at least 2 years for each lot of calibration verification material used by the laboratory during each semiannual calibration verification event in 2024 and one out of two calibration verification events in 2025. Findings include: 1. The laboratory performs total protein testing on 7 refractometers in the specialty of Chemistry, with a reported annual test volume of 108,224. 2. The laboratory's established policy (SOP-243891, page 5) states, "Refer to the manufacturer's package insert to ensure that selected assay ranges are those specified for the brand of refractometer used. The manufacturer's package insert must be retained for future reference." 3. Review of the semiannual calibration verification records from 2024 and 2025 indicated the laboratory performed a calibration verification on each refractometer on the following dates: 1/10/24, 2/14/24, 7/11/24 and 1/17/25. 4. The laboratory failed to provide evidence of the manufacturer's assay sheets for each lot of calibration verification material used during each calibration verification event listed above. 5. The facility personnel interviewed on 4/08/25 at 11:10 AM confirmed the laboratory failed to retain the manufacturer's assay information sheets for at least 2 years for each lot of calibration verification material used by the laboratory during 2024 and in January 2025.</p>