

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  36D2049287	<b>(X3) Date Survey Completed</b>  07/16/2018
<b>Name of Provider or Supplier</b>  Biolife Plasma Services, Lp	<b>Street Address, City, State</b>  5656 Emerald Court, Mentor, OH	
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>D5415</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation and interviews with the Quality Management Representative (QMR), the Plasma Center Manager (PCM) and Testing Personnel (TP) #13, the laboratory failed to label six out of six of the secondary containers containing the refractometer daily calibrator, distilled water, to indicate the expiration date, and other pertinent information (lot number) required for use. Findings Include: 1. Direct observation of six out of six of the laboratory's secondary containers containing the refractometer daily calibrator, distilled water, were found in each of the six plasma center donor processing booths and currently in use. The surveyor did not find any indication of the lot numbers and expirations dates on any of the secondary distilled water containers. 2. The Surveyor requested the lot numbers and expiration dates of the distilled water secondary containers from the QMR, PCM and TP#13. The QMR, PCM and TP#13 stated the distilled water was poured into the six secondary containers from a stock bottle and the checking of the stock bottle expiration date was an item listed on their quality assessment checklist. The QMR, PCM and TP#13 confirmed the lack of the required labeling information on the six secondary containers of distilled water on the date of the inspection. The interviews occurred on 07/16/2018 at 12:35 PM.</p>