

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D2185725	(X3) Date Survey Completed 02/17/2023
Name of Provider or Supplier Biolife Plasma Services L P	Street Address, City, State 5421 Baltimore National Pike, Baltimore, MD	
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
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on quality control (QC) record review and interview with the Group Quality Manager, the laboratory failed to ensure that distilled water used for calibration of the digital refractometer was not used after the expiration date. Findings: 1. The QC records from 2023 for the digital refractometer chemistry analyzer were reviewed. 2. The records did not include the lot numbers and expiration dates of the distilled water used as the zero control to verify each analyzer prior to testing the low and high QC materials. Once the QC materials are found to be acceptable the analyzer is used for testing the donors. If the zero control fails the analyzer is removed from service and the required repairs are performed. 3. During an interview on 02/17/2023 at 12:00 PM, the Group Quality Manager confirmed that the records did not include the lot numbers and expiration dates of the distilled water used as the zero control for each analyzer prior to being used to test donors.</p>