Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2216947	04/24/2026
Name of Provider or Supplier	**Street Address, City, State**	
Biolife Plasma Services Lp	919 Taylor Avenue, Towson, 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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of instrument records, donor records, and the procedure and interview with the quality management representative (QMR), the laboratory failed to follow procedure and update the instrument identification number in the Donor Information System (DIS) when the instrument was placed out of service. Findings: 1. The laboratory used two software databases: 1) the Calibration Maintenance System (CMS) which stored maintenance records for the digital refractometers used to test for total protein and 2) the DIS which stored information for each plasma donor and donation. 2. Each digital refractometer was assigned an equipment identification number. 3. Plasma donors were processed through donor screening stations which had designated computer numbers. 4. Each donor screening station was assigned a digital refractometer which was linked to the computer number for that screening station. 5. The digital refractometer used to test each donor could be identified based on the computer number of the screening station the donor was processed through. 6. The DIS showed that patient B was screened via computer number NEW002TMD on 04 /15/2026 and tested using digital refractometer number 14514-1020. 7. The CMS showed that digital refractometer 14514-1020 was out of service on 04/15/2026 and had been replaced with digital refractometer 14517-1020 on 12/17/2025. 8. The procedure titled "Daily Area Cleaning and Work Area Guidelines" stated that "When placing screening equipment in service, update the Computer Name field in the asset record in CMS to reflect the DIS workstation associated with the equipment prior to use" and the "Digital Refractometer (also requires update in DIS if moved, removed

	from or placed into service)." 9. During the exit interview on 04/24/2026 at 1:50 PM, the QMR confirmed that digital refractometer number 14514-1020 was not removed from the DIS when it was placed out of service.